



ISO/TC 67

Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries Secretariat: American Petroleum Institute, 1220 L Street NW, Washington DC 20005 USA
 Tel. +1 202 682 8000 Fax. +1 202 962 4714

ISO/TC 67 N 837

2003-05-05

TO: ISO/TC 67 P-members

COPY TO: ISO/TC 67 O-members
 ISO Central Secretariat

RE: Ballot results on 67 N 830, P&ngi – Sector specific quality management systems – Requirements for product and service supply organizations

P-member responding	Approve	Disapprove with comments	Abstain	Did not respond
Argentina				X
Austria			X	
Brazil		X		
Canada	X (w/comments)			
China	X			
Denmark				X
Finland				X
France		X		
Germany	X			
Indonesia	X			
Italy		X		
Japan	X (w/comments)			
Kazakhstan				X
Korea, Republic of	X			
Mexico		X		
Netherlands	X			
Norway	X			
Portugal				X
Romania	X			
Russian Federation	X			
Spain	X			
UK	X			
USA	X			
Venezuela				X
Total:	13	4	1	6

O-member responding	Approve	Disapprove with comments	Abstain	Did not respond
Switzerland			X	
Trinidad & Tobago	X			

Template for comments and secretariat observations

Date: 2003-04-30

Document: **DTS or DTR 29001**

1	2	(3)	4	5	(6)	(7)
MB¹	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/Table/ Note (e.g. Table 1)	Type of com- ment²	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
BR				Comments made during the discussion process were not taken into consideration in the version dated 2003-01-13; moreover, part of them was dismissed after being taken into consideration in the version dated 2002-12-12.		All comments were considered but only those comments with a wide consensus were able to be incorporated in the DTS.
CA				Canada wishes to request a DTS document comment period prior to the pre-emptive balloting at this time. We feel that the Conformity Assessment issues in this document make it necessary to include the requested comment period in the development process.		Document 67N830 was itself a DTS. Publication as a TS will permit experience to be gained, as stated in ISO Directives.
FR				The comments done by the French experts of WG 2 have not been discussed in totality, neither taken into account. France requests for discussion of all the comment expressed by the WG 2 experts.		All comments were considered but only those comments with a wide consensus were able to be incorporated in the DTS
FR				Point 0.2 after d: the figure h1 has not been found anywhere		This is a typographical error, the reference should be to "Figure 1" (identical to ISO 9001)
FR				Point 6.4: Add a note on the Safety of the staff to reach the quality of product: The problems bound to the safety of the product and the means to minimize the potential risks for the workers, shall be treated by the organization, particularly in the processes of design and development and in the activities of the fabrication development		Not agreed. While we may agree with the statement, it has not been discussed or agreed that ISO 9001 requires to be supplemented with this statement.
FR				Add a Point 7-1-2 : Confidentiality The organization shall insure the confidentiality of the products and of the projects in development and of the information related to the product during all the duration of the contract with the client.		Not agreed. This has not yet been discussed, and should be raised at the next revision opportunity.

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2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

NOTE Columns 1, 2, 4, 5 are compulsory.

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FR				Add a point 7-2-3-1: Customer communication The organization shall have the possibility to communicate all the necessary information and data in a language and in a client specific format (for example electronic data exchanges, computer assisted design).		Not agreed. While we may agree with the statement, it has not been discussed or agreed that ISO 9001 requires to be supplemented with this statement.
FR				Point 7-3-1-2: it is already indicated in the point b of 7-3-1.		Not agreed. 7.3.1.2 provides specific supplementary requirements.
FR				Point 8-2-2-1: : modify the frequency of internal audits: "...conducted at chosen and documented interval by ...		Not agreed. "... conducted at least annually by ..." was discussed and agreed.
IT				General In accordance with the balloted NWI P 798 ISO Directives and ISO/TC 67 Resolution 12(2002), the preparatory stage shall be finished by a WD available for circulation to the member of ISO/TC 67 as 1 [^] CD. The committee may also decide to publish the Final WD as a PAS to respond particular market need. The ISO TC/67 may wish to consider publishing in the form of TS at the Committee Stage if the technical issues can not be resolved within the appropriate time limits.		The preparation and balloting process for this DTS has been in accordance with ISO rules, as confirmed with ISO Central Secretariat, as well as in accordance with the TC67 Resolution 12 (2002).
IT				Technical the document is conflicting with the spirit and evolution of ISO 9000:2000, which pursues "quality" through the "process control" and the "continous improvement" instead of through the punctual verification of the single activities regulated by single "control features" (procedures). It imposes the maintenance of obsolete criteria without real benefits for the sector.		Not agreed. This was discussed in both the Working Group meetings and in several of the Project meetings. The consensus was that the 29001 document is needed in it current form at this time.

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JP	6.2.2, NOTE 1			It is not necessary to provide on-the-job training for contract or agency personnel because the personnel should have its own management system and is considered out of control by the organization. We do not agree to add NOTE 1.	Delete NOTE 1.	Not agreed. This note is purely explanatory, it does not change the requirements of 6.2.2.1. 6.2.2.1 addresses specifically "personnel who perform activities addressed in the quality management system" and this includes personnel from whatever source.
MX				In accordance with the balloted NWI P 798 ISO Directives and ISO/TC 67 Resolution 12 (2002), the preparatory stage shall be finished by a WD available for circulation to the member of the ISO/TC 67 as 1 [^] CD. The committee may also decide to publish the Final WD as a PAS to respond to particular market need. The ISO/TC 67 may wish to consider publishing in the form of TS at the Committee Stage if the technical issues can not be resolved within the appropriate time limits. Technical the document is conflicting with the spirit and evolution of ISO 9000:2000, which pursues "quality" through the "process control" and the "continuous improvement" instead of through the punctual verification of the single activities regulated by single "control features" (procedures). It imposes the maintenance of absolute criteria without real benefits for the sector.		The preparation and balloting process for this DTS has been in accordance with ISO rules, as confirmed with ISO Central Secretariat, as well as in accordance with the TC67 Resolution 12 (2002) Not agreed. This was discussed in both the Working Group meetings and in several of the Project meetings. The consensus was that the 29001 document is needed in its current form at this time.
US	0.5		Other	The suggested change will readily incorporate other referenced (in product specifications) criteria into the QMS requirements.	Para. 2, add "and industry" in between customer-specific and requirements.	Not agreed. This TS is itself the industry-specific quality management system requirements.

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US	1.1		Te	Change supplemental statement to read: This Technical Specification, defines the quality management system requirements for the business processes affecting the design, development, production, installation, and service of products for the petroleum and natural gas industries. (Reason: this emphasizes process definition of the design and development activities, as well as keeps in tone with the intent of the ISO document)	Change supplemental statement to read: This Technical Specification, defines the quality management system requirements for the business processes affecting the design, development, production, installation, and service of products for the petroleum and natural gas industries. (Reason: this emphasizes process definition of the design and development activities, as well as keeps in tone with the intent of the ISO document)	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	4.2.2		Te	Suggest an addition note to include Q1, 6th Edition wording. Reasoning, during an API audit process, the auditor needs to make a judgement call whether or not there is sufficient interaction between the documented QMS, skills and training.	For the purpose of this international standard, the range and detail of the procedures that form part of the quality system depend on the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully both in ISO and for the Q1 Seventh Edition. Changes such as this may be considered at the next revision.
US	4.2.3.2		Te	Change supplemental statement to read: Changes to required documents shall be reviewed and approved by the same functions that performed the original review and approval. (Reason: This ensures that only those documents and records required by the quality management system are subject to the requirement and audits by external auditors.)	Change supplemental statement to read: Changes to required documents shall be reviewed and approved by the same functions that performed the original review and approval. (Reason: This ensures that only those documents and records required by the quality management system are subject to the requirement and audits by external auditors.)	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	5.6.1.1		Ed	Remove Note from supplemental requirements - this is duplicated from above ISO requirements		Not agreed. The note is merely a note to clarify that "monitoring" should also be included.

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US	6.2.2.1	Note 1	Te	Delete "on the job" and provide only examples of training. (Reason: This restricts the organization to a specific type training and we may want to do class room or a Operator certification process)	Delete "on the job" and provide only examples of training. (Reason: This restricts the organization to a specific type training and we may want to do class room or a Operator certification process)	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	7.4.1.2 Note/5.6.2		Te	Is the NOTE necessary? if a licensee effectively complies with 7.4.1.2 a through d, then they should be in compliance with the suggested note.	Enter another criteria in 5.6.2 which addresses the need to analyze vendor performance data as part of the management review process.	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	7.4.1.2 Note/5.6.2		Te	Is the NOTE necessary? if a licensee effectively complies with 7.4.1.2 a through d, then they should be in compliance with the suggested note.	Enter another criteria in 5.6.2 which addresses the need to analyze vendor performance data as part of the management review process.	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	7.5.3.3		Ed	Suggest that the word "status" be changed.	Change to "conformity or nonconformity at all process stages".	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	7.5.5.2 NOTE		Ed	Change "turns" to "turn"		Not agreed. The plural "turns" is as already used in ISO/TS 16949.

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US	7.6.2		Te	<p>(1) Under NOTE; consider making a statement that requires calibration of employee owned equipment if they use the said equipment for a final process acceptance where no subsequent inspection and test is required. Purpose: calibration of IM&TE for all employees in a manufacturing plant could present a considerable expense. Addressing calibration for final process points could lessen that cost. Justification: companies normally have an inprocess inspection performed by QC.</p> <p>(2) What does "revision following engineering changes" mean with regards to IM&TE?</p> <p>(3) "an assessment of the impact of out-of-specification condition ..." is already addressed in 7.6 above.</p>		Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.
US	8.2.4.2		Te	<p>Delete " or directly supervised" and add statement "or validation activities" after work production. Statement should read: Personnel other than the persons who performed the production or validation activities of the materials or products shall perform final acceptance and product release. (Reason: If this remained as written it could restrict Dresser's ability to fully implement lean manufacturing whereas the Supervisor or another Operator checks and approves the work of the persons performing the work.)</p>	<p>Delete " or directly supervised" and add statement "or validation activities" after work production. Statement should read: Personnel other than the persons who performed the production or validation activities of the materials or products shall perform final acceptance and product release. (Reason: If this remained as written it could restrict Dresser's ability to fully implement lean manufacturing whereas the Supervisor or another Operator checks and approves the work of the persons performing the work.)</p>	Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.

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US	8.5.1.1		Te	<p>Commentor 1: Clause 8.5.1.1 requiring a documented control feature for continual improvement is redundant, can be misleading, and is unnecessary. The intent and scope of the manufacturers Quality system is required to address continual improvement. Continual improvement is a result of all aspects of the quality system.</p> <p>Commentor 2: I am very concerned about paragraph 8.5.1.1 which states "the organization shall define a process and establish control features for continual improvement." This supplemental requirement mandates a definition of a process and a documented method for continual improvement. This mandates continual improvement which may be difficult to achieve; but more importantly how this requirement will be applied by the API to its auditors during an audit. This mandate for continual improvement goes beyond what is already being done through preventative action, audit results, data analysis, corrective actions, etc. and reviewed in the already mandated Management Review and may be quite difficult to achieve as another separate action.</p>	<p>Commentor 1: Remove the requirement for a seperate control feature for continual improvement.</p> <p>Commentor 2: I recommend this paragraph be removed.</p>	<p>Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.</p>

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US	Definitions		Te	<p>The definition of Special Processes: process where the conformity of the resulting product cannot be readily or economically verified by subsequent monitoring or measurement.</p> <p>Who determines 'readily' or 'economically'? By what process is 'readily' or 'economically' determined? Does this mean it no longer becomes a special process if you have enough money?</p> <p>Examples: Copper plating on certain materials. The only way to absolutely prove the thickness is by destroying or x-ray. Fischer has a \$30,000 machine that will verify the plating on any material. S&S has one, so therefore this is not a special process for them. However, for a small shop that could not afford one, this becomes a special process.</p> <p>Welding: Same situation. If someone has enough money to put a x-ray in line after friction/inertia welding, it's not a special process.</p> <p>Upsetting: If someone has an in-house lab, upsets 2" longer and cuts a piece to test off every end, it no longer becomes a special process.</p> <p>Aren't we trying to say it's a special process if you have to destroy it to prove it conforms?</p> <p>The other problem that I have with "Special Processes" is there are differences in the definitions for 5CT, 5L and Q1. I strongly believe that there should only be one definition for all of the specifications (5CT, 5D, 5L, Q1, etc) and each product specification should clearly list what is considered a "special process" for that specification. What manufacturing processes within a manufacturing facility that is producing a product to a given specification should be clearly defined by the controlling specification and should not be left to the discretion of an auditor or end user.</p>	<p>How about changing the definition of Special Processes as follows:</p> <p>Processes that establish the final product attributes, where the resulting output cannot be completely verified without destroying the product.</p>	<p>Not agreed. The current wording was reviewed several times during preparation and the current text has been balloted successfully. Changes such as this may be considered at the next revision.</p>

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