Template for comments and secretariat observations

I McNair – CQI NucSIG Workshop Chorley 25/1/17 Feedback comments.

Date: 25/1/17	Document: **WG 4 Draft DIS 19443**	Project: Quality management systems : Specific requirements for the supply chain of the nuclear energy sector

MB/ NC[1]	Line number (e.g. 17)	Clause/ Subclause (e.g. 3.1)	Paragraph/ Figure/ Table/ (e.g. Table 1)	Type of comment[2]	Comments	Proposed change	Observations of the secretariat
	320	1			"ITS products and services" is too specific should be more aligned to the standard's title.		
	375	3.3				Change heading to "Commercial Grade ITS"	
	376	3.3			Consistency of use of "nuclear safety" culture against "safety "culture		
	376	3.3			Why does definition of commercial grade say "affects nuclear safety" in other areas of the standard commercial grade "may" affect safety		
	380	3.3			Suggest "critical characteristics" needs its own definition		
		3.3			Commercial grade often known as "Commercial off the shelf" COTS or left to contractor to choose. Could lead to configuration control and obsolescence issues.		
	397	3.4				"certification or documentation." …….legal right to manufacture or distribute a specified…"	
	407	3.6				Change "Important to Safety (ITS)" to "Important to Nuclear Safety (ITNS)"	
		3.6			The ITS concept should be linked to IAEA grading/classification systems		
	412	3.6			Is "site personnel" the best choice of words suggest "end user"	Change "site personnel" to "end user"	
	413	3.6			Mention provision of "levels of protection"		
	419	3.7			Add "spares" to the list		
	428	3.8				Add to end of sentence: ",taking into account the likelihood and severity of the consequences with	

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						regard to nuclear safety"	
	435	3.10			Use of word "proper" is inappropriate	Replace "proper" with "appropriate"	
		3.10			The definition needs to be made clearer and be distinguished from normal Occupational Health and Safety. Can we use the SL definition? To clarify Nuclear Safety = quality in design, construction and operation (of nuclear plant)		
	451, 452, 453	3.12			Inconsistent use of commas and full stops. Why not use bullet points like elsewhere.		
		3.12			Include reference to internationally recognised indicators of good nuclear safety culture (e.g. the ten points)		
	453	3.12			"Security aspects" – not clear what the expectation is.		
	456	3.11			Does this definition of "Risk" clash with a definition in Annex SL or ISO 9001?		
	456	3.11			"Foreign Material Exclusion" or FME is an important nuclear risk. Consider mentioning FME.		
	541	5.1.1			Need consistent use of "nuclear safety" throughout rather than just "safety"	Add "nuclear" before "safety"	
	560	5.1.1 k				Replace "fostering "with "promoting"	
	561	5.1.1 l			This topic is already covered in clause 5.1.3.	Delete clause 5.1.1 l	
	584	5.1.3 c			Collaboration? Not clear how this supports nuclear safety culture, examples required.		

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	625	5.3			Prefer Top Management to be "doing" as required by ISO 9001 rather than devolving		
	626	5.3 a			Clause numbering confusing cf Line 617		
	626	5.3 a			How can independence be assured?		
	627	5.3 b			What is meant by b) unrestricted access to them		
		6.1.3 first paragraph			A confusing sentence, consider re-wording.		
	688	6.1.4			"For ITS classified items or activities" – why has this changed from "products and services" stared previously? This applies throughout.		
	688	6.1.4			Add "planning" as a requirement	…the requirements related to planning, quality management….	
	690	6.1.4			Inconsistent use of "safety", always refer to as "nuclear safety"	….the nuclear safety requirements associated to the nuclear safety classification specified by the….	
		6.3			Need to consider the IP's. Shouldn't this be retained as documented information?		
	732	6.3 e			Clarification needed as to what is expected with regard to communication.		
	767	7.1.4 NOTE				After non-blaming add "openness"	
	781	7.1.5.1.a			Important that resources (instruments?) are capable	Replace "suitable" with "capable" or add word capable to 19443 text.	
		7.1.5.1 a and b			Extra 19443 words in red add no value and are not nuclear specific.		
		7.1.5.1			Should there be a reference to ISO 17025 as the		

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					standard?		
		7.1.5.2			Calibration of "testing/measurement software" should be more visible.		
		7.2			Include requirements for nuclear safety competence.		
		7.2			The link with clause 8.6.b is not visible and the competence of the person "authorizing the release"		
	834	7.2 c				Delete "and qualification"	
		7.2.c			Extra 19443 words in red add no value and are not nuclear specific.		
	842	7.2 NOTE			Should this paragraph be identified as a NOTE		
	848	7.2 NOTE b			Already included in 7.5.2 so not needed here.		
	848	7.2 NOTE b			Why are "foreign" languages singled out? Surely this also applies to documents in the native language.		
	853	7.3			Add mention of "importance of nuclear safety".	The organization shall ensure that persons doing work under the organization's control are aware of the importance of nuclear safety and:	
	860	7.3			This clause should be added to 7.2 Competence and deleted from 7.3 Awareness		
	868	7.4 c			e.g. in parenthesis should be a NOTE		
	868	7.4 c			It should not be an expectation that the supply chain communicates directly with regulators, this should be through their customers		

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	891	7.5.2 b				b) retention period and format (e.g. language, software version, graphics) and media (e.g. paper, electronic).	
	893	7.5.2 c			Add "who are"	The organisation shall determine when the review shall be performed by individual(s) who are different from the author(s).	
	911	7.5.3.2			Addition not necessary covered by standard clause 7.5.3.2 c		
	929	8.1 a			Why refer to Project and Configuration management – these are not nuclear specific?		
	935	8.1 d			Add mention of control of interfaces		
	948				Why is this note necessary?		
	951	8.1.1			Suggest that this should be under section 8.4		
	951	8.1.1			Add clause to require full visibility of the supply chain – consider use of supply chain maps		
	952	8.1.1				Delete "prevent" replace with "establish arrangements to minimise the risk of"	
	959	8.1.1			Suggest refer to Clause 8.7 not 10.2	When CFS items are detected, they shall be managed *as* nonconforming product (see 8.7).	
	959	8.1.1			Add a requirement to notify relevant external parties e.g. regulator when CFIs are detected.		
		8.2.2 c and d			These additional requirements re implicit in the specification		
	972	8.2.2			Determining the requirements should be by the Design Authority		

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	979	8.2.2 d			Incomplete sentence, add planning	d) the associated quality requirements are specified including, planning, documentation, control, monitoring and measurement are defined (see 6.1.4.).	
		8.2.3.1			Add requirement for acceptability of items to be "determined by testing"		
	988	8.2.3.1			Add fabrication to the list	(e.g. design, procurement, manufacture, fabrication, quality, inspection and test),	
	1011	8.2.4			"properly managed" – what does this mean? Not formal enough		
		8.2.4			19443 additional words add no value, just keep 9001 words		
		8.3.1			Include requirements for: Technical Queries; and Specification Deviations		
		8.3.1			Revert to ISO 9001 text but retain last new sentence (starting line 1025)		
	1021	8.3.1			Unnecessary wording	Delete "to avoid ambiguity or misunderstanding and"	
	1060	8.3.4			Revert opening sentence to standard 9001 text		
		8.3.4			Suggest use of "Design Authority" and "Technical governance". Also NGD?		
	1086	8.3.4.1			Suggest that test should meet "customer and/or licensee requirements"		
		8.3.5			Design and development outputs should identify the quality grades.		

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		8.3.5 e			Why limit to Commercial Grade items only?		
	1117	8.3.6			Should not design change be considered as a design input and not a design output?		
		8.3.6			Should not all design changes, once item agreed with client be bought? of by the client?		
	1120	8.3.6			Should IP's be informed as well?		
	1138	8.4.1			Would prefer that, the 19443 addition was after Standard 9001 text, turn sentence around.		
	1148	8.4.1			The evaluation criteria needs to take into account the importance of nuclear safety.		
	1150	8.4.1				Add to end of sentence "and appropriate to classification/grading."	
	1152	8.4.1			"Limited period of time" - this should be documented information.		
	1159	8.4.1			This requirement should be in clause 7.53 Control of documented information		
	1161	8.4.1			Add requirement to inform the client of this scenario		
	1172	8.4.2 b			Last sentence should be in clause 5.3		
	1180	8.4.2 d			Should be more specific i.e. specific clause for Commercial Grade		
	1180	8.4.2 d			Why highlight Commercial Grade, what about other ITS items?		
		8.4.3			Be consistent when referring to the supply chain eg – "sub external providers", "supply chain", "sub		

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					tier providers" have all been used.		
	1188	8.4.3			" and review" - incorrect English and not necessary	Delete "and review"	
	1189	8.4.3				Replace "cascading" with "including"	
	1195	8.4.3			Suggest delete "document" should be any changes.		
	1195	8.4.3				Procurement document changes affecting the requirements shall be subject to the same process and control as used in the production and/or receipt of the original documents.	
	1211-1231	8.4.3			Top heavy		
	1212	8.4.3			Use of expression "nuclear safety classification", be consistent e.g. quality grade.		
	1212	8.4.3			Needs a careful explanation to understand the difference between quality grading and nuclear safety classification		
	1216	8.4.3			Unclear		
	1223	8.4.3			This requires the need to highlight changes but what about the need to identify up-front the full supply chain and such details.		
	1226	8.4.3			"product safety requirements classification" – new terminology, be consistent e.g. quality grade.		
	1230	8.4.3			"..at any level" this will require a lot of negotiation to obtain		

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	1230	8.4.3			"…at any level" - not difficult to access if contractually specified.		
		8.5.1.1 and 8.5.1.2			Suggest these fit better in clause 7.1		
	1269	8.5.1.1			Revalidation should be required if equipment is moved and should be time dependant.		
	1278	8.5.1.2			"different from" is this the same as "independent of"?		
	1293	8.5.1.2				Add "9) A defined duration for record retention"	
		8.5.2			"Maximum Traceability Boundary" should be defined in more clarity.		
		8.5.3			Add a clause to require "Authorised disposal or return of property"		
		8.5.4			More emphasis is required on Foreign Material Exclusion (FME)		
	1332	8.5.4 d and e			Is this referring to normal health and safety requirements? Or is it referring to nuclear safety issues?		
	1347	8.5.5 f			Reads very poorly		
		8.6			Should state that documented information is available at release.		
	1373	8.6 b			There should be a requirement regarding competence of the person authorising the release/link to relevant competence clause.		
	1375	8.6			By whom? Competence?		

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		8.7			No mention of Corrective Action		
	1378	8.7.1			Addition of "timely" is poor English	**8.**7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled at the earliest opportunity to prevent their unintended use or delivery.	
	1386	8.7.1			Suggest full stop after ways. Place "b), c), e) shall be mandatory for ITS items and activities" in a NOTE		
	1388	8.7.1 a			What is the difference between correction and re-work?	Delete "or rework"	
	1393	8.7.1 e			Suggest use expression "corrective actions"	taking corrective actions necessary to contain the effect of the nonconformity on other processes or products;	
	1394	8.7.1 f			Add suitably disposed of i.e. verification of disposal		
	1398	8.7.1			This sentence is unnecessary already covered by 8.7.2.		
	1400	8.7.2			Add "maintain" into 8.7.2	The organization shall retain and maintain documented information that:	
	1410	9.1.1			Add a requirement for unannounced surveillances		
	1431	9.1.3			Add reference to issues raised from Operational Experience Feedback (OEF) and Learning from Experience (LFE) i.e. operational experience from nuclear sites.		
	1443	9.1.3 h			More definition required of "safety culture aspects"		

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	1443	9.1.3 h			Add "nuclear"	h) nuclear safety culture aspects	
	1453	9.2.1 a 3			Not necessary as implicit in 9.2.1 a 1		
	1453	9.2.1 a 3				Delete existing add 3) contractual requirements	
	1461	9.2.2.2 c			Can qualified ISO 9001 auditors audit against ISO 19443? What is the requirement for the qualification of auditors?		
	1462	9.2.2.2 c			"Auditors shall not audit their own work;" only necessary when ITS.		
	1462	9.2.2.2 c			"Auditors shall not audit their own work;" Is this feasible for small organisations that may not have resources to achieve independence? Also may need to involve local experts.		
	1470	9.3.1			Significant processes at least annually others as is.		
	1470	9.3.1			Refer to Graded Approach		
	1480	9.3.2 c 2			"Nuclear Safety Culture" should be a clause on its own i.e. 9.3.2 c 8	Add 8) Nuclear safety culture, leadership and commitment.	
	1480	9.3.2 c 2			More guidance required for supply chain understanding of "nuclear safety culture". Maybe refer to the 10 "nuclear safety traits."		
	1480	9.3.2 c 2			Delete "culture". This should be about nuclear safety objectives		
	1488	9.3.2 f			Needs to include "non-nuclear" operational experience e.g. turbine related issues		
	1488	9.3.2 f			Why limit to lessons learned from nuclear experience? There are relevant lessons learned		

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					from other safety critical industries.		
	1510	10.1			Why only these?		
	1511	10.1			Why just "nuclear" should include all safety critical industries.		
	1511	10.1			Needs to include "non-nuclear" operational experience e.g. turbine related issues		
	1516	10.1			Poor English delete "provisions of". Delete "plans".	Replace existing with "The organization shall provide adequate resources for improvement."	
	1516	10.1			Does "resource" mean personnel or other or both? There should be a competence reference.		
	1516	10.1			Adequate resources for "improving processes" not improvement plans.	Replace existing with "The organization shall provide adequate resources for improving processes."	
	1524	10.2			Apply graded approach to NCRs		
	1532	10.2.1			Root Cause Analysis is not mentioned.		
	1532	10.2.1 b 2				Replace existing with "Determine the root cause and any contributory causes as applicable to the nonconformity"	
	1532	10.2.1 b 2			For ITS items the root cause of an escape is particularly important to establish		
	1539	10.2.1			More clarity with respect to complaints and the need to report back to the client.		
	1550	10.3			"and nuclear safety culture" looks like an afterthought.		

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	1550	10.3			Suggest that nuclear safety culture should not be continually improved – just set the standard and stick with it – constant improvement leads to misunderstanding.		

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