

Draft General Safety Requirements DS456 “Leadership and Management for Safety” (Version dated 16 June 2015)
Status: STEP 11 – Second review of the draft safety standard by the SSCs (Version for NUSSC-40)
Compiled comments from Germany (G), Japan (J), France (F), Finland (FIN), ENISS (E), Australia (AUS)

Note: Blue or underlined parts are comments to be added in the text. ~~Red or crossed parts~~ are those to be deleted in the text.

		COMMENTS BY REVIEWER				RESOLUTION			
		Reviewer: IAEA Country/Organization: Germany (G), Japan (J), France (F), Finland (FIN), ENISS (E); Australia (AUS) Date: 2015-09-28		Page 1 of					
Com ment No.	Rele- vance	MS Com- ment No.	Para/Line No.	Proposed new text	Reason	Accept- ed	Accepted, but modified as fol- lows	Rejected	Reason for modifica- tion/rejection
1	1	FIN 2	Main	<p>The structure of whole document and the sequence of requirements should be changed so that the document is easy use and it brings added value to existing leadership practices and management systems</p> <p>The document is proposed to be organized in the order such as:</p> <ol style="list-style-type: none"> 2. Responsibility for safety 3. Leadership and management for safety 4. Safety culture 5. The management system 6. Operation of the organization 7. Measurement, assessment and improvement 	<p>The sequence of requirements is not logical and some requirements are now repeated in several chapters. Most of the organizations that are in the scope of this document has already management system in place. The structure should facilitate the implementation of requirements set in this document. GS-R-3 follows the structure of ISO9000 series and ISO could be considered as a reference also here.</p>	Yes,	<p>Proposal:</p> <ol style="list-style-type: none"> 2. Responsibility for safety 3. Leadership for safety 4. Management for safety 5. Safety culture 6. The management system 7. Managing the organization 8. Measurement, assessment and improvement 		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

2	2	AUS 3	Structure	<p>The section headed “RESPONSIBILITY FOR SAFETY” (page 8) should be labelled 2., “3. LEADERSHIP FOR SAFETY” etc.</p> <p>The non-bolded sub-headings under “4. MANAGEMENT FOR SAFETY” should be identical to those in the list of CONTENTS</p>	Paragraph number is missing from the “Responsibility for Safety” section.	yes	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		
3	1	FIN8	Main	The connection between the main requirement and paras below should be enhanced.	In some cases it is not clear how the paras relate to the main requirement. For example paras 2.2 and 2.3 and , Req. 6 and paras	yes	This comment has been taken into account during the revision of the document by the working group.		
4	2	FIN9	Main	<p>Please check the consistency of to whom the requirements are addressed and to whom the explanatory text is addressed. For example see; Req. 1 and Req. 2.</p> <p>“Requirement 1: Achieving the fundamental safety objective</p> <p>The licensee with the senior management shall ensure...” and “2.2. Regulatory bodies and other governmental organisations...”</p> <p>“Requirement 2: Demonstration of leadership by senior management The senior management of the organization...”</p> <p>and 3.1 last row “Managers at all levels need also to be leaders.”</p>	Consistency of the main requirement and the explanatory requirements; the text should be clear when the requirements are addressed to all organizations and when they are addressed only to the licensees or only to the other bodies, and this should be clear already from the beginning of the requirement.	yes	This comment has been taken into account during the revision of the document by the working group.		

5	2	FIN10	Main	<p>Please check whether using word “safety” is in place; sometimes it may have a restrictive effect. For example, see Req. 4. , Req. 10, Req. 11, and Req. 13.</p> <p><u>Req. 4</u> “Requirement 4: Senior management’s responsibility for the management system</p> <p>Senior management shall establish, apply, maintain and continuously improve a management system for ensuring safety.”</p> <p><u>Req 10.</u> “Provision of resources Senior management shall determine and shall ensure the availability of, the competences and resources necessary to carry out the activities of the organization to ensure safety.”</p> <p><u>Req. 11.</u> Processes and activities shall be developed and managed to achieve the organizations safety goals.</p> <p><u>Req. 13.</u> To effectiveness of the management system shall be measured, assessed and improved so as to enhance safety performance.</p>	<p>This gives an impression that the management system is only for to ensure safety. However, management systems are used also for other purposes.</p> <p>The word ‘safety’ could lead to separate safety management system from IMS and can also be misinterpreted to the management of occupational safety only.</p>	yes	This was discussed in the group and consistency was taken into account during the working group editing.		
6	2	FIN11	Main	<p>This document should treat a management system as an integrated, coherent system, and this is not always obvious in the text. For example see the title on p.11 “RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM”</p>	<p>An integrated management system should be self-evident thus safety shouldn’t just be something to be integrated to the management system but be an essential part of it.</p>	yes	This was discussed in the group and consistency was taken into account during the working group editing.		

7	2	FIN12	Main	The coverage of the document should be ensures so that adequate requirements exist to establish later on guidance for management system.		yes	This was discussed in the group and the transfer of requirements into guidance was identified and was taken into account during the working group editing		
8	2	FIN13	Main	The requirements should be as simple as possible. Several paragraphs contain text that should be shifted into guidance level document		yes	This was discussed in the group and the transfer of requirements into guidance was identified and was taken into account during the working group editing		
9	1	FIN4	General	Safety policy should be better highlighted in this document. For example, see p.9, paragraph e).	Safety [and security] policy should be overriding priority and it should be highlighter better in the document.	yes	This was discussed in the group was taken into account during the working group editing		
10	1	FIN15	General	Please check the main structure and order of this documents. For example see Comments 9 and 11.	Clear and logical structure would help the reader to find relevant requirements in place.	yes	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

11	1	G116	General	In para 1.1, 2.1 c), 4.9, 4.18 b), 4.42 and 5.3 k) only radiation risk is addressed, while in connection with “emergency” both, nuclear or radiation emergency is highlighted. Therefore it is proposed to insert in the above mentioned paragraphs nuclear or radiation risk.	The omission of “nuclear” in connection with risk results from the wording in the corresponding Principle 3 of the Fundamental Safety Principles [1] where only radiation risk is written. In contrast, GS-R-2 [7] as corresponding document to emergency preparedness and response both, nuclear or radiological emergency is addressed. Because the scope of DS456 is related to both, nuclear and radiation issues all paragraphs where radiation risk is addressed should be completed by “ nuclear ” risk			no	Using the terms and description in the IAEA glossary.
12	1	F1	General	As GSR Part 2 will be applicable to organization running any activity or facility, as well as regulators, review each requirement to check whether it is meaningful for all activities and facilities. Are those requirements also relevant for contractors/service providers, especially those for which nuclear business is only a marginal part of their business ? It is suggested to develop an appendix explain how the requirements are to be understood for very small companies or those having not significant safety risk in their business	Some requirements seems inappropriate for small business (a handful of people or even single-run companies) or small risk activities (X-rays). For example, is the requirement on leadership for safety meaningful for a self-employed dentist with an X-Ray ?	Yes	The Group 2 of the working group piloted a reviewed of ‘meaningfulness’ and applicability. This was also sent to the rest of the group for review. Also it has been agreed that an annex or a tech-		

							doc will be developed to explore the aspect of grading and application in different types of organization.		
13	2	AUS1	General	Australia supports development of a new Requirements standard GSR Part 2 that integrates safety and security in the one document “Leadership and Management for Safety and Security”, as suggested from the floor of the June NSGC meeting. This is on the basis that in most MS, safety and security will be the integrated responsibility of the one management structure, in both operating facilities and regulatory bodies. It is acknowledged that such integration would inevitably delay the approval, but this may be the outcome anyway.	Leadership, Management, Management Systems (including quality systems) and Culture are common themes which need to be sustained in both safety and security. Most national organizations integrate the management of both safety and security and this should be reflected within this standard.			no	Security cannot be integrated in the safety standards at this time as this would significantly delay the publication of GSR part 2 and would require a mandate from IAEA .
14	2	AUS2	General	The general safety and security principles described within this Requirements document should be generic in nature such that they would apply equally to all scales of activities. The details for implementation should be captured within a guidance document, which will highlight variances due to large and smaller scales of activities.	If presented as generic safety and security principles, then this standard will apply to all regulated activities, including large and small operations and everything in between	yes	The Group 2 of the working group piloted a reviewed of ‘meaningfulness’ and applicability. This was also sent to the rest of the group for review. Also it has been agreed that an		

							annex or a tech-doc will be developed to explore the aspect of grading and application in different types of organization.		
15	2	AUS4	General		The term “medical” is only mentioned once. Suggest that the reference to “medical” (in Scope) be cross-referenced back to relevant specific requirements documents – e.g. in GSR Part 3.	yes	This will be checked by the medical representative before the draft is posted and the reference to GSR part 3 added.		
16	3	J1	CONTENTS	4. MANAGEMENT FOR SAFETY RESPONSIBILITY FOR <u>INTEGRATION OF SAFETY INTO</u> THE MANAGEMENT SYSTEM	Editorial. Be consisted with the subtitle of chapter 4.	yes	This comment has been taken into account during the revision of the document by the working group.		
17	2	G1	1.1	This Safety Requirements publication establishes requirements for establishing, <u>maintaining</u> , assessing, continuously improving	Leadership and management have to be maintained before they can be assessed and improved.			no	Considered to be evident in the establishing and improving aspects
18	3	AUS5	Para 1.3, lines 1 & 2	“Management systems <u>that are</u> designed to fulfil the requirements of this Safety Requirements publication <u>will</u> integrate safety, health, environmental, security, quality, societal, and economic elements. The management system is based on <u>supports</u> the fundamental safety objective <u>of protect-</u>	The existing first sentence does not read well. In the second sentence, the safety objective needs to be stated otherwise it is unclear what the safe-		”	no	Working group reviewed both comments and settled on the wording below -

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				ing people and the environment from harmful effects of ionizing radiation.”	ty objective is				“Management systems designed to fulfil the requirements of this Safety Requirements publication integrate safety, health, environmental, security, quality, societal, and economic elements ² . The management system is based on the fundamental safety objective, taking into account interfaces to security. ”
19	1	FIN17	p.4, para 1.3	“Management systems designed to fulfil the requirements of this Safety Requirements publication integrate safety, health, environmental, security, quality, societal, and economic elements ² . The management system is based on the fundamental safety objective.” is good as is. Would be better as “...fundamental safety <u>and security</u> objective.	From security point of view, the main point is to manage the safety-security interface to a reasonable degree in this high level publication. Safety and security should be considered in a balanced, risk-informed way to try to achieve the best overall	yes	“Management systems designed to fulfil the requirements of this Safety Requirements publication integrate safety, health, environmental, security, quality, societal, and eco-		

					safety-security result.		conomic elements2. The management system is based on the fundamental safety objective, taking into account interfaces to security.		
20	1	F2	1.4	The management system is based on <u>supports the achievement of</u> the fundamental safety objective.	The management system is not “based on” the fundamental safety objective as it has many purposes, including this one. It should however enable to achieve the fundamental safety objective...	yes			
21	3	E1	1.5 b, page 5	Management for safety, which includes establishing and implementing an d effective management system.	Typo ?	yes			
22	2	F3	1.5 a)	Leadership for safety, by establishing and integrating the organization’s vision, goals, strategies, plans and objectives , and advocating individual commitment to protecting people and the environment from harmful effects of ionizing radiation	What is the difference between “goals” and “objectives” ? If no substantial difference, one word is enough....			rejected	Working group reviewed all comments and settled on alternative wording
23	3	E1	1.5 b, page 5	Management for safety, which includes establishing and implementing an d effective management system.	Typo ?	yes			
24	3	AUS6	Para 1.5(b)	“b) Management for safety, which includes establishing and implementing an d effective management system.”	Typo	yes			

25	1	FIN16	General 1.5 (b), Requirement 7	In some places (1.5 (b), Requirement 7) there is text on “not to compromise safety”. Might be better as “not to compromise safety [and security] objective”. On the other hand, 4.13 states that neither should be compromised, although it may be unrealistic in practice. Referring to “not compromising the fundamental safety and security objective” might be a solution	From security point of view, the main point is to manage the safety-security interface to a reasonable degree in this high level publication. Safety and security should be considered in a balanced, risk-informed way to try to achieve the best overall safety-security result.	yes	Management for safety, which includes establishing and implementing and effective management system. This 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 that safety is not compromised by other requirements or demands. Safety measures and security measures must be designed and implemented in an integrated manner. The management system also has to ensure the promotion of a		
----	---	-------	--------------------------------------	---	--	-----	--	--	--

							safety culture, the regular assessment of safety performance and the application of lessons learned from experience.		
26	1	G2	1.6 a) Footnote	The term ‘facilities and activities’ is a general term encompassing nuclear facilities, uses of all sources of ionizing radiation, all radioactive waste management activities, transport of radioactive material and any other practice or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources: essentially any human activity that may cause people to be exposed to radiation risks.	Delete Footnote: This is an incomplete quote from the Safety Glossary which includes new elements that are not part of the Glossary. For consistency and to avoid confusion the definitions from the Glossary should be followed.	yes	Facilities includes: nuclear facilities; irradiation installations; some mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive material is produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — on such a scale that consideration of protection and safety is required. Activities includes: the production, use,		

							import and export of radiation sources for industrial, research and medical purposes; the transport of radioactive material; the decommissioning of facilities; radioactive waste management activities such as the discharge of effluents; and some aspects of the remediation of sites affected by residues from past activities.		
27	1	G3	1.6 a)	<p>The term ‘radiation risks’ is used in a general sense to refer to [1]:</p> <ul style="list-style-type: none"> – Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring); – Any other safety related risks (including those to ecosystems in the environment) that might arise as a direct consequence of: <ul style="list-style-type: none"> □ Exposure to radiation; □ The presence of radioactive material (including radioactive waste) or its release to the environment; □ A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation. 	Delete Footnote: This is an incomplete quote from the Safety Glossary. For consistency and to avoid confusion the definitions from the Glossary should be followed.	yes	<p>The term ‘radiation risks’ is defined as:</p> <ul style="list-style-type: none"> – Detrimental health effects of exposure to radiation (including the likelihood of such effects occurring). – Any other safety related risks (including those to ecosystems in the environment) that might arise 		

							as a direct consequence of: <ul style="list-style-type: none"> • Exposure to radiation; • The presence of radioactive material (including radioactive waste) or its release to the environment; • A loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation. 		
28	1	FIN18	p.5 para 1.6	add bb) By vendors of nuclear installations and their main suppliers	Vendors and major suppliers (of nuclear installations) may have impact on safety and therefore this requirement document should be used by them as well	yes	By the registrant or licensee, to specify to a vendor or supplier of products and equipment, or a contractor for services, and to any other relevant organization, any requirements that must be met by the vendor's or supplier's management system.		
29	2	G4	1.7	those of the International Standards Organization (ISO 9001, ISO 14001, OHSAS 18001)	OHSAS 18001 is not an ISO Standard.	yes			

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				or the European Foundation for Quality Management					
30	2	G5	1.7	The requirements established in this Safety Requirements publication apply to all facilities and activities specified in item 1.9.	To be more precise	yes			
31	1	G6	1.8	[...] which are key to developing and supporting a strong safety culture, in the organization. All safety requirements in this document should form part of the integrated managements systems for all organizations.	Additional text taken from 2.3. This statement is part of the overarching introduction to the document and has no meaning under R 1.			rejected duplication of 32	
32	1	G7	1.8	The objective of this publication is to establish requirements that support Principle 3 of the Fundamental Safety Principles [1], in relation to establishing, maintaining and continuously improving leadership and management for safety, and a management system, which are key to developing and supporting a strong safety culture, in the organization. All safety requirements in this document should form part of the integrated managements systems for all organizations.	Additional text taken from 2.3. This statement is part of the overarching introduction to the document and has no meaning under R 1	yes	The objective of this publication is to establish requirements that support Principle 3 of the Fundamental Safety Principles [1], in relation to establishing, maintaining and continuously improving leadership and management for safety, and a management system, which are key to developing and supporting a strong safety culture, in the organization. The objective is also to establish re-	See also 69 to 71	

							quirements that support Safety Principle 8 in relation to prevention of accidents.		
33	3	FIN19	p.6 para 1.8	The objective of this publication is to establish requirements that support Principle 3 of the Fundamental Safety Principles [1], in relation to establishing, maintaining and continuously improving leadership and management for safety, and an effective management system, which are key to essential in developing and supporting a strong safety culture, in the organization	editorial	yes			
34	3	J3	1.8/4and a management system, which are key to <u>fostering</u> , developing and supporting a strong safety culture, in the organization.	Editorial. Keep consistency with requirement 14.	yes			
35	1	G8	1.9	The requirements in this publication apply to all types of facilities and activities that give rise to radiation risk, as follows: ... i) ... j) <u>industrial activities involving NORM that are, or may be, subject to the requirements for planned exposure situations</u>	To be in line with DS442 Section 6; furthermore it is proposed to insert this topic after 1.9 b). both activities/facilities belong together	yes	j) <u>industrial activities involving naturally occurring radioactive material (NORM) that are, or may be, subject to the requirements for planned exposure situations</u>		
36	1	G9	1.9	[...] The requirements in this publication also apply in relation to the functions and activities of the regulatory body <u>as far as appropriate</u> [2]. <u>Regulatory bodies and other government organizations shall interpret the requirements in accordance to their own organization's accountabilities and in their interactions with</u>	Not all requirements apply in relation to the function of a regulatory body. Additional text taken from 2.2. This statement is part of the overarch-	yes	The requirements in this publication also apply in relation to the functions and activities of the regulatory body		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				operational organisations.	ing introduction to the document and has no meaning under R 1.		as far as appropriate [2]. Regulatory bodies and other government organizations need to interpret the requirements in accordance to their own organization's accountabilities.		
37	2	AUS7	Para 1.9	Change "radiation risks, as follows:" to " ionizing radiation risks, including: "	The safety objective (1.3) is related to 'ionizing radiation'. Therefore, it should be spelled out in Scope. Also the current wording is confusing as to whether the recommendations apply to facilities and activities not listed.	yes	The requirements in this publication apply to all types of facilities and activities that give rise to radiation risks, including: This Safety Requirements publication establishes requirements for establishing, assessing, continuously improving and sustaining effective leadership and management for safety in organizations concerned with facilities and		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

							activities that give rise to radiation risks ¹ . This includes the regulatory body and other competent authorities, and the organization responsible for the facility or activity. 1) 'Radiation' as used here means ionizing radiation.		
38	1	FIN20	p-7 para 1.9	<p>i) Vendors of nuclear installations and their main suppliers, Design, manufacture of equipment and other works and services to the licensee and authorized organization operating organization, in which is laid the potential impact on the safety of facilities and activities that create risk.</p> <p>The requirements in this publication also apply in relation to the functions and activities of the regulatory body[2] 2.2 Regulatory bodies and other government organisations shall interpret the requirements in accordance to their own organization's accountabilities and in their interactions with operational organisations.</p>	<p>addition this requirement should not be restricted only to the operating organization</p> <p>para 2.2 should be shifted to the scope</p>			rejected See 40	
39	1	F4	1.9 i)	<p>ì) <u>The requirements in this publication may also apply to</u> Design, manufacture of equipment and other works and services <u>provided to the operating organization authorized facility or activity, in which is laid the potential impact</u></p>	<p>It depends whether these activities are or not authorized activities. If they are authorized activities, the pre-</p>			rejected See 40	

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

			<p>on the safety of facilities and activities that create risk.</p>	<p>vious bullets apply. As a reminder, SF-1 states that <i>“The safety principles are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes, and to protective actions to reduce existing radiation risks.”</i> Para 2.2 of SF-1 further states that <i>“The fundamental safety objective applies for all facilities and activities, and for all stages over the lifetime of a facility or radiation source, including planning, siting, design, manufacturing, construction, commissioning and operation, as well as decommissioning and closure. This includes the associated transport of radioactive material and management of radioactive waste.”</i> If para 3.5 of SF-1 recognizes that <i>“Other groups, such as designers, manufacturers and constructors, employers, contractors, and consignors and carri-</i></p>				
--	--	--	---	---	--	--	--	--

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

					<p>ers, also have legal, professional or functional responsibilities with regard to safety.”, para 3.6 is clear that “The licensee is responsible for... verifying appropriate design and the adequate quality of facilities and activities and of their associated equipment;”</p> <p>If they are not, it is for some reason and they are not directly regulated (it is more often regulated via requirements on the licensee). It is suggested to separate this bullet and introduce flexibility in the sentence.</p>				
40	3	J4	1.9 i)	<p>i) Design, manufacture of equipment and other works and services to the operating organization <u>registrant or licensee</u>, in which is laid the potential impact on the safety of facilities and activities that create <u>radiation</u> risk.</p>	<p>Better wording.</p> <p>The wording of “registrant or licensee” should be used systematically in this publication.</p>	yes	<p>Activities involving design, manufacture of equipment and other works and services to facilities or activities that can create radiation risk.</p>		
41	1	E2	Para 1.9 I, page 7	<p>Design, manufacture of equipment and other works and services to the operating organization, in which is laid the potential impact on the safety of facilities and activities that create risk.</p>	<p>Delete sentence.</p> <p>It is agreed in the first objective of this guide that the final responsibility for nuclear safety</p>			<p>rejected See 40</p>	

					is on the licensee. It also goes against § 1.6.B, that leaves to the registrant or the licensee the responsibility to specify its requirements to its suppliers. It feels also inconsistent with § 1.10 that states that “this publication is <u>applicable to organizations (registrants or licensees) throughout</u> the lifetime of facilities ...”, and therefore not to service companies. It is also inconsistent with Requirement 12.				
42	2	AUS8	Para 1.9 (i)	“i) h Design, manufacture of equipment” Consider re-wording, or deleting and moving to guidance.	Remove duplication. The implications of this detail as a requirement across all range of facilities from small operator to the very large are massive, and impractical (unlikely to be applied) in e.g. a small dental practice.	yes		See 40	
43	2	G10	1.10	<u>1.9</u> ‘Safety’ means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks [1]. This publication is applicable to organizations (registrants and licensees) throughout the lifetime of	The definition of safety and the applicability of this Requirement to the whole lifetime of facilities are 2 different subjects and should be stat-	Yes See also 44			

				facilities and for the entire 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.	ed in different paragraphs. Suggestion: Move the definition of ‘safety’ up to be the first sentence under “SCOPE”.				
44	2	G11	1.10	‘Safety’ means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks [1]. This publication is applicable to organizations (registrants and licensees) throughout the lifetime of facilities and for the entire 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.	The definition of safety and the applicability of this Requirement to the whole lifetime of facilities are 2 different subjects and should be stated in different paragraphs.	yes			
45	2	AUS9	Para 1.10	‘Safety’ means the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to the radiation risks [1].	Definition is unnecessary in a Requirements document – it doesn’t add anything to the document and distracts from the rest of the paragraph.	yes	See 43		
46	2	F5	1.10	Furthermore, this publication does not set out to duplicate any of the specific requirements for managing their fulfilment in an integrated manner.	Superfluous It is not true as it establishes specific requirements applicable to a	yes	The paragraph starting with “this publication does not” should		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

					wide range of activities...		be numbered as separated paragraph.		
47	3	FIN23	p.7-8 para 1.11	The paragraph should be updated in line with the enhanced structure		yes			
48	2	J2	STRUC-TURE 1.11.	Add one sentence in the last sentence and a figure. Figure 1 shows main structure and requirements of this publication. See the attached figure.	For clarification of relationship among leadership, management and safety culture, add the schematic structure of these key elements and relevant safety requirements.			rejected	Working group reviewed all comments and settled on alternative wording
49	1	G12	R 1	The licensee with the senior management...	This document applies to all types of organizations that give rise to radiation risks. A requirement should not be limited unnecessarily to just one clientele.			rejected See 51	
50	3	J5	Req.1/1	The licensee with the senior management <u>Senior management of organizations</u> shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved	Editorial. This requirement is NOT limited to the licensee only.			rejected See 51	
51	2	F6	Requirement 1	The licensee, <u>starting</u> with the senior management, shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved	Clarification		The registrant or the licensee, <u>starting with the senior management,</u> shall ensure that the fundamental safety objective of protecting people		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

							and the environment from harmful effects of ionizing radiation is achieved		
52	2	AUS10	Req 1	“The licensee with the senior management, <u>in close cooperation with the regulator</u> , shall ensure that the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation is achieved.”	All the obligations for Requirement 1 relate equally to the regulator and yet the words suggest that this is limited to the licensee. We suggest that the bolded words (or similar) are included in the requirement.			rejected	Working group reviewed all comments and settled on alternative wording
53	2	AUS10	Para 2.2		If this is not agreed then Para 2.2 is really in the wrong place as this relates specifically to the regulator. In this case it would be preferable to relocate para 2.2.	Yes, This paragraph shall be deleted, see 36 above			
54	?	FIN24	p.8.	2.0 The licensee shall ensure that provisions are made to the achieve the fundamental safety objectives.			The registrant or licensee shall:		
55	2	G13	Page 9	The senior management of the organization shall demonstrate leadership for safety ... ?	This sentence should be completed similarly to page 9 “leadership for safety by managers at all levels ...”.			no	Working group reviewed all comments and settled on alternative wording
56	2	FIN25	p. 9, Req. 2	“The senior management of the organization shall demonstrate <i>commitment leadership</i> for	The senior management shall (rather) be com-			no	Working group re-

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

			and p.10 Req. 3.	safety.” “Demonstration of leadership— commitment for safety by managers at all levels”	mitted for safety than for leadership. In addition, how could demonstration for leadership be verified by inspections?				viewed all comments and settled on alternative wording
57	2	F7	2.1 a)	Also ensuring the quality of the associated equipment, and activities important to safety.	No need for such detail as it is already encompassed by safe construction and operation.			rejected	Working group reviewed all comments and settled on alternative wording
58	3	AUS11	Para 2.1(a)	Replace second sentence by “, and that associated equipment and activities meet quality and safety standards.”	Clarity.	yes	Shall be written as a separate sub-bullet		
59	3	F8	2.1 b)	b) Ensure the safe management and control of all radioactive material radiation source that is produced, processed, used, handled, transported, stored, or disposed.	As bullet c) of the previous version, dealing with management of radiation generators as been deleted, current bullet b) should be expanded from radioactive material to radiation sources.	yes	b) Ensure the safe management and control of all radioactive material and radiation source that is produced, processed, used, handled, transported, stored, or disposed.		
60	2	G14	2.1	(e) Ensure that arrangements are made for preparedness and response for a nuclear or radiological emergency, where appropriate.	The scope of this document also includes facilities or activities (e.g. x-ray tubes at dentists, cf. 1.9 f) that do not give rise to a nuclear or radiological emergency as covered by GSR Part 7.	yes) Ensure that sufficient and adequate arrangements are made for preparedness and response for a nuclear or radiological emergency, where appropri-		

61	1	G15	2.1 c)	[...] Ensure that managers employees at all levels in the organization develop an understanding of radiation risks and potential consequences, and how to manage radiation risks relevant to their responsibilities.	The awareness of radiation risks and consequences should be covered by the entire staff in the frame of their responsibilities.		ate.	rejected	Working group reviewed all comments and settled on alternative wording
62	2	E3	para 2.1 c) Page 9	c) Ensure that managers at all levels in the organization develop and keep an understanding of radiation risks and potential consequences, ...	Add words ...and keep...: Just to develop the understanding is not enough to protect people	yes	Ensure that managers at all levels in the organization develop and maintain an understanding of radiation risks and potential consequences, and how to manage radiation risks relevant to their responsibilities.		
63	2	G16	2.1 d)	“Ensure the provision for adequate resources and funding for the long term management (including disposal) of radioactive waste and decommissioning (or closure) of facilities, with due consideration given to the protection of future generations.”	Ensuring consistency with Paras 1.9 h), 1.10 and 2.1 a) of DS456. For radioactive waste disposal facilities, the term ‘closure’ instead of ‘decommissioning’ is used.	yes	See 64		
64	2	F9	2.1 d)	d) Ensuring the provision for adequate resources and funding <u>on the long term, including</u> for the long term management (including disposal) ...	The initial text is still narrow in the way that it requested provision only for resources/funding for long term management of radioactive waste and decommissioning, alt-	yes	“Ensure the provision for adequate resources and funding, including the long term management and		

					though there may be a need to provision for other type of long term charges (e.g. major retrofit)		disposal of radioactive waste, as well as decommissioning (or closure) of facilities, with due consideration given to the protection of future generations.;"		
65	1	G17	2.2	Regulatory bodies and other government organisations shall interpret the requirements in accordance to their own organization's accountabilities and in their interactions with operational organisations.	Overarching statement => delete and move to 'SCOPE' 1.9	yes	See 36		
66	3	FIN21	p. 8, para 2.2	Regulatory bodies and other government organisations shall interpret the requirements in accordance to their own organisation's accountabilities and in their interactions with operational organisations	to be moved into chapter 1 SCOPE check language	yes	See 36		
67	3	F10	2.2	Regulatory bodies and other government organisations shall interpret the requirements in accordance to their own organization's accountabilities and in their interactions with operational organisations.	True. This paragraph may however be located in a more general section of DS456. If an appendix is created on how low risk activities, small business or other organizations where radiation risk is not a significant stake, this sentence on regulator could be also added there.	Yes To be included in a guide.	See 36		
68	3	J6	2.2/3	2.2 Regulatory bodies and other government organisations shall interpret The requirements in accordance to their own organization's accountabilities and in their interactions with	Better wording. The wording of "registrant or licensee" should be used systematically		See 36	rejected	Working group reviewed all comments

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				operational organisations <u>registrant or licensee shall be interpreted by regulatory bodies and other government organisations.</u>	in this publication. See the comment No. 4.				and settled on alternative wording
69	1	G18	2.3	All safety requirements in this document should form part of the integrated management systems for all organizations.	Overarching statement => delete and move to 'OBJECTIVE' 1.8	Yes	See 36		
70	1	FIN22	p. 8, para 2.3	All safety requirements in this document should form part of the intergrated management systems for all organisations	to be deleted , the requirement is not understandable	Yes	See 36		
71	1	J7	2.3	All safety requirements in this document should form part of the integrated management systems for all organizations.	This is clear so it should be deleted.	Yes	See 36		
72	3	F11	2.3	All safety requirements in this document should form part of the integrated management systems for all organizations.	Typo		Not relevant. See 36		
73	1	G19	3.1	The difference between management and leadership can be stated simply; Management is a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources; while leadership is the use of capabilities to give direction, to influence and communicate with the aim of achieving the commitment of all individuals to appropriate goals, shared values and behaviors. Managers at all levels need also to be leaders.	This explanation is 'guide-level' and should not be given the status of a requirement. ⇒ incorporate into Safety Glossary or include as part of par. 1.5 in this document but delete here!		X		Moved to footnote
74	1	FIN26	p. 9, para 3.1	Please remove this paragraph to footnote or to the Introduction.	The paragraph does not express any requirement.		X		Moved to footnote
75	1	J8	3.1	Move to the footnote on "LEADERSHIP".. <u>3.1 The difference between management and leadership can be stated simply; Management is a formal, authorized function for ensuring that an organization operates efficiently and</u>	Clarification. This is just an explanation and description without "shall" should be excluded from main		x		Moved to footnote but kept in management section

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				that work is completed in accordance with requirements, plans and resources; while leadership is the use of capabilities to give direction, to influence and communicate with the aim of achieving the commitment of all individuals to appropriate goals, shared values and behaviors. Managers at all levels need also to be leaders.	text.				
76	1	E5	Para 3.1, page 9	The difference between management and leadership can be stated simply; Management is a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources; while leadership is the use of capabilities to give direction, to influence and communicate with the aim of achieving the commitment of all individuals to appropriate goals, shared values and behaviors. Managers at all levels need also to be leaders.	A search in available definitions of management and leadership shows that this is not a commonly shared definition. We propose to delete it here and to develop a definition in the Safety Glossary.		x		Moved to footnote. The definition is applicable to the text in this section and help understand the concept
77	2	FIN27	p. 9 para 3.1	Senior management shall establish, implement and communicate that the policy on safety which shall <u>establish the fundamental safety [and security] objective</u> as an overriding priority, protection and safety issues receive the attention warranted by their significance Senior management shall ensure that responsibilities and accountabilities are in line with the organization’s policies, strategies, plans and objectives, to ensure that safety and quality requirements are met and goals are achieved.	clarification text to be moved from 3.2 e		x		Safety policy is focused on safety
78	2	AUS12	Para 3.1	Delete current wording of all of para. 3.1. Replace with: “Leadership is required to be demonstrated at all levels of management and includes the	The given definition of management is arguable in this level of document. Detailed defini-		x		Moved to footnote. The definition is applicable to

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				<p>abilities to:</p> <ul style="list-style-type: none"> • impart vision and clear objectives; • establish trust, excellent communication and transparency; and • enhance the safety culture.” 	<p>tions of ‘management’ and ‘leadership’ should be placed in a guidance document.</p>				<p>the text in this section and help understand the concept</p>
79	1	G20	3.2	<p>Senior management shall develop an organization that is able to:</p> <p>(a) Advocate an approach to safety that Establish, adhere and advocate an organizations safety policy which stipulates that as an overriding priority, protection and safety issues receive the attention warranted by their significance. The safety approach shall encompass interactions between human, technology and the organization that demonstrate leadership for safety.</p> <p>(b) Establish, adhere to and advocate individual and organizational values that demonstrate leadership for safety.</p> <p>(c)</p> <p>(e) (b)-Establish behavioural expectations and promote a strong safety culture, as part of establishing and maintaining a strong safety culture and implementing the organizations safety policy.</p> <p>(d) (c) Establish the acceptance of personal accountability in relation to safety on the part of all individuals in the organization and that decision making at all levels are guided by the priorities</p>	<p>General comments: there are too many bullets. it is thus proposed to merge some of them and delete the one which have more a guidance character.</p> <p>(a) The establishment of a safety policy should appear at the beginning.</p> <p>Merge (b) into (a), since HTO interactions addresses individual and organizational values already.</p> <p>(c) “promote a strong safety culture” to be consistent with GS-R-3</p>		<p>2.1The senior management of the organization shall demonstrate leadership for safety by :</p> <p>(a) Establishing, adhering and advocating an organization’s policy on safety which stipulates that as an overriding priority, protection and safety issues receive the attention warranted by their significance and acknowledges that safety encompasses interactions between human, technology and the organization</p> <p>(b) Establishing behavioural expectations and promoting a strong safety culture.</p>		

				<p><u>and accountabilities for safety.</u></p> <p>(e) Establish and communicate that the policy on safety which shall establish that as an overriding priority, protection and safety issues receive the attention warranted by their significance. Ensure that responsibilities and accountabilities are in line with the organization's policies, strategies, plans and objectives, to ensure that safety requirements are met and goals are achieved.</p> <p>(f) Establish that decision making at all levels are guided by the priorities and accountabilities for safety.</p> <p>(g) Develop and maintain leadership competences at all levels in the organization, including competences for leadership in dealing with incidents and nuclear and radiological emergencies as well as unanticipated events.</p> <p>(h) Support the leaders at all levels in their promotion of safety and development of a strong safety culture.</p> <p>(i) (d) Ensure that the organization structure is in line with the management for safety.</p> <p>(j) Encourage open communication within the organization.</p> <p>(k) Seek information on manager's effectiveness of actions at all levels in</p>	<p>Merge (e) into (a) by establishing a safety policy</p> <p>Merge (f) into former (d)</p> <p>(g) as rather a guidance character and should be deleted here.</p> <p>(h) already covered by former (c)</p>	<p>(c) Establishing the acceptance of personal accountability in relation to safety on the part of all individuals in the organization and that decision making at all levels take account of the priorities and accountabilities for safety.</p> <p>(d) Ensuring that the organization structure is in line with the management for safety.</p>		
--	--	--	--	--	---	--	--	--

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				the organization in achieving, ensuring and enhancing safety, and shall take action as appropriate.	(j) and (k) have more a guidance character				
80	2	AUS14	Para 3.2(a)	Replace with: “Use an approach to safety that encompasses the interrelationships and interactions between technology, human and organizational factors in order to prevent technological, human and organizational failures, and to take advantage of human capabilities in recovering from failures and dealing with degraded, non-familiar or unexpected situations.”	This paragraph refers to a systemic approach to safety and reflects the latest, best practice, approach to safety. This should be a firm requirement for leadership and management for safety and not just an aim to advocate. The text in bold is the core requirement. The remaining text provides the desired outcome and is valuable in conveying the benefit of the systemic approach to safety.			See comment 79	
81	3	FIN28	p. 9, para 3.2	“Senior management shall develop an organization that is able to: ”	This requirement should be consistent with the title and be rather for the senior management (than for the organization).			See comment 79	
82		AUS13	Para 3.2(e)	Delete “is able to” “Senior management shall develop an organization that will.”	The objective of a requirements document is to state the required outcome rather than the required capability. The use of the word “able” relates to a capability and not an outcome.			See comment 79	
83	3	FIN29	p. 9 para	e)	to be moved			See	

			3.2					comment 79	
84	3	J9	3.2(e)	<p>Split two sentences.</p> <p>(e) Establish and advocate communicate that the policy on safety which shall establish that as an overriding priority, protection and safety issues receive the attention warranted by their significance.</p> <p>(1) Ensure that responsibilities and accountabilities are in line with the organization's policies, strategies, plans and objectives, to ensure that safety requirements are met and goals are achieved.</p>	<p>Better wordings.</p> <p>Suggest to change "communicate" with "advocate" which includes the meaning with the aim of achieving the commitment of leader.</p> <p>Communicate means including the behavior of both leader and all individuals.</p>			See comment 79	
85	3	AUS15	Para 3.2(e)	<p>Replace with: "Establish and communicate a policy on safety and security to ensure that safety and protection issues are the overriding priority. Ensure that responsibilities and accountabilities are in line with the organization's policies, strategies, plans and objectives, to ensure that safety requirements are met and goals are achieved."</p>	Existing text is confusing			See comment 79	
86	2	E4	para 3.2 e) Page 9	Establish and communicate that the policy on safety ...	Rewrite the first sentence; To clear the sense and to simplify.			See comment 79	
87	3	AUS16	Para 3.2(f)	Replace " are " by " <u>is</u> ".	Grammar		X		
88	2	E6	para 3.2 g) Page 9	Develop and maintain leadership competences at all levels in the organization, including competences for leadership in dealing with incidents and nuclear and radiological emergencies ...	<p>Delete second part of the sentence.</p> <p>It is not explicitly leadership in the moment of accident or incident.</p> <p>There should be clear, simple, agreed, well</p>		X		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

					known and trained hierarchy and lines of command in the management ...				
89		AUS17	Para 3.2(i)	Replace with: “ Ensure that the organizational structure is consistent with the organization’s safety objectives by providing a focus on safety that, where necessary, is able to withstand other organizational priorities and pressures. ”	Original wording is ambiguous			x	Wording is clear
90	3	J10	3.2(k)	(k) Seek information on manager’s effectiveness of actions at all levels in the organization in achieving, ensuring and enhancing safety; and shall to take action as appropriate.	Editorial.			x	Not relevant. See also requirement 13 (Assessment of effectiveness)
91	2	E7	Requirement 2, para 3.2 k) Page 11	Seek and evaluate information on manager’s effectiveness ...	Just seek would be not enough for good safety management system.			x	Not relevant. See also requirement 13 (Assessment of effectiveness)
92	2	AUS18	Para 3.2(k)	Modify to read: “ Establish objectives and standards for managers at all levels, and seek information on managers’ effectiveness of actions at all levels in the organization in achieving, ensuring and enhancing safety, and shall take action as appropriate. ”	It is imperative that the senior management establishes the objectives and standards for managers. Otherwise, the effectiveness of management cannot be evaluated.			x	Not relevant
93	2	F12	3.2	3.2 Senior management shall establish and advocate : (a) an approach to safety that encompass interactions between human, technology and the organization	Bullet list is very long. Suggestion to reorganize in 2 para, the first one dealing with senior		X	See comment 79	

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				<p>(b) individual and organizational values that demonstrate leadership for safety, personal accountability for safety, and support a strong safety culture.</p> <p>(c) the organization’s policy on safety which shall establish that as an overriding priority, protection and safety issues receive the attention warranted by their significance.</p> <p>To this end, senior management shall in particular encourage open communication within the organization and support the leaders at all levels in their promotion of safety and development of a strong safety culture.</p> <p>3.# Senior management shall ensure that, consistent with para 3.2 :</p> <p>(a) behavioural expectations are established,</p> <p>(b) responsibilities and accountabilities within the organization are established, in line with the organization’s safety policy, strategies, plans and objectives, to ensure that safety requirements are met and safety goals are achieved.</p> <p>(c) decision making at all levels in the organization are guided by the priorities and accountabilities for safety.</p> <p>(d) leadership competences are developed at all levels in the organization, including competences for leadership in dealing with incidents and nuclear and radiological emergencies as well as unanticipated events.</p>	<p>manager own work, the second for task to be performed under the direction of senior managers (the top management is unlikely to do it by himself). It is however questionable whether this 3.# is relevant to “leadership for safety”....</p> <p>Item (i) in initial bullet list is deleted as already covered by suggested 3.3 (b).</p> <p>Item (k) of the initial bullet list is deleted (too detailed)</p>				
94	3	FIN30	p. 10 Req. 3	<p>Requirement 3: Goals, Strategies, plans, and objectives.</p> <p>Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organiza-</p>	<p>OBS. Numbering of requirements should be changed This was req. 5 in June version</p>			x	Not relevant

				<p>tion's safety policy.</p> <p>4.4 Senior management shall establish goals, strategies, plans and objectives, in consultation and with feedback of information from individuals in the organization. The goals, strategies, plans and objectives of the organization shall be developed in such a manner that safety is not compromised by other priorities.</p> <p>4.5 Senior management shall establish measurable safety objectives in line with the goals, strategies and plans are established at various levels in the organization.</p> <p>4.6 Senior management shall ensure that the execution of plans is periodically reviewed against the safety objectives and goals, and that actions are taken where necessary to address any deviations from the plans.</p>					
95	1	G21	R 3	<p>Managers at all levels in the organization shall demonstrate leadership for safety in application of the management system, establishing continuous improvement, and in the <u>for</u> fostering of a strong safety culture.</p>	<p>Delete half sentence. Demonstration of leadership should not be narrowed down to applying the Management System as it comprises more than that. "in application of the management system and continuous improvement" is covered by 3.3 and therefore redundant.</p>		X edited by working group		
96	2	FIN31	p.10 R 3	<p>Managers at all levels in the organization shall demonstrate leadership for safety in application of the management system, establishing continuous improvement, and in the fostering of a strong safety culture.</p>	<p>This requirement should be reformulated to more concrete and easily understandable.</p> <p>New formulation could</p>		X edited by working group		

					be for example: The decisions and activities of the management at each organisation level shall reflect its commitment to practices and solutions that promote safety.				
97	2	F13	Requirement 3	Managers at all levels in the organization shall, <u>taking into account their duties</u> , demonstrate leadership for safety...	Clarification		X edited by working group		
98	2	F14	Requirement 3	Managers at all levels in the organization shall demonstrate leadership for safety in application of the management system, establishing continuous improvement, and in the fostering of a strong safety culture.	This is not leadership. Management system and safety culture are addressed in other requirements.		X edited by working group		
99	2	F15	3.3	3.3 Managers at all levels in the organization shall ensure that their leadership includes: (a) The involvement of teams and individuals in the organization in the application and continuous improvement of the management system to ensure safety (b) The advocacy of adherence to the management system and development of individual and institutional values and expectations for safety, throughout the organization by means of their decisions, statements and actions.	This is not leadership, or in a very indirect way.		2.2 Managers at all levels in the organization shall, taking into account their duties, ensure that their leadership includes: (a) setting goals for safety consistent with the organisation's policy for safety and actively seeking information on safety performance within their area of responsibility, and demonstrat-		

							ing commitment to improving safety performance. (b) Development of individual and institutional values and expectations for safety, throughout the organization by means of their decisions, statements and actions. (c) Ensuring that their actions serve to encourage the reporting of safety issues, develop questioning and learning attitudes, and to correct acts or conditions adverse to safety.		
100	3	E8	para 3.3 a) Page 10	The involvement of teams, <u>co-workers, subordinates</u> and individuals...	To be more precise add co-workers and subordinates as well.			x	To detailed for a requirement
101	2	AUS19	Para 3.3	Add additional point 3.3©: “ Support when appropriate for innovative approaches in achieving safety. ”	Managers at all levels should encourage innovative approaches in achieving safety which in turn will ensure continuous improvement.			x	To detailed for a requirement
102	1	G22	3.4	within their area of responsibility with appro-	Delete as not clear who		X		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				p riate monitoring, and shall	is monitoring whom and why. Added value unclear. Requirement is to actively seek information on safety. By which means is rather guidance level.				
103	2	AUS20	Para 3.4	Modify as follows: “Managers at all levels in the organization shall set clear goals for safety performance , shall actively seek information on safety performance within their area of responsibility with appropriate monitoring, and shall share this information within the organization and shall demonstrate commitment to improving safety performance.”	Without goals for safety performance, it would be difficult to measure whether safety performance is actually improved.			x	Goals and actual achievements are addressed under requirement 5
104	1	G23	3.5	Managers at all levels in the organization shall ensure that their actions serve to encourage the reporting of safety issues, develop questioning and learning attitudes, and to correct acts or conditions adverse to safety.	Learning attitude is an important aspect at this point – in particular prerequisite for corrections.		X		
105	2	G24	3.6 (a)	(a) Shall encourage all individuals to achieve their work safety goals and to perform their tasks safely, and shall support them in this;	Corresponds to a general and commonly accepted requirement for leadership, addressing employment protection provisions which are relevant for any organization even those not concerned with facilities and activities that give rise to radiation risks.		X		
106	3	J11	3.6	Managers at all levels in the organization shall : (a) S hall e ncourage and support all individu-	Editorial. Use the same form in		X		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				als to achieve their work goals and to perform their tasks safely, and shall support them in this; (b) Shall <u>e</u> Engage all individuals in enhancing safety performance; (c) Shall <u>e</u> Communicate to make transparent the basis of safety decisions.	the document				
107	2	FIN32	p.10 para 3.6	d) shall empower the personnel to take the responsibility on their own work and encourage them to identify conditions adverse to safety.	Addition The personnel shall have opportunity to participate to the continuous development of safety.				2.3a addresses empowerment (encourage and support)
108	2	AUS21	Section 3 “MANAGEMENT FOR SAFETY”	Change numbering to “4.” Change sub-heading to: “ RESPONSIBILITY FOR THE INTEGRATED MANAGEMENT SYSTEM FOR SAFETY ”	The current heading ‘Responsibility for Integration of Safety into the Management System’ is related to Requirement 7. The overall sub-heading should be more general	x	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		
109	1	G25	R4, R5, R6, R7	Swap Requirements to following order: R5, R4, R7, R6	The inner logic of the document is unclear. Goals, strategies, etc are tools of leadership and governance that are needed to steer the organisation. The MS is a tool or frame to help the discharge of the established strategies etc in a systematic manner. It is also important to establish the integration of the MS first, i.e. be-	x	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		

					come clear what my organisaiton <u>is</u> before starting interaction with stakeholders = interested parties.				
110	2	FIN33	p 11 R4	Requirement 7: Senior management's responsibility for the management system Senior management shall establish, implement, maintain and continuously improve an integrated management system for ensuring that ensures safety.	to be moved under Management System New numbering (previously R4 , now R7) plus some editorial changes		X		
111	2	G26	R 4	Senior management shall establish, implement, maintain and continuously improve a management system for ensuring safety . based on the fundamental safety principle.	Consistency with 1.3 and R1.	x	This comment has been taken into account during the revision of the document by the working group.		
112	2	F16	Requirement 4	Senior management shall <u>have</u> establish, implement, maintain and continuously improve a the management system for ensuring safety <u>established</u> .	Maintenance and improvement of the management is addressed in requirement 13. It won't be the senior management that will establish the management system by itself (this is acknowledged by paragraph 4.3 and 4.1). But it is the senior management that retain this responsibility The purpose of the management system is broader than safety. Safety is furthermore	x	This comment has been taken into account during the revision of the document by the working group.		

					addressed in 4.2				
113	3	J12	Req. 4	Add the footnote on “Senior management” as follows; <u>‘Senior management’ means the person or persons who are accountable for meeting the terms established in the licence, and/or who direct, control and assess an organization at the highest level. Several different terms are used, including, for example: board of directors, chief executive officer (CEO), director general, executive team, plant manager, top manager, chief regulator, site vice-president, managing director and laboratory director and owner.</u>	This footnote should be retained from GS-R-3 for clarification. It is beneficial for users to recognize the extent of “senior management”.	x			
114	2	E9	3 Management for Safety, page 11	RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM FOR SAFETY	Original headline should be kept: Integration is only a part of the whole process. There is a related requirement 7.	x	This comment has been taken into account during the revision of the document by the working group.		
115	1	G27	4.2	Senior management shall establish, implement, maintain <u>and continuously improve</u> the management system, in order to ensure safety and to meet regulatory and other requirements <u>that apply to the organisation. Regulatory requirements shall be identified within the Management System.</u>	“continuously improve” => consistency “apply to the organisation” => specification “identification of requirements” => requirements need to be actively identified before they can be met. This is an issue currently not addressed in the document.	x	This comment has been taken into account during the revision of the document by the working group.		
116	2	FIN34	p.11 para 4.2	Senior management shall establish, implement , maintain and continuously improve the man-	In addition to safety also quality needs to be	x	This comment has been taken		

				agement system, in order to ensure safety and quality and to meet regulatory and other requirements.	addressed in management system and its continuous improvement		into account during the revision of the document by the working group.		
117	2	F17	4.2	Senior management shall have establish, implement and maintain the management system <u>established</u> , in order to ensure safety and to meet regulatory and other requirements.	Superfluous. For consistency with previous comment.	x	This comment has been taken into account during the revision of the document by the working group.		
118	1	G28	4.3	Senior management shall assign to a designated individual the responsibility for coordinating the development, application <u>implementation</u> and maintenance of the management system, <u>where appropriate</u> . [...]	Consistency and to cope with the scope of the document	x	This comment has been taken into account during the revision of the document by the working group.		
119	2	G29	4.3	coordinating the development, and maintenance of	Consistency. Has “continuous improvement” been left out intentionally???	x	This comment has been taken into account during the revision of the document by the working group.		
120	2	F18	4.3	Senior management shall assign to a designated individual the responsibility for coordinating the development, application and maintenance of the management system. The designated individual shall be given the necessary authority to discharge this responsibility and shall be given direct access to senior management. This assignment of responsibility to an individual shall not detract from the line management’s responsibility and accountability for safety.	Too detailed for a requirement applicable to any size of organization (even self employed companies)	yes	X This comment has been taken into account during the revision of the document by the working group.		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

121	2	G30	R 5	Goals, Strategies, plans, and objectives. Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy and the fundamental safety objective	Objectives are set by e.g. the fundamental safety objective, IAEA Safety Requirements (e.g. SSR 2/1) and legislation. The organization needs to break them down into goals, strategies, etc. and align with them.			x	This reflects the IAEA terminology.
122	2	FIN35	p. 12	Requirement 65: Interactions with interested parties Interactions with interested parties shall be integrated into the management system specified by the senior management. 4.7 Senior management shall identify the 'interested parties' for their organisation and the appropriate strategy for interaction with them. Senior management shall ensure that there is appropriate timely and effective communication and consultation with interested parties ⁷ and shall ensure that relevant information is disseminated to them. 4.8 Senior management shall make arrangements to ensure that for processes for meeting legal and regulatory requirements and/or taking initiatives for interactions with interested parties are specified in the management system, and are understood and acted on by all individuals in the organization. 4.9 Senior management shall establish appropriate means of informing and consulting interested parties with regard to radiation risks associated with the operation of facilities or	This requirement (req 6) should be moved to Leadership and management These requirements are set to the senior management and not general management system requirements. As lessons learned from TEPCO Fukushima Dai-ichi accident it can be justified emphasize this requirement	yes	4.7 Senior management shall identify the 'interested parties' for their organisation and define the appropriate strategy for interaction with them. 4.8 Senior management shall ensure the processes and plans resulting from the strategy include: (a) appropriate means of informing and consulting interested parties with regard to radiation risks associated with the operation of facilities or the conduct of activities. (b) appropriate		

				the conduct of activities. 4.10 Senior management shall make arrangements to consider in its decision making processes the concerns and expectations of interested parties in relation to safety and to take appropriate actions.			timely and effective communication and consultation with interested parties and shall ensure that relevant information is disseminated to them. (c) appropriate means to consider in decision making processes the concerns and expectations of interested parties in relation to safety.		
123	2	F19	Requirement 5		What is the difference between “goals” and “objectives”? If no substantial difference, one word is enough.... Comment also valid for the following paragraph.			x	This reflects the IAEA terminology
124	2	F20	4.4	Senior management shall establish arrangements for the development of goals, strategies, plans and objectives, with in consultation of and with feedback of information from individuals in the organization. The goals, strategies, plans and objectives of the organization shall be developed in such a manner that safety is not compromised by other priorities.	First part of sentence duplicates the overarching requirement with no added value. Second part of the sentence is too detailed for an overarching requirement	yes	X		
125		E11	para 4.4 Page 11	<u>Based on the general company vision</u> , senior management shall establish goals, strategies, plans and objectives, in consultation ...	Add the first sentence: Licensee has to see the link between vision, strategies, goals...				

126	2	G31	4.5	Senior management shall establish measurable safety objectives in line with the goals, strategies and plans are established at various levels in the organization.	A periodically review of goals, strategies and plans implies automatically the establishment of measurable objectives which is covered by bullet 4.6.	x	This comment has been taken into account during the revision of the document by the working group.see127		
127	2	F21	4.5	Senior management shall <u>make arrangement for the establishment of</u> measurable safety objectives in line with the goals, strategies and plans are established at various levels in the organization.	Same formulation as 4.4 that would more accurately reflect what is expected from the senior management (make arrangements rather than make certain by itself).	x	4.5 Senior management shall ensure measurable safety objectives in line with the goals, strategies and plans are established at various levels in the organization.		
128	1	G32	4.6	Senior management shall ensure that the <u>goals, strategies and plans are</u> execution of plans is periodically reviewed against the safety objectives and goals , and that actions are taken where necessary to address any deviations from the plans .	Senior management must monitor that the organization as a whole develops into the right direction. This issue is missing in the document at the moment. With respect to the execution: the execution should be part of the management system and should be monitored as part of the assessment of the application of the management system. Therefore, monitoring the execution of plans should be mentioned under R 11 or R 13.	yes	X		

129	2	F22	4.6	Senior management shall make arrangements for the ensure that the execution of plans is periodically reviewed of plans against the safety objectives and goals, and that so that actions are taken where necessary to address any deviations from the plans.	Same formulation as 4.3 that would more accurately reflect what is expected from the senior management (make arrangements rather than make certain by itself)		This comment has been taken into account during the revision of the document by the working group.	See 127	
130	2	AUS22	Para 4.6	“Senior management shall ensure that the execution of plans is periodically reviewed against the safety objectives and goals, and that actions are taken where necessary to address any deviations from the plans.”	It is not entirely clear what is meant by “plans” and whether these include processes and instructions. In general it is important that deviations between plans and actions are addressed to avoid unintended organisational drift. It is a good practice to ensure that plans accurately reflect actions and maintained accordingly.		This comment has been taken into account during the revision of the document by the working group.	See 127	
131	1	F23	Requirement 6 and associated requirements		This part of DS456 deals with the responsibilities of the senior management, not the content of the management system. Although the associated requirements do start with “Senior management shall...”, the overarching requirement is not emphasizing senior management role. Transfer to the next section (the management system) should be consid-	yes	X		

					ered....				
132	2	F24	4.7	Senior management shall identify the ‘interested parties’ for their organisation and <u>define</u> the appropriate strategy for interaction with them.	Clarification	yes	X		
133	2	AUS23	Para 4.7	“Senior management shall <u>establish appropriate policy and standards related to interaction with interested parties</u> , identify the ‘interested parties’ for their organization and ...”	It is the senior management’s responsibility to ensure that appropriate policy and standards are in place for interaction with interested parties to achieve efficient and effective communication.	yes	4.7 Senior management shall identify the ‘interested parties’ for their organisation and define the appropriate strategy for interaction with them. 4.8 Senior management shall ensure the processes and plans resulting from the strategy include: (a) appropriate means of informing and consulting interested parties with regard to radiation risks associated with the operation of facilities or the conduct of activities. (b) appropriate timely and effective communication and consultation with interested parties and shall ensure that		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

							relevant information is disseminated to them. (c) appropriate means to consider in decision making processes the concerns and expectations of interested parties in relation to safety		
134	1	G33	4.7 Footnote	Interested parties may include: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.	Delete. This is guide level.		X see 133		
135	2	FIN35	p. 12	Requirement 65: Interactions with interested parties Interactions with interested parties shall be integrated into the management system specified by the senior management. 4.7 Senior management shall identify the ‘interested parties’ for their organisation and the appropriate strategy for interaction with them. Senior management shall ensure that there is	This requirement (req 6) should be moved to Leadership and management These requirements are set to the senior management and not general management system requirements.		This comment has been taken into account during the revision of the document by the working group.	See 122	

				<p>appropriate timely and effective communication and consultation with interested parties⁷ and shall ensure that relevant information is disseminated to them.</p> <p>4.8 Senior management shall make arrangements to ensure that for processes for meeting legal and regulatory requirements and/or taking initiatives for interactions with interested parties are specified in the management system, and are understood and acted on by all individuals in the organization.</p> <p>4.9 Senior management shall establish appropriate means of informing and consulting interested parties with regard to radiation risks associated with the operation of facilities or the conduct of activities.</p> <p>4.10 Senior management shall make arrangements to consider in its decision making processes the concerns and expectations of interested parties in relation to safety and to take appropriate actions.</p>	As lessons learned from TEPCO Fukushima Dai-ichi accident it can be justified emphasize this requirement				
136	3	J13	4.7/3	Senior management shall ensure that there is appropriate timely and effective communication and consultation <u>interaction</u> with interested parties ¹⁰ and shall ensure that relevant information is disseminated to them.	Better wording.		This comment has been taken into account during the revision of the document by the working group.		
137	2	G34	4.8	Senior management shall make arrangements to ensure that processes for meeting legal and regulatory requirements and/or taking initiatives for interactions with interested parties are specified in the management system, and are understood and acted on by all individuals in the organization.	Meeting legal requirements and interacting with stakeholders are two different subjects. Meeting legal requirements should be mentioned under R 7.	yes	X		

138	2	FIN37	p.12, Req.6	Please remove Req. 6 under the next title THE MANAGEMENT SYSTEM, or combine Req. 4-9 under one title.	Interactions with interested parties belongs rather together with Req. 7. On the other hand, Req.7 is about integration of the management system but integration is dealt under the previous subtitle.	x	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		
139	2	F25	4.9		It would be better to have 4.9 located before 4.8		All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		
140	2	FIN36	p. 12 Req 7	Req 7: Integration of the management system	This requirement should be compared with GS-R-3 and missing requirements should be added and consolidated as appropriate. Also renumbering is needed	To be done	All titles and order of sections were discussed in the working group meeting and have been incorporated in the DS456 October revision		
141	2	E10	Req. 7, page 12	Integration of all management elements of management in of the management system	Not the management system will be integrated, but the different systems will be integrated in one common system	1	This comment has been taken into account during the revision of the document by the working group		
142	2	F26	4.10	Senior management shall make arrangements to consider in its decision making processes	It's one of the senior management responsibil-	NA	This comment has been taken	4.8 (c) appropri-	

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				the concerns and expectations of interested parties in relation to safety and to take appropriate actions.	ity to consider the concerns and expectations of interested parties in its decision making process. It is not enough for the senior management to make arrangement in that case. Last words in paragraph are superfluous		into account during the revision of the document by the working group	ate means to consider in decision making processes the concerns and expectations of interested parties in relation to safety.	
143	2	G35	4.11	The management system shall be developed , implemented, maintained assessed and continuously improved. It shall be aligned with the safety goals of the organization and shall contribute to their achievement.	Consistency of wording with respect to other paragraphs. The safety goals shall be achieved.	1	This comment has been taken into account during the revision of the document by the working group		
144	2	G36	4.12	The management system <u>with all arrangements and processes</u> shall be implemented to achieve, and to enhance safety <u>and promote safety culture performance</u> by:	Clarification	yes	2 The management system with all arrangements and processes shall be implemented to achieve, and to enhance safety and promote to foster a strong safety culture by:		
145	2	E12	para	The management system shall be implement-	To change meaning of	1	This comment		

			4.12 Page 12	ed to achieve <u>goals safely</u> and to enhance safety performance by:	the sentence: The main target of NPP commercial operation is to produce electricity safely using safety goals		has been taken into account during the revision of the document by the working group		
146	2	G37	4.12 (a)	Bringing together in a coherent manner all the requirements and processes for managing the organization and its activities for safety	Requirements are not introduced so far.		2 Bringing together in a coherent manner all the requirements and processes <u>elements</u> for managing the organization and its activities for safety .		
147	2	F27	4.12 (a)	(a) Bringing together in a coherent manner all the requirements and processes for managing the organization and its activities for safety ;	The purpose of the management system is broader than safety (see requirement 7)	1	See 146		
148	3	E13	para 4.12 a) Page 12	Bringing together in a coherent manner all the requirements and processes for managing the organization and its activities for safety <u>performance</u> ;	Safety performance is a correct description of main NPP activities.		See 146	1	
149	2	G38	4.12 (b)	Describing the arrangements made for management of the organization and its activities as part of the integrated management system, in order to achieve a high level of safety performance, and describing the planned and systematic actions necessary to provide confidence that all requirements are met ;	Merged in to 4.12 Delete. Duplication of 4.12	1	Describing the arrangements made for management of the organization and its activities as part of the integrated management system, in order to achieve a high level of		Document deals about IMS, Safety performance is mentioned in the first sentence All requirements in-

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

							safety performance, and describing the planned and systematic actions necessary to provide confidence that all requirements are met;		cludes legal and regulatory requirements Future guidance should address the content of GS-R-3 ; para 2.3
150	2	F28	4.12 (b)	(b) Describing, <u>within the frame of the integrated management system</u> , the arrangements made for management of the organization and its activities as part of the integrated management system , in order to achieve a high level of safety performance, and describing the planned and systematic actions necessary to provide confidence that all <u>safety related</u> requirements are met;	Clarifications To stress the focus on safety		2 See 149		
151	1	G39	4.12 (d)	Promoting safety culture	Merged in to 4.12	1	See 144		
152	2	G40	4.12 (x)	<u>Identifying and meeting legal and regulatory requirements in a comprehensive and systematic manner.</u>	New. Taken from R 6 and inserted here.		See 149	3 with a prerequisite that the guidance will take the notes	Future guidance should address the content of GS-R-3 ; para 2.3
153	1	AUS24	Requirement 7: Integration of the man-	“The management system shall be implemented to achieve safety <u>and security</u> and to enhance safety <u>and security</u> performance by: (a) Bringing together in a coherent manner all the requirements and processes for managing the organization and its activities for safety	Wherever possible in the text, it should be made clear that the Integrated management system includes both safety and security re-			1	See discussion on first day Security not incorporated into this

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

			agement system Para 4.12	<u>and security</u> ; (b) Describing the arrangements made for management of the organization and its activities as part of the integrated management system, in order to achieve a high level of safety <u>and security</u> performance, (c) Ensuring that safety is <u>and security are</u> taken into account during decision making and is <u>are</u> not compromised by any decisions taken.	sponsibilities.				standard at this time.
154	1	G41	4.13	Provision shall be made in the management system to identify potential impacts of security measures on safety and potential impacts of safety measures on security, in order to plan and integrate measures to be taken without compromising safety or security.	Clarification. Easier to understand.			1	4.13 is clearly worded
155	2	F29	4.13		Deletion may be considered as 4.13 doesn't had much since it is already covered by 4.110 a) and c) (safety/security interfaces is one of the requirements that should be brought together in a coherent manner in the management system)			1	4.13 is clearly worded
156	1	G42	4.14	The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations, including with a parent organization, shall be clearly specified in the management system.	The management system is only for one organization. The interfaces between different parent or external organizations must be clear in the organizational structure and the interfaces processes.		3 The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces (within the organization and outside the or-		The management system describes also to interfaces to other organizations

							ganizations), including with a parent organization, shall be clearly specified in the management system.		
157	1	G43	4.15	4.15 Any proposed significant changes, (including organizational changes and cumulative changes), shall be analysed with regard to their implications for safety.	Fits better ruder requirement 13. It is part of the PDCA Cycle.			Should not be merged under Req. 13 because issues are different	<ul style="list-style-type: none"> It stays at 4.15
158	2	AUS26	4.15	<p>“Any proposed significant changes, (including organizational changes and <u>the</u> cumulative effect of minor changes), shall be analysed with regard to their implications for safety.”</p> <p>Alternatively replace with: <u>“A risk assessment shall be conducted for any change, (including organizational changes and the cumulative effect of minor changes). Any changes that have potential for significant implications to safety shall be appropriately analysed.”</u></p>	<p>Comment: There is no definition of what a significant change is, i.e. when does a change become significant. (Also relevant to Para 4.16).</p> <p>A clear understanding of what constitutes a significant change is important to the implementation of this requirement. Good practice is to risk-assess any changes for their implications for safety</p>	1 accepted as replacement of 4.15	... Provision shall be made in the management system for Any changes (including organizational changes and the cumulative effect of minor changes). that have potential for significant implications to safety shall be appropriately analysed.”		
159	2	G44	4.16	Arrangements shall be established in the management system for independent review before decisions significant for safety are made.	The independents of a review are only being given if it is a review	No	Wording will remain the same, independent var-		4.16 could be deleted: Should be

				The requirements on the independent nature of the review and on the competences of the reviewers shall be specified in the management system.	from outside the organizations. Maybe this point fits better under the Requirement 13.		ies between CM . Work group 3 decision is 4.16 stays as is		merged with 4.12 c; independence should be kept. Nature of independence should be described in the guidance
160	2	G45	4.17	Arrangements shall be established in the management system for the resolution of conflicts in decision making processes that affect safety..	Not useful duplication.			Rejected	
161	1	AUS27	4.17	Arrangements shall be established in the management system for the resolution of conflicts in decision making processes that affect safety- <u>and security</u> .			2 Arrangements shall be established in the management system for the resolution of conflicts in decision making processes that affect safety- and security .		Safety is ensured by Req. 7 All conflicts affects safety
162	1	FIN39	p. 13, Req.8	“ Graded approach to the definition and implementation of the requirements for the management system The requirements for of the management system shall be implemented by using a graded approach based on the safety significance of each activity and process.”	Text is not clear as such. Small practices may have lighter management systems than bigger license holders, thus, defining the requirements should be done appropriate.		The Group 2 of the working group piloted a reviewed of ‘meaningfulness’ and applicability. This was also sent to the rest of the group for review.	4	

							Also it has been agreed that an annex or a tech-doc will be developed to explore the aspect of grading and application in different types of organization.		
163	2	F30	Requirement 8	The requirements for arrangements within the management system shall be <u>defined and</u> implemented by using a graded approach, based on the safety significance of each activity and process.	To be consistent title of the requirement Grading should first be considered when defining the provisions of the management system. “Arrangement” is a better word as “requirements” have to be implemented (no grading possible).		Undecided, made suggestion to use the following Main requirement of GS-R-3 2.6: The application of the management system shall be graded so as to deploy adequate resources Need to clarify what requirements	4 See 164	Re draft the requirement The management system shall be developed and implemented using a graded approach
164	2	AUS28	Requirement 8	<u>“All requirements for the management system shall be implemented, with a graded approach based on the safety significance of each activity and process dictating the mode of implementation.”</u>	Important to clarify that all the Requirements of DS456 are essential to be implemented for the whole range of facilities, with the graded approach dictating the mode of implementation of each one.		All requirements for <u>and of</u> the management system shall be implemented, 4.18 should cover	Can't refer to Techdoc in DSS-456 See TECDO C-1740 2.1	Resolved review writing of 4.18 to 4.1? with the decision. What is graded? Options 1. Does the

							the development and application of the graded approach	GS-R-3, 2.3; 2.6	graded approach applies to section 4.11 – 4.17 (requirements for management system) Or 2. The grading applies to the requirements contained in the Management System, which is all legal and reg. requirements. Grading applies to the management systems of the licensees
165	2	G46	4.18	1 st sentence: “The criteria for grading the application of the management system requirements shall be documented in the management system [34] [36].”	Wrong reference is cited in this paragraph. The criteria for grading the application of the management system requirements are specified in TECDOC-1740. With respect to this proposal, see also the IAEA resolution table of SSC comments (June 2015), Canadian comment No. 36 on Para 4.16. This comment has	1	All references will be developed and amended once main text body has been approved.		

					been accepted but incorrectly implemented.				
166	2	G47	4.18	The criteria for grading the application of the management system requirements shall be documented in the management system [34]. The following shall be taken into account	For facilities and activities with very low risks (e.g. x-ray tube at a dentist), the formal detailed documentation lying down all grading criteria should also be graded. The source is the “Code of Conduct on the Safety of Research Reactors, IAEA, Vienna (2006)”. May be this fits not very proper into an origination responsible for a power reactor.	1	The Group 2 of the working group piloted a reviewed of ‘meaningfulness’ and applicability. This was also sent to the rest of the group for review. Also it has been agreed that an annex or a tech-doc will be developed to explore the aspect of grading and application in different types of organization.		
167	2	F31	4.18	The criteria for grading the <u>safety related arrangements application</u> of the management system <u>requirements and their implementation</u> shall be documented in the management system [34]. The following shall be taken into account:	To be consistent with previous comment on overarching requirement To focus on the safety related aspects of the management system. (the bullet list is clearly related to safety)		The Group 2 of the working group piloted a reviewed of ‘meaningfulness’ and applicability. This was also sent to the rest of the group for review. Also it has been agreed that an annex or a tech-	Resolved	

							doc will be developed to explore the aspect of grading and application in different types of organization.		
168	1	G48	4.18 (a)	The significance for safety and the complexity of the process, activity, structure, system, component, item of equipment, product or service;	This is a duplication of the requirement		2 The significance for safety and the complexity of the process, activity, structure, system, component, item of equipment, product or service <u>And the organisations size and complexity.</u>		Would lose too much information
169	1	G49	4.18 (b)	The hazards and the magnitudes of the radiation risks, including potential radiological consequences, associated with the safety, health, environmental, security, quality, societal, economic and other elements of each activity or product;	Is not focused on management processes or on the management of processes. Is too detailed. Move to guidance level.			x	<u>Decision is to keep it as is in the draft</u> 4: Integrating 4.18 c in 4.18 b
170	3	AUS29	4:18	Correct reference [34].	Reference [34] is incorrect. It should be replaced by an appropriate reference on application of the graded approach.	1	All footnotes and references will be amended and developed once main text is approved.		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

171	3	J14	4.7/3	Senior management shall ensure that there is appropriate timely and effective communication and consultation <u>interaction</u> with interested parties ¹⁰ and shall ensure that relevant information is disseminated to them.	Better wording.		Wrong line		
172	1	G50	4.18 (c)	The possible consequences if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.	Is not focused on management processes or on the management of processes. Is too detailed. Move to guidance level.				Decision made stays as is
173	3	F32	4.18 (c)	(c) The possible consequences <u>on safety</u> if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.	Clarification	Agree			4: Integrating 4.18 c in 4.18 b
174	2	AUS30	4.18	The criteria for grading the application of the management system requirements shall be documented in the management system [34]. “ <u>An evidence-based, risk-informed approach shall be adopted that takes into account appropriate safety and security considerations.</u> ”	Additional text, possibly for use in guidance: “ Safety risk will be informed by an appropriate hazard assessment of the controlled facility or apparatus, combined with the radiological and non-radiological consequences of an accident. Security risk will be informed by an appropriate threat assessment, combined with the radiological and non-radiological consequences of a deliberate act. ”		RESOLVED		4. Option: 1.Forms a high level requirements and shift a,b,c, in the guidance 4. Keep a,b,c

175	2	AUS31	Requirement 9	<p>The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.</p> <p><u>“The management system shall be documented in an appropriate quality system format.”</u></p>	The current text is unclear and as a Requirement it does not read well. Such details should in a guidance document. A quality system format means it is properly controlled, good readability, useable etc.				Would a step back in the format
176	2	G51	4.19	The documentation of the management system shall include, as a minimum , the following:	Clarification that this is not the minimal content required for all facilities and activities without modifications in the context of a graded approach.	1			Shall is already describing the minimum
177	2	G52	4.19 (a)	(a) The <u>description of the</u> policy statements of the organization, <u>the safety policy, the safety goals, the structure of the organization</u> that includes a statement of the values and behavioural expectations as defined by senior management.	4.19 (b) and (c) can be merged in (a)				<p>Group agreed to proposal</p> <p>3. Should be restructure in a logical order</p> <ul style="list-style-type: none"> • Policy • Description organisation, roles and responsibilities including decision making • descrip-

									tion if management system complies
									<ul style="list-style-type: none"> • description of processes • Interactions between participated parties
178	1	G53	4.19 (b)	A safety policy, stating that achieving the fundamental safety objective of protecting people and the environment from harm is an overriding priority.	Merged in to 4.19 (a)				177
179	3	E14	Para 4.19 b, page 14	The hazards and the magnitudes of the radiation risks, including potential radiological consequences, associated with the safety, health, environmental, security, quality, societal, economic and other elements of each activity or product facility.	Harmonization of terms				177
180	2	FIN41	p 14 para 4.19	(b) — A safety policy, stating that achieving the fundamental safety objective of protecting people and the environment from harm is an overriding priority.	and b) can be combined (b is already required in 3.2 e				177
181	1	G54	4.19 (c)	A description of the structure of the organization;	Merged in to 4.19 (a)				177
182	3	F33	4.19 (d)	(d) A description of how the management system the provisions to comply with the all regulatory requirements that apply to the organization;	Is (d),as initially written, part of the management system ? Alternate wording suggested to focus on what				177

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

					is to be done, and not why it has to be done				
183	2	G55	4.19 (e)	(e) A description of the responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work <u>including the of ‘when, how and by whom’ decisions are to be made;</u>	Merge old 4.19 (f) in to old 4.19 (e)				177
184	1	G56	4.19 (f)	A description of ‘when, how and by whom’ decisions are to be made;	Merged in to old 4.19 (e)				177
185	1	G57	4.19 (g)	(g) A description of the organizational <u>work flow</u> processes, with supporting information that explains how work is to be planned, performed, verified, recorded and assessed and how safety, quality and security are to be assured.	It is not necessary to describe the how. Is too detailed. Move to guidance level.				177
186	?	FIN40	p. 14, para 4.19 (g)	A description of the organizational processes, with supporting information that explains how work is to be planned, performed, verified, recorded and assessed and how safety, quality and security are to be assured.”	This is good requirement because the integration of safety and security in the management system is essential and this is a good publication to mention it.				177
187	2	AUS32	4.19 (g)	Add two additional clauses after (g). The first: <u>“A description of how the system is reviewed to ensure that there is continued alignment between the management system requirements and how work is undertaken (to avoid unexpected and unassessed organizational drift).”</u>	There is a need to ensure that a management system is kept relevant and not simply a paper system. Work practices invariably vary (drift) over time as often subtle changes are applied in the workplace. Experience shows that risks associated with these changes are often not				177

					properly assessed with the result that normal operations tend to move closer or impinge on safety margins (Texas City, Challenger are examples). This clause is intended to avoid this.				
188	2	AUS33	4.19(g)	The second: <u>“A description of how operational experience, including any deviations from expected practice and outcomes, is used to improve operational safety. Learning shall be gained from positive as well as negative deviations.”</u>	The need to learn from operational experience is not explicitly stated in the list of minimum requirements for the management system. Accidents rarely occur without previous, precursor incidents and occurrences, many of which still have a positive outcome. This proposed clause requires consideration of deviations and encourages understanding why a deviation has occurred. It helps to build resilience for safe operation. Note 4.43 is a similar requirement.				177
189	1	G58	4.19 (h)	A description of the interactions with <u>regulatory body, the TSO, the public, other</u> interested parties and with external <u>or parent</u> organizations, including interactions with the parent organization, if any, and interactions with the regulatory body, as applicable.	Clarification.				177
190	1	G59	4.21	Changes to documents shall be reviewed, <u>and</u>	For a better understand-		2.		Documents

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

			<p>recorded and shall be subject to the same level of approval as the documents themselves. The Records shall be controlled readable, complete, identifiable and easily retrievable. Where necessary, records shall be marked unambiguously for identification. The identification code shall contain reference to the state of the revision of the individual document.</p>	<p>ing merge 4.22 in to 4.21.</p> <p>There are safety significant areas and activities where it is necessary to mark each document unambiguously</p>		<p>Changes to documents shall be reviewed, and recorded and shall be subject to the same level of approval as the documents themselves. The Records shall be controlled readable, complete, identifiable and easily retrievable. Where necessary, records shall be marked unambiguously for identification. The identification code shall contain reference to the state of the revision of the individual document.</p>	<p>and records have different characters.</p>
--	--	--	--	--	--	--	---

191	1	G60	4.22	Records shall be specified in the management system, and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.	For a better understanding merge 4.22 in to 4.21.		2 Group suggested to remove yellow part		Information about revision of the individual document should be in the guidance Recommendation
192	2	FIN42	p. 15 para 4.22	<u>The processes for producing the records shall be described.</u> Records shall be specified in the management system, and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.	Addition see also next comment			Rejected Addition should be kept in the guidance	
193	2	FIN43	p. 15, Paragraphs 4.22 and 4.23	Please consider to extend the main requirement to cover also records.	Para 4.22 and 4.23 address records but the main requirement is about documentation (not mentioning records at all). Or reformulate and shift to a better place			Rejected	
194	2	FIN44	p. 15 Req. 10	Senior management shall determine and provide shall ensure the availability of, the competences and resources necessary to carry out	reformulation, clarification	Accepted			

				the activities of the organization to ensure safety so that safety is continuously improved and not compromised.					
195	2	FIN45	p. 15 para 4.24	Senior management shall make arrangements to ensure that the organization maintains access to the full range of competences and resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity.	clarification			Rejected	See 196
196	3	F34	4.24	Senior management shall make arrangements to ensure that the organization has <u>in-house or</u> maintains access to the full range of competences and resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity.	For consistency with 4.25. Clarification to stress that in(house resources are important even if contracted resources may be needed to a various extent...	Accepted			
197	2	FIN46	p. 15 para 4.25	4.25 Senior management shall determine which competences and resources it has to retain or to develop internally, and which competences and resources may be obtained externally to maintain safe operations .	clarification		Senior management shall determine which competences and resources it has to retain or to develop internally, and which competences and resources may be obtained externally to <u>maintain safe operations ensure safety</u>		
198	2	AUS34	4.26	Replace “training is” by “ <u>training and retraining are</u> ” after training.	Training is followed by retraining. In order to increase the effectiveness of training, ‘re-training’ is essential.			Rejected	Is already covered in the req.: ...and sustain the required lev-

									els of competence.
199	2	FIN47	p. 15 – 16 para 4.27	<p>Competences to be maintained in-house by the organization shall include</p> <p>competences for leadership competencies at all management levels of the organization and competence for developing and sustaining a safety culture, and expertise to understand and maintain the design and operation for ensure safety of the facility or activity.</p> <p>Senior management shall ensure:</p>	<p>editorial, clarification</p> <p>A separate requirement from this on ----</p> <p>Change was done to make the requirement applicable for a larger variety of licensee</p>		<p>Competences to be maintained in-house by the organization shall include competences for leadership competencies at all management levels of the organization and competence for developing and sustaining a strong safety culture, and expertise to understand and maintain the design and operation <u>technical and organisational aspects to ensure safety</u> related to the of the facility or activity to ensure safety.</p>		
199a		Canada	4.27a	That individuals at all levels, including manager and workers, are competent to <u>safely and effectively</u> perform their assigned tasks and work;		Accepted			
200	3	F35	4.27		4.26 and 4.27 should be located together as both deal with internal resources.			Rejected	There is a clear distinction between the focus of 4.26 and 4.27

201	2	F36	4.27	Competences to be maintained in-house by the organization shall include competences for leadership at all levels and for developing and sustaining a safety culture, and expertise to understand and maintain the design and operation for safety of the facility or activity.	Leadership and safety culture are already addressed in other requirements (3.2 (g), requirement 3... for leadership; requirement 14for safety culture) so no need to replicate them again.			Rejected	There is a clear distinction between the focus of 4.26 and 4.27. Leadership and SC should remain.
202	3	F37	4.27		Wording “design and operation for safety” is unusual... Wording to be checked by Technical Editors	Accepted			Death in 199
203	2	AUS35	4.28	Replace “ shall be trained in relevant requirements ” by “ shall be trained and retrained in relevant requirements ”.	As above		Was incorporated in the second sentence . Such training shall ensure that an individuals is knowledgeable about the relevance and importance
204	2	FIN48	p. 16 para 4.29	The information and knowledge of the organization shall be managed as a resource that includes supporting safety and promote a strong safety culture	Clarification	Accepted			
205	3	F38	4.29	The information and knowledge of the organization shall be managed as a resource that includes supporting safety and promote a strong safety culture.	Superfluous (and unclear)	Accepted			
206	2	E15	para 4.29 Page 16	<i>Senior management shall ensure that expertise in human factors and organizational factors is applied as part of the development of</i>	The former deleted 4.29 text (italic) was dedicated to HF and organisa-				Group decision is to include re-

				<p><i>leadership and management for safety, and of process and plant safety requirements.</i></p> <p>The information and knowledge of the organization shall be managed as a resource that includes supporting safety and promote a strong safety culture.</p>	<p>tional factors to highlight these important skills.</p> <p>The new sentence is not easy readable and the sense is not clear. May be something is missed We propose to return to the former text. Should be discussed in the WG.</p>				<p>requirement for HOF competencies in the requirement 10 bold section</p> <p>4. Needs to be discussed: Proposal does not fit on 4.29, however we recognize the importance to have HOF competencies: Where ? Consideration that small licensees could have HOF in-house</p>
207	3	AUS36	4.29	Replace “ promote ” by “ promoting ”.	Grammar			Rejected	See204
208	1	G61	Requirement 11	<p>Requirement 11: Management of processes and activities Processes and activities shall be developed and managed at all levels of authority to achieve the organization’s safety goals. Each existing or new process and the interactions between processes shall be developed and managed to ensure requirements are met without compromising safety.</p>	4.31 and 4.32 moved to requirement level. Is important for understanding.			Rejected	Addition of text too detailed for a general requirements.
209	2	FIN50	p. 16 R.11	Requirement 10: Management of system pro-	New number Requirement 10		Req 11: Management of pro-		

				<p>cesses and activities</p> <p>Processes and activities shall be developed and <u>effectively</u> managed to ensure safety to achieve the organization's safety goals.</p>	<p>reformulation of the requirement</p>		<p>cesses and activities</p> <p>Processes and activities shall be developed and <u>effectively</u> managed to ensure safety to achieve the organization's safety goals <u>safely</u></p>		
210	1	G62	4.30	The management of processes and activities shall ensure that there are measures in place for:	<p>The order of all sup points has to be changed. (PDCA)</p> <ol style="list-style-type: none"> 1. Develop a process including all possible interactions. 2. Implementing the process and us the process in the daily work. 3. Check the process if it fits well or any lessons have to be learned. 4. Review the process in necessary to implement lessons learned. 	Accepted			
<p>Requirement 11:</p> <p>4.30 – 4.35:</p> <p>Comment 211 – 216: Removal of the Process Owner (function) compared to GS-R-3 5.6 leads to unclarity to clearly understand the distinction of 4.30 to 4.35.</p> <p>Two options:</p>									

- ~~Bring back the roles according to GS R-3~~

- Rewrite the requirements 4.30 to 4.35 focusing the topics, e.g. incorporating 4.30 b with 4.32... **Accepted by the group**

210 The management of processes and activities shall ensure that there are measures in place for :

(a) Developing and documenting the process and maintaining the necessary supporting documentation, ensuring that process documentation is consistent with any existing documents;

~~(a)(b) Ensuring that there is effective interaction between interfacing processes;~~

~~(b) Ensuring that process documentation is consistent with any existing documents;~~

(c) Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;

(d) Monitoring and reporting on performance of the process;

(e) Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization.

(f) Bringing about improvements in the process;

211	3	F39	4.30	The management of processes and activities shall ensure that there are measures in place for <u>The management system shall include arrangements for:</u>	For consistency with wording of 4.38			Rejected	Content of Management System is done in THE MANAGEMENT SYSTEM.
212	2	G63	4.30 (a)	Developing and documenting the process and maintaining <u>including</u> the necessary supporting documentation <u>and interaction between interfacing processes</u>	For a better understanding merge 4.30 (b) in to 4.30 (a).			<u>Rejected</u> combined was a and c.	

								see above	
213	2	G64	4.30 (e)	performance of the process and process results.	Completeness			Rejected, because it is already addressed in c.	
214	1	G65	4.31	Each process shall be developed and managed to ensure requirements are met without compromising safety.	Moved to requirement level.			Rejected See general comment 208	
215	1	G66	4.32	The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Particular consideration shall be given to interactions between processes within the organization and interactions with processes conducted by external service providers.	First sentence moved to requirement level.			Rejected See general comment 208	
216	1	G67	4.33	New processes or changes to existing processes shall be designed, verified, approved and implemented so that safety is not compromised.	Can be deleted. Is part of the requirement. Requirement is for existing and new processes.			Rejected Rejected See general comment 208	
217	3	E16	Requirement 12, page 17	Footnote: <u>services that may influence safety include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refuelling, and modifying items or products that may influence safety.</u>	<i>Add a footnote at the end of the requirement to clarify:</i> Clarification of “services that may influence safety” + link with current nuclear QA guidance			Rejected; Should be captured in the guidance in more detail	
218	2	G69	4.36	“The organization shall retain responsibility	More detailed guidance	Accept-		Group	

				for safety when contracting any processes and/or when receiving any item, product or service in the supply chain [38].”	on supply chain management is provided in TECDOC-919. Please insert a reference to this publication. With respect to this proposal, see also the IAEA resolution table of SSC comments (June 2015), Canadian comment No. 52 on Req. 12. This comment has been accepted but not implemented.	ed		decision rejected to include TECDOC in DS	
219	3	E17	Para 4.37, footnote 10 Page 17	The organization shall have a clear understanding <u>and knowledge</u> of the product or service being supplied. Footnote 10 The capability of the organization to have a clear understanding and knowledge of the product or service to be supplied is sometimes termed an ‘informed customer’ (or ‘intelligent customer’ or ‘knowledgeable customer’) capability.	Clear understanding is not efficient. Knowledge should be also available. Harmonization with footnote 10.	Accepted			
220	2	J15	4.38/1 (h)	4.38 The management system shall include arrangements <u>using a graded approach</u> for: (h) Periodic assessment of the management system of suppliers and of their performance using a graded approach;	All elements of para 4.38 should be performed in accordance with graded approach.		4.38 The management system shall include arrangements using a graded approach for: (h) Periodic assessment of the management system of suppliers and of their performance		

							using a graded approach; <u>Graded approach is already mentioned in Req. 8</u>		
221	2	G70	4.38 (i)	“Verification that items, products and services supplied meet the organization’s specifications and are authentic. [35] [37].”	Wrong reference is cited in this paragraph. The management of counterfeit, fraudulent and suspect items is addressed in more detail in TECDOC-1169. With respect to this proposal, see also the IAEA resolution table of SSC comments (June 2015), Canadian comment No. 50 on Para 4.38 (h). This comment has been accepted but incorrectly implemented.			Remove the reference to tecdoc	
222	2	F40	4.38		Those requirements are appropriate for NPP operators and other “big” licensees. For “small” licenses, it is unlikely such requirement will be fully complied with.... May be it could be summarized to : (a) Selection of vendors/suppliers/contractors, taking account of their technical ca-		Two options 1. Use French proposal and improve with e: (a) Qualification and Selection, taking account of their technical capabilities and management system (a,b) (b) Specification of contrac-		

					<p>pabilities and management system</p> <p>(b) Specification of contractual requirements, including safety requirements</p> <p>(c) Verification that items, products and services supplied meet the organization's specifications.</p> <p>(d) When relevant, information or training to supplier's staff.</p>	<p>tual requirements, including safety requirements (e)</p> <p>(c) Verification that items, products and services supplied meet the organization's specifications.)</p> <p>(i)</p> <p>(d) When relevant, providing information or training to supplier's staff. (f)</p> <p>(e) Provisions for providing oversight over the supply chain (d, g.c)</p> <p>Agreed by the group 2nd option Second option: One single requirement</p> <p>The management system shall include arrangement for the Qualification, selection, evaluation, procurement</p>		
--	--	--	--	--	---	--	--	--

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

							and oversight of the supply chain.		
							Details for 4.38 a) to i) must be contained in the guidance.		
223	2	F41	4.38				See 222		
					Several bullets are dealing with the management system of the provider. It would be useful to group them together (or even make it only one but of higher level)				
224	3	FIN56	p.18 R 13	Requirement 1314: Measurement, assessment and improvement of the management system The effectiveness of the management system shall be measured, assessed and improved so as to enhance safety performance systematically.	New numbering (14)		A new section has been created for Measurement Assessment and Improvement. See 225		
225	2	G68	Requirement 13	Measurement, assessment and improvement of the management system The effectiveness of the management system shall be verified, validated, measured , assessed and improved on the basis of lessons learned so as to enhance safety performance .	Better understanding and clear structure.	x	6.11 The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended and to identify opportunities for its improvement.		
226	3	F42	Requirement 13	MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM	Measurement is one way of assessment...			x	GSR3 included measurement as part

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				Requirement -13: Measurement , assessment and improvement of the management system The effectiveness of the management system shall be measured , assessed and improved so as to enhance safety related performance.					of guidance and identifies them differently.
227	1	G71	4.40	The effectiveness of the management system shall be monitored and measured. to confirm the ability of the organization to achieve the results intended, to share feedback on and to learn from successes and strengths and weaknesses, and to identify opportunities for its improvement.	It is impossible to find problems in a management system if the monitoring is used to confirm the intended results. Everything will be good. Better is to keep the suggested monitoring. The how can be move to guidance level.	x	6.11 The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended and to identify opportunities for its improvement.	x	Organization use many different measurement and monitoring methods to assure the effectiveness of their systems. These are not necessarily part of the regulators oversight.
228	2	FIN57	p. 18 para 4.40	The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended, to share feedback on and to learn from successes and strengths and weaknesses , and to identify opportunities for its improvement.	clarification, to be balanced (the removed text could be used in the guide)	yes			
229	2	F43	4.40	The effectiveness of the management system shall be monitored and measured to confirm the ability of the organization to achieve the results intended...	Superfluous (see previous comment)			x	GSR3 included measurement as part of guidance and identifies them differently.
230	2	G72	4.41	Performance indicators shall be developed and used in order to assess the effectiveness of the management system. and to confirm the suitability of processes or activities for achieving	All used performance indicators will be green if only used to confirm the intended outcome. It	x	Performance indicators have been moved to be included in guid-		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				the intended outcomes. Trends in performance indicators shall be analysed and evaluated at regular intervals.	is absolutely enough to request the existents of performance indicators.		ance		
231	2	F44	4.41	Performance indicators shall, where practicable, be developed and used in order to measure the effectiveness of the management system	Performance indicators may not be always relevant	x	Performance indicators have been moved to be included in guidance		
232	1	G73	4.42	All processes shall be periodically evaluated for their effectiveness and ability to ensure safety. Performance indicators should be used. Assessments shall be made of radiation risks arising from particular processes and activities and used to decide when significant revision of the management system is required.	Move to guidance level.	x	Performance indicators have been moved to be included in guidance		
233	3	E18	para 4.42 Page 19	Performance indicators should be used.	Delete second sentence; same is written in the previous sentence.	x	Performance indicators have been moved to be included in guidance		
234	1	J16	4.42/2	“Performance indicators should be used.” should be modified as follows; 1) Performance indicators shall be included as one of the evaluation element. or 2) Performance indicators shall, where practicable, be developed and used in order to measure the effectiveness of the management system.	All processes shall be periodically evaluated for their effectiveness and ability to ensure safety, using performance indicators or other equivalent indexes. Assessments shall be made of radiation risks arising from particular processes and activities and used to decide when significant revision of the management system is required.	x	Performance indicators have been moved to be included in guidance		
235	3	F45	4.42	Performance indicators should be used.	Duplicates 4.41	x	Performance indicators have		

Relevance: [1 – Essentials](#) [2 – Clarification](#) [3 – Wording/Editorial](#)

							been moved to be included in guidance		
236	3	F46	4.42	Assessments shall be made of radiation risks arising from particular processes and activities and used to decide when significant revision of the management system is required.	Unclear. Superfluous considering the first part of 4.42	x	Performance indicators have been moved to be included in guidance		
237	3	G74	4.43	The causes of non-conformances of processes , events and safety issues that arise shall be determined and the potential consequences shall be evaluated, managed and mitigated. Corrective actions for eliminating the causes of non-conformances and preventative actions to avoid the recurrence of the same or similar safety issues shall be determined and shall be taken in a timely manner. The status and effectiveness of all corrective and preventive actions taken shall be monitored and shall be reported to management at an appropriate level in the organization.	Clarification.	yes			
238	2	J17	4.43/1-3	“The causes of non-conformances, events and safety issues that arise shall be determined and the potential consequences shall be evaluated, and shall be managed and mitigated the problems. ”	Logical clarification After the “cause” is identified and its consequence is evaluated, some measures will be taken. In this case, some measures is management and mitigation of deficiencies generated by “cause”.			x	
239	2	E19	para 4.43 Page 19	Corrective actions for eliminating the causes of non-conformances, <u>root causes of events</u> and preventative actions ...	Add to the second sentence; For continuity - in the beginning of that sentence events are		Will be incorporated in guidance	x	

240	2	AUS37	4.43	Proposed amendment: <u>“The causes of non-conformances, events and deviations from expected conduct and outcomes (positive as well as negative) shall be assessed and the potential consequences shall be evaluated, managed and mitigated. Improvements for eliminating the causes of non-conformances and preventative actions to avoid the recurrence of the same or similar safety issues shall be determined and shall be taken in a timely manner. The status and effectiveness of all improvement actions taken shall be monitored and shall be reported to management at an appropriate level in the organization.”</u>	mentioned as well. Para 4.43 focuses on negative issues. Learning should come from positive as well as negative issues. The proposed amendment reflects a more resilient approach which learns from positive and negative outcomes.	x	6.13 Organizations should learn from success and strengths in order to develop their continuous improvement.		
241	2	F47	4.44	Self assessment of the management system for safety shall be performed by managers and by individuals at all levels in the organization <u>Managers, and other individuals when relevant, shall carry out self-assessment on the performance of work for which they are responsible with the following purposes...</u>	It seems very dubious that any individual in the organization will perform a self-assessment. Proposition to clarify that it falls under the responsibility of the managers and to specify the scope of the self-assessment.		6.17 Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization. This review and	x	Self-assessment guides are available in all areas of management and safety culture. The self-assessment of leadership will be developed.

							subsequent improvements shall cover all significant sources of information on safety performance.		
242	1	G75	4.44 (a)	to identify and to learn from successes and strengths, and to correct weaknesses that hinder the achievement of the organization's safe delivery of objectives as part of continuous improvement.	To detailed move to guidance level.		See 241		
243	2	AUS38	4.44(a)	Proposed amendment: <u>“(a) to learn from successes and strengths, in order to identify opportunities for improvement and to correct weaknesses that hinder the achievement of the organization's safe delivery of objectives as part of continuous improvement.”</u>	This proposal places more emphasis on continuous improvement rather than limiting it to the correction of weaknesses. The objective is to keep improving safety (robustness) even when there is no apparent weakness.		See 241		
244	1	G77	4.44 (b)	to confirm that the management system is delivering to the required standard for safety;	To detailed move to guidance level.	x	6.12 All processes shall be periodically evaluated for their effectiveness and ability to ensure safety.		
245	1	G78	4.44 (c)	to enhance leadership and safety culture and to ensure the effectiveness of processes and activities;	To detailed move to guidance level.	x	Moved to Requ 15		
246	2	F48	4.44(c)	(c) to enhance leadership and safety culture and to ensure the effectiveness of processes and activities;	Self-assessment <u>of the management system</u> is not directed at leadership and safety culture.	x	6.12 All processes shall be periodically evaluated for their		

					Self-assessment of practices may help assess leadership and safety culture....		effectiveness and ability to ensure safety.		
247	1	G79	4.44 (d)	to participate in the sharing of experience with the nuclear industry.	To detailed move to guidance level.	x	Moved to guidance		
248	3	J18	4.44 (d)	(d) to participate in the sharing of experience with the nuclear industry <u>appropriate interested parties.</u>	Better wording. Not limiting the nuclear industry.		See247		
249	2	F49	4.44 (d)	(d) to participate in the sharing of experience with the nuclear industry.	It is not the purpose of self-assessments... Furthermore, how could it be relevant for a dentist...		See 247		
250	1	G80	4.45	Independent assessments (including audits) of the management systems, shall be conducted regularly by senior management <u>by an independent external organization</u> to evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following:	Important clarification. An entity of the same organisation or an individual with in the organisation is never independent. No further details are needed.	x	6.15 Independent assessments (including audits) of the management system shall be conducted regularly by an independent external organisation to evaluate its effectiveness, and identify opportunities for improvement.		
251	2	FIN58	p. 19 para 4.45	Independent assessments (including audits) of the management system, shall be conducted regularly by senior management to evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following:	Need to be clarified, not clear what is required	x	See 250		

252	2	FIN49	p.19 para 4.45	Independent assessments (including audits) of the management system, shall be conducted regularly by senior management to evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following	Senior management shall ensure that these are done regularly (nominate a group of people etc.)	x	See 250		
253	2	AUS39	4.45	Replace existing 4.45 by: “Senior management shall ensure that independent assessments (including audits) of the management system are conducted regularly. Senior management shall evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following:”	The full intent of this clause is not entirely clear. It is arguable that senior management is independent; however, it is accepted that senior management needs to show leadership. This amendment is designed to strengthen the independence whilst retaining senior management involvement.	x	See 250		
254	2	J19	4.45/2	Independent assessments (including audits) of the management system, shall be conducted regularly on behalf of by senior management to evaluate its effectiveness, and identify opportunities for improvement. Independent assessments of the management system shall critically evaluate the following:	Retain the original sentence. Senior management is required to evaluate the results of the independent assessment (para 4.46). If the wording “on behalf of” is deleted, senior management will evaluate the independent assessment which is conducted by himself. This will be against the principle of evaluation..	x	See 250		
255	1	J20	4.45/3	Add one sentence between two sentences;	Added sentence is es-	X	See 250		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				4.45 Independent assessments (including audits) of the management system for safety, shall be conducted regularly <u>on behalf of</u> senior management to evaluate its effectiveness, and identify opportunities for improvement. <u>Persons conducting independent assessments shall not assess their own work.</u> Independent assessments of the management system shall critically evaluate the following:	sential element to perform independent assessment. This proposed sentence is coming from item 6.5 of GS-R-3.				
256	2	F50	4.45 (c)	(e) Leadership performance and safety culture;	See previous comment It is not the purpose of self-assessments... Furthermore, how could it be relevant for a dentist...	x	Moved to requirement 15		
257	2	FIN51	p. 16-17		This requirement and paras related should be compared with GS-R-3 and missing requirements should be added and consolidated as appropriate.				
258	2	FIN52	p. 20 para 4.50	The management system shall include evaluation and timely use of the following:	text should be clarified, should there be a process for operational experiences or is this more like benchmarking IMS with other organisations			x	Sub clauses a) b) and c) clarify the application Includes benchmarking and OE , wider sharing of operating experience, , research and development, and other 'good prac-

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

										tice develop- ment’ – de- tails to be in the guidance.
259	1	G81	4.45 (a)	The fulfilment of requirements, goals, strategies, plans and objectives;	To detailed move to guidance level.	x				
260	1	G82	4.45 (b)	Delivery of the required standards for safety, and the integration of safety requirements by the management system	To detailed move to guidance level.	x				
261	1	G83	4.45 (c)	Leadership performance and safety culture;	To detailed move to guidance level.	x				
262	1	G84	4.45 (d)	The adequacy of resources provided for individuals to be able to meet requirements, and to achieve goals and objectives in accordance with strategies and plans;	To detailed move to guidance level.	x				
263	1	G85	NEW	<u>The management shall evaluate the results of the self-assessments and the independent assessments. Any lessons learned and following significant changes shall be analyzed with regard to their implications for safety.</u>	New moved from 4.15.	x	See 6.18			
264	1	G86	4.46	Senior management shall evaluate the results of the independent assessments and self-assessments of the management system, shall take any necessary actions, and shall record and communicate within the organization their consequent decisions and the reasons for them.	Is implemented in the paragraph above.	x				
265	2	G87	4.47	4.47 Plans for the conduct of <u>self-assessments independent assessments</u> and <u>independent assessments self-assessments</u> of the management system shall be reviewed and adjusted to reflect concerns of management and problems with performance as well as opportunities for	Matter of order.	x	See 6.18			

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				improvement.					
266	2	FIN59	p. 21 para. 4.48	An organizational entity shall be established or an individual shall be appointed with the responsibility for conducting the responsibility of the independent assessments of the management system shall be allocated. This entity The organization entity or individual shall have sufficient authority to discharge these responsibilities and shall have direct access to senior management. Individuals conducting independent assessments of the management system shall not assess areas of responsibility of their own line management.	In most of the organizations a common practice is that independent assessments are coordinated by an organization entity or individual. There is no reason to require an organization entity to be established or an individual to conduct the independent assessments.	x	6.16 The responsibility for conducting independent assessments of the management system shall be allocated. The organization entity or individual shall have sufficient authority to discharge these responsibilities and shall have direct access to senior management. Individuals conducting independent assessments of the management system shall not assess areas of responsibility of their own line management.		
267	1	F51	4.48		Applicability for small organizations?	x	The Group 2 of the working group piloted a reviewed of 'meaningfulness' and applicability. This was also		

							sent to the rest of the group for review. Also it has been agreed that an annex or a tech-doc will be developed to explore the aspect of grading and application in different types of organization.		
268	1	G88	4.49 (a)	(a) Results delivered and objectives achieved by the organization by means of its processes and activities;	This is too detailed. Move to guidance level.	x	Moved to guidance		
269	1	G89	4.49 (b)	(b) Non-conformances and the progress and effectiveness of corrective actions and preventive measures;	This is too detailed. Move to guidance level.			x	GSR 3 included non-conformances.
270	3	E20	para 4.49 (b), Page 20	<u>Safety issues, events and non-conformances and the progress and effectiveness of corrective actions and preventive measures; actions</u>	Add to the beginning of sentence; In the context of previous paragraphs. For harmonization.		Moved to guidance	x	
271	1	G90	4.49 (c)	(c) Operating experience, including lessons and good practices from other organizations;	This is too detailed. Move to guidance level.	x			
272	1	G91	4.49 (d)	(d) Opportunities for improvement.	This is too detailed. Move to guidance level.	x			
273	1	G92	4.50	4.50 The management system shall include evaluation and timely use of the following:	The idea is moved to the requirement level.			x	See 275
274	1	G93	4.50 (a)	(a) Lessons from experience gained and events occurring, both within the organization and outside the organization, and from the causes of events;	This is too detailed. Move to guidance level.			x	See275

275	2	F52	4.50	The management system shall include evaluation and timely use of the following: (a) Lessons from experience gained and events occurring, both within the organization and outside the organization, and from the causes of events; (b) Technical advances and research and development; (c) Methods for identifying good practices.	4.50 may be better located in the section “The management system”, for example after 4.17	x	6.19 The management system shall include evaluation and timely use of the following: (a) Lessons from experience gained and events occurring, both within the organization and outside the organization, and from the causes of events; (b) Technical advances and research and development; (c) Methods for identifying good practices.		
276	3	AUS40	SAFETY CULTURE	“5. SAFETY CULTURE”	Correct numbering.	x	All titles and numbering will be corrected onn agreement with the order and text.		
277	2	FIN53	p.21	4. SAFETY CULTURE Requirement 6: Strong safety culture Strong safety culture shall be established and maintained in the organization. All individuals in the organization, from senior management downwards, shall promote a strong safety culture.	The whole chapter should be moved after the chapter on Leadership and Management for safety (and before the chapter on Management System)	x	See new section drafted by the working group. All text and comments were reviewed and new section re-		

			<p>5.1. Attitudes and behaviours that contribute to a strong safety culture shall be defined and developed through leadership and use of the management system.</p> <p>5.2. All individuals in the organization shall contribute to fostering and supporting a strong safety culture.</p> <p>5.3. Managers and leaders shall advocate and support the following:</p> <p>(a) A collective commitment to safety by teams and individuals;</p> <p>(b) Acceptance by individuals of personal accountability for attitudes and behaviour with regard to safety;</p> <p>(c) A common understanding of safety and safety culture;</p> <p>(d) A culture that encourages trust, collaboration and communication, and that values the reporting of issues relating to human and organizational factors;</p> <p>(e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;</p> <p>(f) The reporting of any deficiencies in structures, systems and components to avoid degradation of safety;</p> <p>(g) The timely acknowledgement and</p>	Also some reformulating		drafted .		
--	--	--	--	-------------------------	--	-----------	--	--

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				<p>feedback of information on problems identified and suggestions made;</p> <p>(h) The means by which the organization seeks to enhance safety and safety culture;</p> <p>(i) Responsibility and accountability of organizations and of managers at all levels for safety;</p> <p>(j) A common understanding of the key elements of safety and safety culture within the organization;</p> <p>(k) An awareness of radiation risks and hazards relating to the work and to the work environment, and an understanding of their significance for safety;</p> <p>(l) Risk based and conservative decision making in all activities.</p>					
278	2	F53	Requirement 14	<p><i>Option 1</i> Requirement14: Fostering and continuous improvement of safety culture</p> <p><i>Option 2</i> : keep current title but delete requirement 15, 5.5 to 5.7 and create a requirement 5.5 5.5 <u>The safety culture of the organization shall be regularly assessed, using independent assessment when necessary, so that safety culture is improved and inadequate behaviors/practices/processes are corrected as necessary</u></p>	<p>Continuous improvement is addressed in Requirement 15... Either change the title or delete requirement 15 and associated requirement.</p> <p>Option 2 is favored.</p>	x	<p>See new section drafted by the working group.</p> <p>All text and comments were reviewed and new section re-drafted</p>		
279	2	F54	Requirement 14	<p>Individuals in the organization, from senior management downwards, shall <u>demonstrate</u></p>	<p>Promotion (do what I say...) is nice but actual-</p>	x	<p>Term Foster is accepted</p>		

				<u>and</u> promote a strong safety culture. .	ly showing (do what I do) safety culture is expected....				
280	1	F55	Requirement 14	The leadership for safety and the management system shall be used to foster and support a strong safety culture.	Do not mix leadership and safety culture as leadership is for managers and safety culture for everybody.	x	See redrafted section.		
281	3	J21	5.1.	5.1. Attitudes and behaviours that contribute to a strong safety culture shall be defined and developed through leadership <u>for safety</u> and use of the management system.	Editorial. Consistency with requirement 14.	x	See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
282	2	F56	5.1	<i>Option 1</i> Individuals in the organization, from senior management downwards, shall promote a strong safety culture. . The leadership for safety and the management system shall be used to foster and support a strong safety culture. <i>Option 2</i> Attitudes and behaviours that contribute to a strong safety culture shall be defined and developed through leadership and use of <u>in</u> the management system <u>and advocated by managers, including through their own practices and leadership.</u>	Clarification. Avoid mixing safety culture and leadership. Suggestion to stop after ‘management system’ as para 5.3 deals specifically with managers.		See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
283	2	F57	5.3(a) (c) (j)	(a) <u>A common understanding of key elements of safety and safety culture within the organization and a collective commitment to safety</u>	Merge (a) and (c) and (j) : same idea		Will part of guidance See new section		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				by teams and individuals; (e) A common understanding of safety and safety culture; (j) A common understanding of the key elements of safety and safety culture within the organization;			drafted by the working group. All text and comments were reviewed and new section re-drafted		
284	3	E22	Para 5.3 c and k, page 21/22	(c) A common understanding of safety and safety culture and their key elements within the organisation ; (k) A common understanding of the key aspects elements of safety and safety culture within the organization	Simplification		Will part of guidance See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
285	2	F58	5.3 (d), (f)	(d) A culture that encourages trust, collaboration and communication,, and that values the reporting of issues relating to human and organizational factors <u>and of any deficiencies in structures, systems and components to avoid degradation of safety and that timely acknowledges and acts on problems identified and suggestions made;</u> (f) The reporting of any deficiencies in structures, systems and components to avoid degradation of safety; (g) The timely acknowledgement and feedback of information on problems identified and suggestions made;	Merge (d) and (f) : same idea (reporting issue and managing them)		See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
286	2	AUS41	5.3(e)	“Measures to encourage <u>understanding, and</u> a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;”	It is important that all aspects of an activity are fully understood. The amendment is designed		See new section drafted by the working group.		

					to strengthen this aim		All text and comments were reviewed and new section re-drafted		
287	2	J22	5.3.(m)	(m) Risk informed based and conservative decision making in all activities.	Retain the original sentence. The coverage of “risk_ based decision making” is limiting. “Risk <u>informed</u> decision making” is more comprehensive in covering all of the elements above.	x	Will be part of guidance See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
288	2	F59	5.3 (1)	Risk based and conservative decision making in all activities.	Not all topics can be “risk based”....	x	See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
289	2	F60	5.4	Locate 5.4 under Requirement 7 The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including field activities).The management system shall include arrangements to support teams and individuals in carrying out their tasks successfully with regard to safety, with account taken of interactions between human, technology and the organization11.	5.4 is not really directed at safety culture. Managers could be in the field and have behavior and deliver messages opposite to safety culture... 5.4 would therefore be better located under requirement 7, before 4.9	x	See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		

290	2	E23	Para 5.4, page 22	The management system shall include arrangements to ensure the participation and visible presence in the field activities of management at all levels in the organization. The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including field activities).	This para was dedicated to the field presence of managers of all levels. With the new text this is diluted. Proposal: Return to the former text.	x	See new section drafted by the working group. All text and comments were reviewed and new section re-drafted		
291	3	FIN60	p. 22 Req 15	Senior management shall regularly commission independent assessments of leadership and safety culture, and shall provide for self-assessments of, leadership and safety culture shall be made periodically. leadership and safety culture.	new numbering Please rephrase		Re-numbering makes this requirement 13.		
292	3	J23	Requirement 15	Assessment, continuous improvement and maintenance of leadership for safety, and of safety culture Senior management shall regularly commission independent assessments of, and shall provide for self-assessments of, leadership for safety and safety culture .	“Leadership for safety and safety culture” is liable to cause misunderstanding. It is better to separate “leadership for safety” and “safety culture”. Consistency with the title of requirement 15.	yes			
293	?	F62	Requirement 15	Assessment, continuous improvement and maintenance of leadership for safety and safety culture Senior management shall regularly commission <u>assessment, and when needed</u> independent assessments of, safety culture.	<i>No input</i>			x	Leadership is an essential part of safety culture.
294	1	F61	Requirement 15 and associate requirements	If requirement 15 is kept (see previous comment), refocus it on assessment of safety culture, not assessment of leadership	Leadership is addressed in Requirements 1 and 2. This section of DS456 is only on safety culture			x	Leadership is an essential part of safety culture.

295	3	FIN61	p. 22 para 5.6	Senior management shall ensure that the independent assessment of leadership and safety culture is conducted including experts in the sciences of applying leadership. S and safety culture independent assessments methods shall be used to inform the basis of continuous improvement of safety culture . -	Consider to simplify, this text could be used in guidance document	x	6.111 Senior management shall ensure that the independent assessment of leadership for safety and safety culture is conducted to inform the continuous improvement of safety culture.		
296	2	G94	5.42	<u>Text unchanged –new Order (old 5.4)</u> All individuals in the organization shall contribute to fostering and supporting a strong safety culture. <u>The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including field activities).The management system shall include arrangements to support teams and individuals in carrying out their tasks successfully with regard to safety, with account taken of interactions between human, technology and the organization</u>	Move to 5.2 5.4 fits logically better before 5.2	x	See new safety culture text		
297	3	G95	5.23	<u>Text unchanged –new Order (old 5.2)</u> <u>All individuals in the organization shall contribute to fostering and supporting a strong safety culture.</u> Managers and leaders shall advocate and support the following: (a) A collective commitment to safety by teams and individuals; (b) Acceptance by individuals of personal	Change in numbering because of movement 5.4. to 5.2 5.2 move to 5.3	x	All numbering and alignment of references etc will be carried out after final text approval.		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				<p>accountability for attitudes and behaviour with regard to safety;</p> <p>(c) A common understanding of safety and safety culture;</p> <p>(d) A culture that encourages trust, collaboration and communication, and that values the reporting of issues relating to human and organizational factors;</p> <p>(e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;</p> <p>(f) The reporting of any deficiencies in structures, systems and components to avoid degradation of safety;</p> <p>(g) The timely acknowledgement and feedback of information on problems identified and suggestions made;</p> <p>(h) The means by which the organization seeks to enhance safety and safety culture;</p> <p>(i) Responsibility and accountability of organizations and of managers at all levels for safety;</p> <p>(j) A common understanding of the key elements of safety and safety culture within the organization;</p> <p>(k) An awareness of radiation risks and hazards relating to the work and to the work environment, and an understanding of their significance for safety;</p> <p>(l) Risk based and conservative decision making in all activities.</p>					
298	3	G96	5. 34	<p><u>New Order – old 5.3</u></p> <p>The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including</p>	Change because of movement 5.4. to 5.2 5.3 move to 5.4	x	This was discussed in the group and the transfer of requirements into		

				<p>field activities). The management system shall include arrangements to support teams and individuals in carrying out their tasks successfully with regard to safety, with account taken of interactions between human, technology and the organization</p> <p><u>Managers and leaders shall advocate and support the following:</u></p>			guidance was identified and was taken into account during the working group editing		
299	2	G97	5.- 34 (a)	<p>A collective commitment to safety by teams and individuals;</p> <p><u>A common understanding of the key elements of safety and safety culture within the organization;</u></p>	Starting bullet list with (j) fits logically better. Move (j) to a)		See 298		
300	3	G98	5.- 34 (b)	<p>-Acceptance by individuals of personal accountability for attitudes and behaviour with regard to safety;</p> <p><u>A collective commitment to safety by teams and individuals;</u></p>	Deleted – covered by 3.2 (d) and replaced by old (a)		See 298		
301	1	G99	5.- 34 (c)	<p>A common understanding of safety and safety culture;</p> <p><u>An environment that encourages trust, collaboration and communication, and that values the reporting of any safety issue. This includes timely acknowledgment and feedback.</u></p>	<p>Deleted - double to old (j) (or new (a))</p> <p>New text – on basis of old (d) - includes now old (f) and old (g)</p> <p>The right environment is needed for improving safety culture.</p>		See 298		
302	1	G100	5.- 34 (d)	<p>A culture that encourages trust, collaboration and communication, and that values the reporting of issues relating to human and organizational factors;</p> <p><u>Safety oriented decision making in all activities.</u></p>	<p>Old (d) now under (c). Old (l) moved to (d) with text changes.</p> <p>Decisions shall always be safety oriented. Risk-based implies a certain risk is acceptable – but who defines the risk?</p>		See 298		

303	1	G101	5.- 34 (e)	Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;	Deleted - covered by 3.5 (added “ and learning” to 3.5)		See 298		
304	3	G102	5.- 34 (f)	The reporting of any deficiencies in structures, systems and components to avoid degradation of safety;	Deleted - covered by new (c) and 3.5		See 298		
305	3	G103	5.- 34 (g)	The timely acknowledgement and feedback of information on problems identified and suggestions made;	Deleted - included in new c)		See 298		
306	1	G104	5.- 34 (h)	The means by which the organization seeks to enhance safety and safety culture;	Deleted - means for enhancing safety covered by 4.35. Safety culture itself is the result of a good management. No direct influence by any mean possible.		See 298		
307	2	G105	5.- 34 (i)	Responsibility and accountability of organizations and of managers at all levels for safety;	Deleted - covered by 3.2 (d), 3.4 and 4.3 Not a specific safety culture aspect – this is a general point und might be stated in the introduction.		See 298		
308	2	G106	5.- 34 (j)	A common understanding of the key elements of safety and safety culture within the organization;	Deleted - moved to a) Common understanding is necessary before any commitment can be made.		See 298		

309	2	G107	5.- 34 (k)	An awareness of radiation risks and hazards relating to the work and to the work environment, and an understanding of their significance for safety;	Deleted - aspects radiation risks and hazards should be covered by the general understanding of the key elements of safety (old (j) oder new (a)). Otherwise all aspects for environment, people etc. have to be listed – which would be too detailed for a requirement.	x	See 298		
310	1	G108	5.- 34 (l)	Risk based and conservative decision making in all activities.	Deleted - moved to (d) with changes.	x			
311	1	FIN54	p.22 para 5.4	The management system shall include arrangements to ensure the participation and visible presence of management at all level, in the activities of the organisation (including field activities).The management system shall include arrangements to support teams and individuals in carrying out their tasks successfully with regard to safety, with account taken of interactions between human, technology and the organization11.	to be moved into the chapter on management system	x	See 298		
312	1	G109	Requirement 15	Requirement15: Assessment, continuous improvement and maintenance of leadership for safety and safety culture Senior management shall regularly commission independent assessments of, and shall provide for self-assessments of, leadership and safety culture.	Delete whole Req 15 The content is mainly covered by Req 13 (4.44, 4.45, 4.46, 4.48) - 3.4 and new 3.5 are also relevant. Integrate with Req 13. Integrated organizational models like EFQM			x	Methods used in assessment of safety culture are very different to those used traditionally in assessment of management systems eg audit methods are

					integrate all, assessment of leadership, management system and culture into <u>one</u> self-assessment. No added value in separating these.				not used in safety culture assessment.
313	3	J24	5.5	5.5. Senior management shall designate a team representing all organizational levels and functions in the organization, and with expertise in the assessment of leadership for safety and safety culture, to carry out a self-assessment to inform the basis of continuous improvement of safety culture.	Editorial. Consistency with requirement 15.			x	Simplified in line with requirement 13.
314	3	E24	Para 5.5 page 22	Senior managers management shall designate a team representing all organizational levels and functions in the organization, and with expertise in the assessment of leadership and safety culture, to carry out a self-assessment <i>to inform the basis of continuous improvement of safety culture</i> .	Meaning of sentence in Italic is not clear.			x	Simplified in line with requirement 13
315	3	E25	Para 5.6 page 22	Senior managers management shall ensure that the independent assessment of leadership and safety culture is conducted including experts in the sciences of applying leadership and safety culture independent assessments methods <i>to inform the basis of continuous improvement of safety culture</i> . .	Meaning of sentence in Italic is not clear.	x	edited		
316	1	FIN55	p. 22	7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF THE MANAGEMENT SYSTEM, LEADERSHIP FOR AND MANAGEMENT FOR SAFETY AND SAFETY CULTURE THE MANAGEMENT SYSTEM	Combine all the measurement, assessment and improvement requirements into same chapter Consider to shorten the title (Suggestion: MEASUREMENT, ASSESSMENT AND	x	See new section 6 – all comments taken into account in simplified text.		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

					IMPROVEMENT)				
317	1	F63	5.5 5.6 5.7	Replace 5.5 to 5.7 by 5.5 <u>The safety culture of the organization shall be regularly assessed, using independent assessment when necessary, so that safety culture is improved and inadequate behaviors/practices/processes are corrected as necessary</u>	Too detailed for a requirement		See new section 6 – all comments taken into account in simplified text.		
318	1	G110	5.5.	Senior management shall designate a team representing all organizational levels and functions in the organization, and with expertise in the assessment of leadership and safety culture, to carry out a self-assessment to inform the basis of continuous improvement of safety culture.	Deleted - covered by 4.44, 4.48 and 3.4	x	See new section 6 – all comments taken into account in simplified text.		
319	1	G111	5.6.	Senior management shall ensure that the independent assessment of leadership and safety culture is conducted including experts in the sciences of applying leadership and safety culture independent assessments methods to inform the basis of continuous improvement of safety culture	Deleted - covered by 4.45 and 3.4 (share information within the organization)	x	See new section 6 – all comments taken into account in simplified text.		
320	3	J25	5.6.	5.6.Senior management shall ensure that the independent assessment of leadership <u>for safety</u> and safety culture is conducted including experts in the sciences of applying leadership <u>for safety</u> and safety culture independent assessments methods to inform the basis of continuous improvement of safety culture .	Editorial. Consistency with requirement 15.	x	See new section 6 – all comments taken into account in simplified text.		
321	1	G112	5.7	The results of independent assessments and self-assessments of leadership and safety culture¹² shall be communicated at all levels in the organization and shall be acted upon to enhance safety culture and to foster a learning attitude within the organization.	Deleted - covered by 4.46, 3.4 and new 3.5 .	x	See new section 6 – all comments taken into account in simplified text.		

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

322	3	J26	5.7.	5.7. The results of independent assessments and self-assessments of leadership <u>for safety</u> and safety culture shall be communicated at all levels in the organization and shall be acted upon to enhance safety culture and to foster a learning attitude within the organization.	Editorial. Consistency with requirement 15.	x	See new section 6 – all comments taken into account in simplified text.		
323	1	G113	Footnote 11	Human, technology, and organization (HTO) term is the same as the older terms Man, technology and organization (MTO) and the Individual, technology and organization (ITO). General note: We are aware that in the Draft Safety Guide DS472 “Organization, Management and Staffing of a Regulatory Body For Safety” (latest version dated 5 June 2015; see Paras 2.19, 4.30 and 4.59) the term ‘Individual, technology and organization’ (ITO) is used instead of ‘Human, technology, and organization’ (HTO).	Delete - not necessary Comment: If HTO is the valid term, as suggested in the footnote, the NUSC Scientific Secretary should ensure that it is implemented into other Draft Safety Standards as well. Ensuring consistency between current IAEA Safety Standards with regard to the terminology used therein.	x	See new section 6 – all comments taken into account in simplified text.		
324	1	G114	Footnote 12	Assessment of leadership and safety culture is a form of assessment requiring a specific approach and perspective on how human and organizational factors such as values, attitudes and behaviour can affect safety. Assessments of leadership and safety culture and of human factors and organizational factors make use of particular methods such as surveys, interviews, focus groups, field observations and reviews of documents.	Delete - Too detailed for a requirement,	x	See new section 6 – all comments taken into account in simplified text.		
325	3	G115	Ref. [36]	“INTERNATIONAL ATOMIC ENERGY AGENCY, Tech Doc 1740 Use of a graded	Citation of the correct title of TECDOC-1740.	x			Tech docs not referenced –

Relevance: 1 – Essentials 2 – Clarification 3 – Wording/Editorial

				<p>approach in the application of the management system requirements for facilities and activities; ...”</p>					<p>stardards and guidances will be.</p>
--	--	--	--	--	--	--	--	--	---