

Update on the Development of ISO TS 29001/API Spec Q1

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Presentation Overview

- Process Used
- Important Changes
- Ballot and Publication Schedule
- Questions?

Update process

- Coordinated effort between API SC18 and ISO TC67/WG2
- Proposed changes submitted to TG/WG chair
- Task Group recommendations presented to API SC18 for acceptance
- If agreed by SC18, item forwarded to ISO TC67/WG2 for approval and inclusion in draft for next revision of ISO TS29001

Proposed Revisions

- 62 items suggested for revision
- 15 items approved for inclusion in draft TS29001

Approved Proposed Revisions

- Delete term “special processes”
- Clarify nonconforming product/concession
- Eliminate need for control feature on “Continual Improvement”
- Add requirement for purchased product verification recordkeeping
- Clarify final acceptance of product

Approved Proposed Revisions

- Add requirement for design and development output documentation
- Add requirement for customer notification of nonconforming product
- Properly identify all Supplemental Requirements
- Add requirement for control of outsourced products/services
- Modify product realization planning requirement

Approved Proposed Revisions

- Delete concession documentation requirement
- Revise Scope/Field of Application language
- Change review input supplemental requirement to a “Note”
- Add processes needing validation
- Add requirement to identify response time for detected nonconformance

Important Revisions

- Delete term “special processes”
- Add processes needing validation
- Clarify final acceptance of product

Important Revisions

- Add requirement for customer notification of nonconforming product
- Add requirement for control of outsourced products/services
- Add requirement to identify response time for detected nonconformance

Special Processes Processes Requiring Validation

- Proposal to delete the term “Special Processes” from the document and to have the product specification committees identify those processes that require validation.
- Proposed revision of clause 7.5.2.1:
““The organization shall validate any process as required by the applicable product specification. The product specification is the controlling documents. However, if the product specification does not address the processes requiring validation, the processes requiring qualification and validation shall include, as a minimum, non-destructive examination, welding, and heat treating.”

Final Acceptance of Product

- Proposal to revise the terminology “Final Acceptance” as it is used in clause 8.2.4.2. Neither ISO 9000 or API Spec Q1/ISO TS29001 provides a definition of “Final Acceptance” or Product Release”.
- Proposed revision of clause 8.2.4.2:
“Final acceptance inspection shall be performed or controlled by personnel other than those who performed or directly supervised the production of product. Acceptance inspection is the demonstration, through monitoring or measurement that the product complies with specified requirements.”

Control of Nonconforming Product

- Proposal to add a supplemental requirement to clause 8.3 for informing the customer of nonconforming product detected after delivery or use has started.
- ISO TC176 issued an interpretation (016 N698, 1r) saying that the organization does not need to inform customers of nonconforming product identified after delivery or use.
Rationale: The last paragraph of Clause 8.3 specifies that it is the organization's responsibility to take appropriate action regarding the nonconforming product.
- Proposed addition of Supplemental clause 8.3.4:
“Customers shall be notified in the event that product that does not conform to design acceptance criteria has been delivered. Records of such notifications shall be maintained (see 4.2.4).”

Control of Outsourced Products and Services

- Proposed addition of Supplemental clause 4.1.1:

4.1.1 Outsourced processes and/or services

“Ensuring control over outsourced processes and/or services shall not absolve the organization of the responsibility of conformity to specified requirements.”

- Proposed addition of Supplemental clause 7.4.1.3:

7.4.1.3 Supplier provided processes that require validation

“Where an organization chooses to outsource any process that requires validation, the organization shall require that the supplier comply with the requirements of 7.5.2, as applicable (see 4.1)”

Response Time for Addressing Nonconformance

- Proposed revision of clause 8.2.2.2:

8.2.2.2 Internal Audit Response Times

“Response times to address detected nonconformities shall be identified.”

Ballot and Publication Schedule

- September 2006: Working Draft review by ISO TC67/WG2 and API SC18
- October 2006: Send to ISO Central Secretariat for processing
- November 2006: Ballot starts
- February 2007: Ballot ends
- June 2007: Publication of TS29001, 2nd Ed./ API Spec Q1, 8th

Thank You!

Questions?

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