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Addendum 1

Introduction, 2nd paragraph: The paragraph shall be changed as indicated by the red text.

> This specification may be applied by organizations that provide product (3.1.16) for use in the petroleum and natural gas industry. As defined in 3.1.16, this specification uses the term "product" to refer to the "output of an organization intended to be provided to a customer".

3.1.12: The term/definition shall be changed as indicated by the red text:

> **3.1.12**
> **management personnel**
> A person or group of persons with authority and responsibility for the conduct and control of all or part of an organization.
>
> NOTE For some organizations, top management (see ISO 9000) and management personnel are the same.

3.1.13: The definition shall be changed as indicated by the red text:

> **3.1.13**
> **manufacturing acceptance criteria**
> **MAC**
> Requirements applied to characteristics or combinations of those characteristics, of materials, products, or components to achieve conformity to the applicable DAC (see 3.1.7) and other product manufacturing requirements.
>
> NOTE 1 MAC can be equal to DAC.
>
> NOTE 2 For services, product realization can be substituted for product manufacturing.

3.1.15: This item (preventive maintenance) shall be deleted and all subsequent terms shall be renumbered.

3.1.17 (formerly 3.1.18): The definition shall be changed as indicated by the red markup:

> **3.1.17**
> **product realization**
> Set of interrelated or interacting activities ~~(processes)~~ necessary to provide product.

3.1.20 (formerly 3.1.21): The definition shall be changed as indicated by the red markup:

> **3.1.20**
> **servicing**
> Maintenance, adjustment, and/or repair performed ~~on a product~~ after delivery and/or on-site installation.

4.1.3: The paragraph shall be changed as indicated by the red text:

4.1.3 Quality Objectives

Quality objectives, including those needed to meet product and customer requirements, shall be established at relevant functions and levels within the organization by management personnel with approval from top management.

4.1.4.1, item a): The item shall be changed as indicated by the red text:

a) define the scope of the quality management system, that identifies product(s) covered (see 3.1.16) and includes any limitations and exclusions (see 4.1.4.2);

4.1.4.2, 2nd paragraph: The second bullet item shall be changed as indicated by the red text:

Allowable exclusions shall be limited to the following sections of this specification:

- 5.4, Design
- 5.6.4, Validation of Processes
- 5.6.7, Externally Owned Property
- 5.6.8, Preservation of Product
- 5.8, Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)

4.2.3: The paragraph shall be changed as indicated by the red text:

4.2.3 Management Representative

Top management shall appoint and maintain a member of the organization's management personnel who, irrespective of other responsibilities, shall have responsibility and authority that includes:

4.4.1: The section shall be changed as indicated by the red markup:

The quality management system documentation shall include:

a) the scope of the quality management system that identifies product(s) covered (see 3.1.16) and includes justification for any exclusions (see 4.1.4.2);

b) statements of quality policy and quality objectives;

c) identification of legal and other applicable requirements to which the organization claims compliance that are needed to achieve product conformity;

~~d) identification of how the quality management system addresses each requirement of this specification;~~

d) identification of processes that require validation (see 5.6.4); and

e) procedures, documents, and records necessary for the planning, operation, and control of its processes and conformance with specified requirements.

4.4.2: The paragraph shall be changed as indicated by the red text:

4.4.2 Procedures

All procedures (see 3.1.15) required by this specification shall describe the organization's method for performing an activity and shall be documented, implemented, and maintained for continued suitability.

5.4.1: The section shall be changed as indicated by the red markup:

5.4.1 General

When the organization is responsible for the design of products, the requirements of 5.4 shall apply. ~~The design requirements of 5.4 shall not apply if the product is production activities, servicing, storage, distribution, or logistics (see 3.1.17).~~

5.5.1.2, 1st paragraph: Item c), subitem 2) shall be changed as indicated by the red text:

2) performing a remote assessment (see 3.1.18) to verify that relevant product realization processes are being performed in accordance with process controls and are effective in achieving conformity to requirements,

5.6.2: Item a) shall be changed as indicated by the red text:

a) description of the product (see 3.1.16) or scope of quality plan;

6.2.2.3: The paragraph shall be changed as indicated by the red text:

6.2.2.3 Audit Review and Closure

The organization shall identify response times for addressing detected nonconformities. The management personnel responsible for the area being audited shall ensure that any necessary corrections and corrective actions follow the requirements of 6.4.2. Records of internal audits shall be maintained (see 4.5).

6.4.2, 2nd paragraph: Item h) shall be changed as indicated by the red text:

h) criteria for updating the risks and opportunities identified during planning (see 4.1.4);

6.5.1: The paragraph shall be changed as indicated by the red text:

6.5.1 General

The organization's quality management system shall be reviewed at least every 12 months (not later than the end of the same calendar month as the prior year review) by the organization's management personnel to evaluate the quality management system's continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement, adequacy of resources, and the need for changes to the quality management system, including the quality policy and quality objectives.