>> DIN (Germany) <<

Template for comments and secretariat observations

Date: 2013-11-01	Document: **ISO/TC 85 N 1273**	Project: NWIP 19443

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
P-1					Q. 1: In my view, a common international standard providing requirements for a “Quality Management System” for the nuclear industry could be advantageous for both business and safety. It could unify and improve international sourcing.		
P-2					Question 1) An international Standard for Quality Management System requirements for the nuclear industry will be beneficially for our business. International sourcing will be improved and German supplier may get a better change for international business.		
P-1					Q. 4: Relevant are the German KTA standard KTA 1401 “General Requirements Regarding Quality Assurance” and in parts KTA 1403 “Integrated Management Systems for the Safe Operation of Nuclear Power Plants”. Also the IAEA Safety Series No. 50-C/SG-Q „Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, Code and Safety Guides Q1–Q14“ (1996) is covering that topic extensively and is certainly relevant.		50-C/SG-Q is not in force today If the NP become an ISO standard, it could be a good way to comply with GSR-2 Correspondence matrice between KTA and NSQ-100 is on going
P-1					Q. 5: The Project should be based on KTA 1401 (see above, also: http://www.kta-gs.de).		

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P-2					Question 5) The Project shall consider international (IAEA) German Quality Management Requirements (KTA)		See Q.4

P-1: Gerhard Roos, KTA-GS

P-2: Peter Völlmecke,, AREVA GmbH

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>> GOST R (Russian Federation) <<

Template for comments and secretariat observations

Date: 2013-11-15	Document: **ISO/TC 85 N 1273**	Project: NWIP 19443

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
P-1					We use interstate standard ГОСТ ISO 9001-2011QUALITY MANAGEMENT SYSTEMS. REQUIREMENTS (ISO 9001:2008, IDT), but we haven't standard with additional requirements for nuclear field only safety requirements IAEA.		

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>> ISIRI (Iran) <<

Form for Comments

NSQ-100 Nuclear Safety and Quality Management Requirements

Comment No.	Para/Line No.	Title	Proposed New Text	Observation of the secretariat
1	**4.1.1**	Nuclear Safety Culture	– Periodically conducting independent assessments and self-assessments of safety culture – Communicating the results of such assessments to all levels in the organization and acting upon them to ensure improvements Note: According to legal aspects and in order to ensure transparency on product realization, the organization shall be required to make available to the licensee all necessary information linked to safety.	It's written elsewhere (it's part of management review and audit process also)
2	**4.1.3**	Grading the Application of Quality Requirements	For classified items or activities, the associated quality management level, inspection & surveillance levels and documentation requirements shall be graded in accordance with the classification of the item or activity or potential consequences of their failures associated with safety, health, environmental, security, quality and economic elements.	ISO 9001 is under review at the time being and the risk management for all aspects defined is included in the risk management part of NSQ-100 (see part 7.1.2 and also at the beginning of part 7.1) Moreover, all these aspects are addressed through many other parts of NSQ-100
3	**4.2.1**	General	– Organizational structure of the organization; – The values and expectations of senior management; – A description of the responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work; – A description of the interaction with interested parties. Documentation shall be provided to the personnel to be clear, unambiguous, user friendly and in an appropriate language for its understanding.	- In ISO 9001, the quality manual is already defined - In the quality and safety policies, the values and expectations of senior management are already written (see part 5.1) - The customer aspect and requirements for connections, interactions with safety authorities are already included - Appropriate languages for understanding the document is enough

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4	**4.2.4**	Control of Records	The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers. (repeated in the first paragraph)	NSQ-100 introduces this sentence regarding records issued by supplier of the organization that must be controlled
5	**5.3**	Quality Policy	f) shall state that nuclear safety aspects related to the product has an overriding priority.	This proposal is accepted
6	**5.4.2**	Quality Management System Planning	Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality and nuclear safety objectives	This proposal is accepted
7	**5.5.4**	Communication with Regulatory Bodies	The text doesn't clearly express the meaning.	When applicable, with regards to the nuclear safety related product issues, the organization shall ensure that appropriate procedures are defined in liaison with the customer to address any communication from nuclear safety Regulatory Bodies, according to the national authorities requirements
8	**6.1**	Provision of Resources	The organization shall determine and provide the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness; b) to enhance customer satisfaction by meeting customer requirements; c) to ensure the fulfillment of the nuclear safety requirements	This proposal is accepted
9	**6.2.2**	Competence, Qualification, Training and Awareness	b) ~~where applicable,~~ providing training or take other actions, as maintenance of proficiency to achieve the necessary competence	The needs are defined in the previous § (see ISO 9001 under item 6.2.2 a)) Thus, this proposal is not accepted
10	**7.1**	Planning of Product Realization	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the	The comment was considered no relevant because of its redundancy. This proposal is not accepted

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			requirements of the other processes of the quality management system (see 4.1) and nuclear safety requirements. a) quality objectives and requirements for the product, which may include and not limited to aspects such as:	
11	**7.2.1**	Documentation of Requirements Related to the Product	The supplier has to establish a documented list of items and activities classified as IFS or important for the final quality of the product and their safety classification and determine the associated quality management level, surveillance level and documentation requirements. Note 2: Nuclear safety aspects concern the safety culture, the graded approach, IFS items and activities and their safety class and the implementation of applicable construction codes and standards.	To be discussed/clarified later "Supplier" must be changed to "The Organization" "and their safety class" in NOTE 2 : the comment was considered not relevant in this case
12	**7.3.2**	Design and Development Inputs	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include: a) functional and performance requirements; b) technical bases of design	It's already included in ISO 9001, addressed in same § under item a) and d)
13	**7.4.2.1**	Content of the Procurement Documents	e) …any critical characteristics (reliability, failure modes)	It would limit the sense of critical characteristics. Not accepted.
14	**7.5.1**	Control of Production and Service Provision	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics and requirements related to the product; The supplier shall confirm that products meet the specified requirements and shall ensure that products perform satisfactorily in service.	Requirements are defined before, during the design phase. This comment is not accepted. It appears to be difficult to confirm that at this stage. To be discussed later.

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15	**7.5.1.3**	Inspection and Surveillance Activities	– statements' details – acceptance Criteria – results or acceptability	– This proposal is accepted : reference to acceptance Criteria for inspection only
16	**7.6**	Control of Monitoring and Measuring Equipment	Calibration/verification method shall be based against standards. Where no such standard exists, the basis for calibration/verification shall be defined. Note: The above-mentioned text is repeated in item (a) of part 7.6 of ISO 9001:2008.	It is accepted to remove the repeated text. In addition, it is proposed to introduce in the document the ISO 17025 accreditation request for external calibration and testing. To be discussed later.
17	**8.2.2**	Internal Audit	Auditors shall not audit their own work and shall be appointed by personnel independent of the audited activity. Note: The specified sentence is repeated in the first paragraph of part 8.2.2 of ISO 9001:2008.	It is accepted to remove the repeated text.
18	**8.2.3**	Monitoring and Measurement of Processes	a) Take appropriate action to correct the nonconforming process Note: The above-mentioned item is repeated in the first paragraph of part 8.2.3 of ISO 9001:2008.	It is accepted to remove the repeated text.
19	**8.5.3**	Prevention Action	– Feedback from other organizations and international experiences	This comment is not accepted because it's already included in another bullet and it would not be good to be limited to international experience

>> SIS (Sweden) <<

Template for comments and secretariat observations

Date: 2013-11-05	Document: **ISO/TC 85 N 1273**	Project: ISOPWI Nuclear safety and quality management system - Requirements - NSQ-100

MB/ NC[1]	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment[2]	Comments	Proposed change	Observations of the secretariat
SE		General		ge	According to ISO/TMB it is expected that new management system standards should follow the high level structure and identical text presented in ISO/IEC Directives, Part 1, Annex SL, Appendix 3. ISO 9001:2008 is expected to be replaced with a new issue in 2015 where the new structure and identical text will be introduced.	The change from ISO 9001:2008 to the next issue should be considered in due course.	Of course
SE		Contents		ed	ISO Directives, Part 2, 6.1.2 says: “Terms in the “Terms and definitions” clause shall not be listed in the table of contents.”	Delete all terms under “3. Terms and definitions” in the table of contents.	Accepted but we have to check with the standard itself
SE		0.2 and 0.3		ed	“No additional requirement” Since the clause “Introduction” does not include any requirement the statement does not seem relevant.	Amend to “No additional text.” in 0.2 and 0.3.	OK
SE		2		te	ISO 9001:2008, Quality management systems — Requirements, IAEA GS-R-3:2006 - The management system for facilities and activities – Safety Requirements. Those two documents also appear in the Bibliography.	Include reference to a document either in Clause 2 or in the Bibliography, but not on both places.	OK
SE		3		te	It is understood that the manner terms and definitions are presented is taken from GS-R-3. The question is whether this is permissible in an ISO standard. If the ISO Directives, Part 2, 2011, Annex D (and ISO 10241-1) is to be followed a redrafting of several of them is necessary. For example, requirements are not permitted in a definition. After redrafting, in some cases, one or more notes might be added for explanatory purposes.	ISO Central Secretariat should be consulted on this matter. If it is appropriate and permissible, the Note in Clause 2 should be moved to Clause 3.	To be clarified but today GSR-3 is a public document.

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MB/ NC[1]	Line number	Clause/ Subclause	Paragraph/ Figure/ Table/	Type of comment[2]	Comments	Proposed change	Observations of the secretariat
SE		3.12	definition	te	It should be observed that the definition in 3.12 is different from the one in Annex SL and in ISO 31000.	A Note indication difference from other definitions should be considered.	To be checked
SE		3	New	te	The term “qualification” is used in subclause 6.2, but has no definition.	Include a definition for the term “qualification”.	The definition will be added
SE		3.1 3.11 7.2.2 7.3.1 d) 7.3.3	definition definition of product e) last bullet 3rd para Note 1	ed	“…manufacturing, erection, commissioning and related services… of the product” “…manufacturing, inspection, testing, handling, transportation, storage, cleaning, site erection and any operation…” “…manufacturing, erection, testing and commissioning of the product.” “… produce, inspect, install, test and maintain the product.” “…manufacture, test, installation, operating, maintenance and preservation of product” The expressions probably are intended to cover the same activities.	Consider using more consistent expressions.	To be checked during the review
SE		7.1.3 Bibliography	Note	ed	Add “ISO 10007 Configuration management” in the Bibliography.		OK
SE		7.3.1	Last line	ed	The term “respected” might be misinterpreted.	Possibly amend to “applied”.	OK

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