Product Design and Manufacturing Conformance Certification

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— Should: As used in a standard, “should” denotes a recommendation or that which is advised but not required to conform to the standard.

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Suggested revisions are invited and should be submitted to the Standards Department, API, 200 Massachusetts Avenue, Suite 1100, Washington, DC 20001, standards@api.org.

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Introduction

This standard has been developed to be used when product specifications, recommended practices, or jurisdictional requirements call for independent certification of design verification, design validation, and/or manufacturing assurance. A manufacturer can elect to follow this standard independently or an end-user can require certification of conformance contractually. A product conformity assessment by an independent certification body, in conjunction with a manufacturer's quality management system and appropriate final factory inspection and acceptance testing, provides a holistic approach to confirm the product's conformity to applicable requirements and standards.

The objective of product design conformance certification (PDCC) and product manufacturing conformance certification (PMCC) is to provide confidence to interested parties that a product fulfills specified requirements. The certification is established by an impartial and competent demonstration of fulfillment of specified requirements by a third party. Parties that have an interest in and are stakeholders of PDCC and PMCC include but are not limited to the following:

— the certificate requestor;

— the independent type conformance organization (ITCO) that issues the certification;

— the end-users of the certified product;

— governmental authorities;

— non-governmental organizations; and

— consumers and other members of the public.

The PDCC process (Section 6) is intended to provide assurance that the product's design meets a set of specified requirements, which may include:

— API product specification or other industry standards;

— functional specification or technical specification; and

— material selection and qualification to meet functional or technical specifications.

A PDCC states that the design of a product is in conformity with specified requirements and forms the basis for a future PMCC (if desired).

The PMCC process (Section 7) provides assurance that the product has been produced in compliance with a current PDCC.

A PMCC states that a unique, serialized, manufactured product is in conformity with specified design and fabrication requirements at the date of manufacture.

Implementation of the PDCC and PMCC processes should:

— minimize duplication of product manufacturing conformance verification efforts;

— facilitate the approval of product designs through a transparent process acceptable to multiple stakeholders;

— facilitate and accelerate regulatory approval; and

— provide a consistent approach and defined scope for effective and efficient PDCC and PMCC activities.

Product Design and Manufacturing Conformance Certification

1 Scope

1.1 General

This document defines the necessary processes for product design conformance certification (PDCC) and product manufacturing conformance certification (PMCC). This document also defines processes for an independent type conformance organization (ITCO) to perform PDCC and/or subsequent PMCC for the manufactured product to confirm that the design and/or manufacturing requirements are met. As part of this process, this document defines the requirements for the competence, consistent operation, and objectivity of the independent party who performs these activities.

This document can be applied when an independent review of designs and/or manufacturing is desired or required (including but not limited to equipment for novel applications such as high-pressure high-temperature environment, subsea technologies, and/or new or unusual technologies). The independent review process is intended to assess a specific product's conformity to specified API or other industry standards or functional specifications.

Verification of the accuracy and validity of the user's specified conditions, loads, and other technical requirements, including deterioration or damage due to activities after the product has been manufactured and certified, are not in the scope of this document.

1.2 Applicability

The PDCC process (Section 6) is applicable to any design where it has been requested by a certificate requestor.

The PMCC process (Section 7) is applicable to any tangible product for which a current PDCC exists in conformance with Section 6 and where the PMCC certificate has been requested by a certificate requestor.

2 Normative References

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition (including any addenda or errata) applies.

API Specification Q1, *Quality Management System Requirements for Organizations Providing Products for the Petroleum and Natural Gas Industry*

ISO 9000,[1] *Quality management systems — Fundamentals and vocabulary*

ISO 9001, *Quality management systems — Requirements*

3 Terms, Definitions, and Abbreviations

3.1 Terms and Definitions

For the purposes of this standard, the terms and definitions given in API Q1, ISO 9000, and the following shall apply. When identical terms are defined in API Q1 and ISO 9000, API Q1 shall apply. When identical terms are defined in API Q1 and this document, the following definitions shall apply.

[1] International Organization for Standardization, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, www.iso.org.

3.1.1
certificate requestor
An entity requesting an ITCO to perform an evaluation of the design or manufacture of a product in accordance with the requirements of this standard.

NOTE The term “certificate requestor” can apply to either an end-user or manufacturer and is the entity requesting the ITCO to evaluate either the design or the manufacture of a product.

3.1.2
documentation review
Quality plan activities generating documents or certificates that are reviewed by the ITCO after completion.

3.1.3
end-user
An entity intended to receive or use a product that has been certified by an ITCO.

3.1.4
functional specification
A document that defines the needed performance and requirements of the product.

NOTE See ISO 13879 for additional information on functional specifications.

3.1.5
hold point
A quality plan inspection point that occurs prior to a mandatorily witnessed activity.

3.1.6
independent type conformance organization
ITCO
An entity separate from the purchaser, manufacturer, and requestor that evaluates the design or manufacture of a product in accordance with the requirements of this standard at the request of a certificate requestor.

3.1.7
manufacturer
An entity designing and/or manufacturing a product that is certified by an ITCO.

3.1.8
monitor activity
Quality plan activities that are periodically checked by the ITCO to confirm conformance.

3.1.9
product
A tangible item for which an assessment of a design or its manufacture is performed in conformance with this document.

3.1.10
type conformance
A process that provides evidence that a product meets requirements in accordance with applicable standards and specifications.

3.1.11
technical product definition
TPD
A means of conveying all or part of a design definition or specification of a product.

3.1.12
technical product specification
TPS
Documentation comprising the complete design definition and specification of a product for manufacturing and verification purposes.

3.1.13
technical specification
A document that defines the performance capabilities of a product.

NOTE See ISO 13880 for additional information on technical specifications.

3.1.14
substantive design change
A design change that affects the performance of the product in the intended service.

3.1.15
verify
To confirm through objective evidence that specific requirements have been fulfilled.

3.2 Abbreviations

DAC	design acceptance criteria
FAT	factory acceptance testing
FMEA	failure modes and effects analysis
FMECA	failure modes, effects, and criticality analysis
HAZOP	hazard and operability analysis
ITCO	independent type conformance organization
ITP	inspection and test plan
MAC	manufacturing acceptance criteria
NDE	non-destructive examination
PDCC	product design conformance certification
PMCC	product manufacturing conformance certification
QMS	quality management system
TPD	technical product definition
TPS	technical product specification

4 General Requirements

4.1 Application

4.1.1 General

The certificate requestor shall submit to the ITCO a PDCC and/or PMCC application to begin the review process.

The application shall define the scope for which certification is requested. The scope of certification shall also include the products or designs to be certified and the specifications to which they will be certified.

4.1.2 Product Design Conformance Certification Application

The following information shall be submitted in the application for a new PDCC:

a) the certificate requestor’s name and physical address;

b) the manufacturer's name and physical address if different than the certificate requestor;

c) the product(s) to be certified;

d) a list of functional and technical specification(s);

e) applicable document(s) inclusive of edition to which the certificate requestor is seeking certification;

f) a list of applicable design documents to be reviewed; and

g) details of any special or additional requirements (if any/as applicable).

NOTE Refer to 8.2 for renewals or recertification.

4.1.3 Product Manufacturing Conformance Certification Application

The following information shall be submitted in the application for a new PMCC:

a) the certificate requestor’s name and physical address;

b) the manufacturer's facility information for where the product will be manufactured;

c) product(s) to be certified;

d) reference to the PDCC;

e) the manufacturer’s current quality management system (QMS) conformance in accordance with API Q1, and applicable licenses for product manufacture;

f) applicable document(s) inclusive of edition to which the product will be manufactured;

g) a quality plan (QP)/inspection testing plan (ITP) indicating significant process and operations inclusive of outsourced operations and details of any special or additional requirements (if any/as applicable).

4.1.4 Application Review

The ITCO shall review the PDCC or PMCC application information to ensure the following:

a) The application information and scope are sufficient to conduct the certification process.

b) Differences in understanding between the certificate requestor, manufacturer, and ITCO are resolved, and there is an agreement on the standards and other normative documents that will be applied.

c) A valid PDCC exists (for PMCC only), or is also being applied for (for PMCC only).

d) The ITCO resources are available to perform evaluation and certification activities.

e) The ITCO has the competence and capability to perform the certification activities.

The ITCO shall decline to accept the application if it lacks competence or capability for the product being submitted for certification.

4.2 Evaluation and Assessment Requirements

4.2.1 The ITCO shall maintain a documented procedure for evaluation and assessment activities to ensure that necessary arrangements are suitably managed in accordance with Section 6 and Section 7, as applicable.

4.2.2 The ITCO shall assign personnel to perform each evaluation task required to provide the PDCC and/or PMCC for which the certificate requestor has applied.

4.2.3 The ITCO shall request that necessary information and/or documentation be made available for performing the evaluation tasks from the certificate requestor and/or manufacturer.

4.3 Certification Decision

4.3.1 The ITCO shall assign at least one primary reviewer to make the certification recommendation. The certification decision shall be made by authorized personnel other than the primary reviewer.

4.3.2 If the decision is made not to grant certification to the certificate requestor, the ITCO shall notify the certificate requestor of that decision and identify the reasons for the decision.

4.4 Record of Certified Products

The ITCO shall maintain a listing of certified products in a record, where legally allowed, containing the following at a minimum:

a) manufacturer's unique identification of the product;

b) standards, specifications, and any other normative documents referenced in the certification;

c) name and address of the certificate requestor;

d) name and address of the manufacturer (if different than the certificate requestor);

e) type of certificate (PDCC or PMCC);

f) date the PDCC or PMCC was issued;

g) date the PDCC or PMCC expires.

5 Independent Type Conformance Organization (ITCO) Requirements

5.1 General

5.1.1 The ITCO shall be responsible for its conformance assessment activities.

5.1.2 The ITCO activities shall be structured and managed to ensure freedom from bias and conflicts of interest.

5.1.3 The ITCO shall document its organizational structure and define the responsibilities and authorities of personnel performing certification.

5.1.4 The ITCO shall have processes to safeguard the confidentiality of information obtained during certification.

5.2 Organizational Qualifications

The ITCO shall be an entity capable of providing the required certifications and verifications specific to product requirements.

NOTE The ITCO can be a technical classification society, a licensed professional engineering firm, registered professional engineers, or technically competent individuals who are duly accredited.

5.3 ITCO Scope of Work

5.3.1 The ITCO shall establish a scope of work and provide it to the certificate requestor.

5.3.2 To support the ITCO's activities, the certificate requestor or manufacturer may establish provisions for examining documentation and records, and grant access to the relevant equipment, location(s), area(s), personnel, and the investigation of non-conformance(s) identified during execution.

5.4 Personnel

5.4.1 The ITCO shall employ or have access to an adequate number of competent personnel to conduct the operations of the certification processes.

5.4.2 Personnel competence and training shall conform to API Q1 and Annex A.

5.4.3 Personnel qualification records shall conform to Annex B. The ITCO shall provide credentials of personnel to the certificate requestor or end-user upon request.

5.5 Quality Management System (QMS)

5.5.1 The ITCO shall establish and maintain a QMS that ensures the consistent fulfillment of the requirements. The ITCO's QMS shall conform to the requirements of ISO 9001 and any additional requirements specified in this document.

5.5.2 The ITCO shall maintain documented procedures for:

a) design verification and validation reviews to be conducted in accordance with Section 6;

b) product manufacturing conformance reviews to be conducted in accordance with Section 7;

c) managing certificates, non-conforming products, and complaints; and

d) addressing changes to certification.

5.6 Management of Change (MOC)

The ITCO shall maintain a procedure for MOC in conformance to requirements in API Q1.

6 Product Design Conformance Certification (PDCC)

6.1 General

6.1.1 The PDCC process is a review of the technical product specification (TPS) and technical product definition (TPD) with the determination by the ITCO that the product conforms to the TPS. When there are no standards for the product, analysis methods may need to be established.

6.1.2 The manufacturer and the ITCO shall agree on the TPD that is to be made available when performing the review (see 6.3).

NOTE See Annex C for information on technical product definition.

6.1.3 After the ITCO has previously reviewed and issued a certificate for a product, the manufacturer or the certificate requestor may request a recertification or certification of a related subcomponent, component, or assembly. The PDCC change process and renewal process are described in 8.2.

6.2 Engineering Verification Review

The design verification review conducted by the ITCO shall confirm that engineering methods used in developing designs are in accordance with requirements specified in the TPD.

NOTE The design information can include the manufacturer's design analysis methodology and whether the methodology is based on an "alternate analysis method" (i.e., equipment designed using alternate analysis methods).

6.3 Product Design Conformance Certification Process

6.3.1 General

6.3.1.1 The ITCO shall verify that the product design conforms to the TPS.

6.3.1.2 The ITCO shall verify the design process and the manufacturer's use of the following QMS elements in the design and development of the product:

a) planning;

b) inputs;

c) outputs;

d) review;

e) verification and final review;

f) validation and approval;

g) changes.

6.3.1.3 For product design conformance certification (PDCC), the following requirements shall be included in the ITCO's procedure for design conformance certification and shall be followed.

a) review and verification of the manufacturer's product design documentation required to conform with the design elements listed in 6.3.1.2, including review of design and verification of calculations, materials specifications, system design specifications and failure modes and effects analysis (FMEA) reports, as applicable;

b) witness of design validation testing and review of design validation reports, when applicable, otherwise for existing designs, review of prior validation testing and reports.

6.3.2 Design Verification Review

6.3.2.1 The ITCO assigned to perform the review and verification of the manufacturer's product design verification shall confirm that necessary documentation, drawings, and data are available and provided for review in the manner agreed with the manufacturer and certificate requestor.

6.3.2.2 For new product designs or established products used in new applications, where a risk assessment [e.g., failure modes, effects, and criticality analysis (FMECA/FMEA or HAZOP)] is applicable, the review of design verification and applicable design validation should identify the potential failure modes and the mitigation method(s) used to adequately evaluate the equipment.

6.3.2.3 The review and verification of the manufacturer's product design verification may include but is not limited to the following:

a) an analysis of the equipment under specified loading conditions;

b) failure assessment that identifies the failure mode(s);

c) fatigue assessment and system analysis, with design simulations as applicable;

d) other analysis techniques as applicable (e.g., stress relaxation, creep, embrittlement, vortex-induced vibrations, or flow-induced vibrations);

e) material suitability.

NOTE 1 Analysis methods such as finite element analysis (FEA) can include advanced methods, such as elastic analysis, elastic-plastic analysis, elastic-perfectly plastic analysis, strain-based design, elastic-plastic analysis based on work-hardening/softening, or other methods.

NOTE 2 See Annex D for more information on the ITCO verification review process.

6.3.3 Design Validation Review

6.3.3.1 The ITCO assigned to perform the review and verification of the manufacturer's product design validation shall confirm that necessary validation test reports and records are available and provided for review in the manner agreed with the certificate requestor and manufacturer.

6.3.3.2 The design validation review shall include review of the design validation testing, functional testing process, and procedures used to validate the performance of the design to the TPS.

6.3.3.3 The ITCO shall verify that any applicable design validation scaling and product family rules of the applicable API product specification have been satisfied and documented.

6.3.3.4 The manufacturer's design validation testing program, including identified potential failure modes, shall be confirmed and accepted by the ITCO to be in conformance to the TPS.

NOTE 1 Typical validation techniques can include the following:

— pressure testing;

— load testing;

— functional testing;

— non-destructive examinations;

— destructive examinations;

— life-cycle testing;

— thermal testing;

— fatigue testing.

NOTE 2 See Annex D for more information on the ITCO validation review process.

6.3.4 Issuance of PDCC

The following apply to issuing a PDCC to the certificate requestor.

a) At a minimum, the PDCC shall include the following information:

- name and address of the manufacturer;
- description of product, including make and model;
- product ratings (e.g., load, pressure, temperature, fluid exposure, combined load rating, etc.);
- intended application, restrictions, and limitations, or other conditions applicable;
- specified API standard or another standard to which the product conforms, if applicable;
- additional environmental tests performed, if applicable;
- design verification/validation detail(s), including acceptance/rejection criteria (unless this is proprietary information that will be covered by agreement);
- certificate number;
- date of issue;
- date of expiry;
- specific documents reviewed (e.g., a master document register).

b) PDCC certificates shall include the following comments in the section for limitations or other conditions:

"PDCC does not eliminate the need for normal inspection required by API standards or other standards."

c) If additional requirements are above and beyond API standards or other standards being verified, these additional requirements should be clearly listed on the certificate in a separate section.

6.4 PDCC Documentation

6.4.1 The ITCO shall retain records to provide objective evidence that all certification process requirements have been satisfactorily completed.

6.4.2 Records shall be maintained as confidential and handled in a manner that ensures that confidentiality is maintained.

6.4.3 Records shall be retained in accordance with API Q1 or the applicable product specification, or as required by the certificate requestor, or by legal, regulation, or other applicable requirements, whichever is longer.

7 Product Manufacturing Conformance Certification (PMCC)

7.1 General

a) The ITCO shall verify that the manufacturer receiving the PMCC conforms to applicable product-specific standards and specifications and has a management system that conforms to the requirements of an internationally recognized quality standard, such as API Q1, API Q2, ISO 9001; and

b) a quality management system that is audited at least annually by a QMS certification body accredited to ISO 17021-1 at a minimum.

7.2 ITCO Verification Prior to Manufacture

The ITCO shall perform the following.

a) Confirm current PDCC according to Section 6 and record the PDCC certificate number.

b) Review relevant design output required to manufacture the product to verify that documents are approved, such as drawings, bills-of-materials, and engineering specifications, and that revision levels correspond with the PDCC.

c) Review the manufacturing facility's requirements to confirm that the product being manufactured meets the certificate requestor or end-user's stated requirements.

d) Confirm that the manufacturing facility has achieved performance requirements for processes requiring validation identified by the applicable product specification, API Q1, or both.

7.3 Manufacturing Quality

7.3.1 Manufacturer's Quality Plan

The ITCO shall confirm that the manufacturer has a quality plan and review the manufacturer's quality plan and ITP to confirm that the requirements of product quality plans in API Q1, the approved PDCC, and the following are incorporated.

a) The quality plan includes monitoring activities (3.1.8), witness activities following hold points (7.3.2.3), documentation review (see 3.1.2), and hold points (3.1.5) that require action(s) by the ITCO.

b) Provisions exist for the ITCO to be advised of the manufacturing schedule to allow monitoring of required processes.

c) Provisions exist for the written notification to the ITCO for hold points.

d) The quality plan includes hold points prior to the execution of the following witnessed activities:

— set-out prior to final assembly;

— final inspection and testing.

7.3.2 Activities During Manufacturing

7.3.2.1 Documentation Review

The ITCO shall review the following manufacturer's documentation, as applicable to the product, to verify conformance with the approved PDCC:

a) welder qualifications;

b) material test report certificate;

c) heat treatment procedures;

d) non-destructive evaluation (NDE) capabilities and procedures;

e) coating processes (including thermal spray and traditional coatings);

f) pressure- and load-testing procedures;

g) assembly records, such as drift, operating torque, bolt torque, tubular make-up, or press fit, when recorded values are required;

h) databook completion signoff.

7.3.2.2 Monitor Activities

The ITCO shall monitor the following manufacturer's processes as applicable to the product to confirm conformance to the manufacturer's requirements:

a) welding processes, including welding start-up;

b) material traceability;

c) pre-heat and post-heat treatment processes;

d) NDE;

e) coating processes;

f) factory acceptance testing conducted;

g) quality control processes;

h) test equipment calibration.

7.3.2.3 Hold Point and Witness Activities

7.3.2.3.1 The ITCO shall witness the activities following the designated hold points and a signature of the ITCO representative shall be required. Hold points shall not be waived by the ITCO.

7.3.2.3.2 The following minimum hold point and witnessed activities shall be included for manufacturing conformance assessment:

— set-out prior to final assembly;

— factory acceptance testing (FAT).

7.3.2.3.3 For testing activities executed over a period more than 8 hours, the ITCO shall be present at the commencement and completion of the testing. Activities occurring within the testing duration may be monitored.

7.4 Review of Manufacturing Records for Non-verified Activities

The ITCO shall review manufacturing records for non-verified activities and existing components to verify conformance with engineering drawings, bills-of-materials, and engineering specifications.

7.5 Product Nonconformances

7.5.1 The PMCC final report shall include or reference a listing of all MAC nonconformances that occurred during the manufacture of the product.

7.5.2 The ITCO shall review the disposition of each MAC nonconformance and confirm that it includes acceptance by the respective engineering and production departments in accordance with the manufacturer's quality process.

7.5.3 For DAC nonconformances, the ITCO shall require the manufacturer to modify the DAC and update the PDCC to reflect the new DAC.

7.5.4 The PMCC final report shall include records of any modifications to the DAC, including the dispositioning authority, the rationale for continued use, and evidence of review and acceptance by the end-user.

7.6 PMCC Documentation

7.6.1 The ITCO shall prepare a final report on the PMCC activities and provide a copy to the certificate requestor. The report shall include or reference the following:

a) facility quality registration and any applicable licenses for product manufacture;

b) the PDCC and revision that was manufactured;

c) the activities verified through document review, monitoring, or witnessing, and applicable quality plan and ITP identification;

d) planned activities that were waived;

e) MAC nonconformances;

f) DAC nonconformances;

g) the date that the PMCC is issued;

h) the name of the ITCO;

i) the name of the certificate requestor;

j) the name of the manufacturer if different than the certificate requestor.

7.6.2 The ITCO shall retain records to provide objective evidence that all certification process requirements have been satisfactorily completed.

7.6.3 Records shall be maintained as confidential and handled in a manner that ensures that confidentiality is maintained.

7.6.4 Records shall be retained for a minimum of five years or as required by the certificate requestor, or by legal, regulation, or other applicable requirements, whichever is longer.

8 Changes to Certification

8.1 General

PDCCs shall expire after five years; refer to 8.2 for renewal requirements.

NOTE PMCCs are product and serial number-specific and remain valid for the life of the product unless modified, as described in 8.3.

8.2 PDCC Changes and Renewals

8.2.1 Certification Updates

PDCC certificates can require renewal or change for numerous reasons, including:

a) expiration of original certificate;

b) changes to the TPS and TPD;

c) substantive design changes.

8.2.2 Renewals, Changes, or Certification of a Related Sub-component, Component, or Assembly

8.2.2.1 Renewal Without Substantive Design Changes

8.2.2.1.1 To renew a PDCC after its five-year expiration with no substantive design changes, the ITCO shall confirm with the manufacturer or the certificate requestor that no substantive design changes have been implemented since the last PDCC issuance.

8.2.2.1.2 The ITCO may renew a certificate to an older revision of a specification.

8.2.2.1.3 The ITCO shall:

a) review changes affecting certification;

b) review the manufacturer's updated documentation;

c) make the certification determination and decision on renewal;

d) revise the certification document(s) to reflect the requested changes.

8.2.2.2 Renewal with Substantive Design Changes and Reduced Scope

The following apply when substantive design changes are made.

a) When the need to update or renew a PDCC with changes is identified, the ITCO shall confirm with the manufacturer or the certificate requestor that:

    1) the design changes implemented since the last evaluation and review are identified;

    2) the TPD meets relevant specifications or standards; and

    3) the TPSs have been updated (if required).

b) The ITCO shall also:

    1) review changes affecting certification:

    2) review the manufacturer's updated documentation:

    3) make the certification determination and decision on renewal; and

    4) revise certification document(s) to reflect the requested design codes (if applicable).

8.2.2.3 Reduced-scope Certification

For a reduced-scope certification, the ITCO shall ensure that the reduced scope is communicated to the certificate requestor and clearly documented in the certificate.

8.3 Termination, Reduction, Suspension, or Withdrawal of Certification

8.3.1 General

8.3.1.1 The ITCO shall process nonconforming certified product(s) to ensure that the continuation of certification is justified.

8.3.1.2 Depending on the root cause analysis and/or corrective action report analysis, the ITCO may determine that appropriate actions are necessary. These may include, for example, but are not limited to the following:

a) continuation of certification under conditions specified by the ITCO;

b) reduction in the scope of certification to remove nonconforming product variants or risks;

c) suspension of the certificate requestor's certification pending remedial action by the certificate requestor;

d) withdrawal of the certification.

8.3.2 Certification Status Information

8.3.2.1 If certification is terminated, suspended, or withdrawn, the ITCO shall ensure that required certification documents and the certificate requestor's registry listing are revised appropriately, to ensure that they provide no indication that the product continues to be certified.

8.3.2.2 For a suspended certification, the ITCO shall ensure that the actions needed to end suspension and restore certification for the product(s), both in accordance with the ITCO's requirements and any other actions required, are communicated to the certificate requestor.

8.3.2.3 Evaluations required to release the suspension or required by the ITCO shall be completed in accordance with the ITCO's program and procedures.

8.3.2.4 If certification is reinstated after suspension, the ITCO shall ensure that required certification documents and the certificate requestor's registry listing are revised appropriately, to ensure that appropriate indications exist that the product continues to be certified. Reinstated certifications may also be conditioned.

8.3.2.5 If a decision to reduce the scope of certification is made as a condition of reinstatement, the ITCO shall ensure that required certification documents and the certificate requestor's registry listing are revised appropriately, to ensure that the reduced scope of certification is clearly communicated to the certificate requestor and clearly specified in both certification documentation and public information.

Annex A
(normative)

ITCO Personnel Qualification Requirements

A.1 PDCC Reviews

ITCO personnel (design reviewer and supervisor) performing PDCC reviews shall meet the following requirements:

a) bachelor's degree or equivalent in engineering, technology, science, or mathematics from a recognized institute;

b) working knowledge of applicable API or other standards and specifications, applicable interpretations, and reference codes and standards;

c) related experience on the design of product(s) [i.e., equipment assembly or assemblies and component(s)].

A.2 PMCC Assessments

ITCO personnel (inspector and supervisor) performing PMCC assessments shall meet the following requirements:

a) knowledge of quality assurance requirements, including shop and field procedures and quality control techniques (e.g., non-destructive testing, etc.);

b) ability to monitor and evaluate shop and field procedures and performance;

c) working knowledge of applicable API or other standards and specifications, applicable interpretations, and reference codes and standards;

d) related experience on the product(s) being certified [i.e., equipment assembly or assemblies and component(s)];

e) knowledge of the requirements for quality assurance records.

Annex B
(normative)

ITCO Personnel Qualification Records

B.1 Records of the relevant qualifications, training, and experience of each member of the personnel involved in PDCC and PMCC processes shall be maintained by the ITCO for a minimum of five years after the date each individual ceases to work for the ITCO.

B.2 Records of personnel qualifications shall include:

a) name and contact information;

b) organization affiliation and position held;

c) ITCO task-specific procedure qualifications providing evidence of competency for product(s) [e.g., equipment assembly or assemblies and component(s) and/or quality assurance/quality control (QA/QC) process or processes, QMS auditor/lead auditor, non-destructive examination (NDE) disciplines, and inspection techniques the individual is competent to evaluate];

d) educational qualification;

e) professional qualifications and certifications held;

f) experience and training;

g) competency assessment and reassessment frequency;

h) date of most recent updating of records;

i) performance appraisal;

j) authorizations held within the ITCO.

B.3 Records shall be signed and dated by the authorized ITCO individual reviewing and accepting the individual's record file(s) to attest that the employee or contractor is deemed competent for the specific product(s) and/or QA/QC process or processes the individual is qualified to perform.

Annex C
(informative)

Technical Product Definition

C.1 The collection of the technical product definition (TPD) related to product performance; product configuration; materials of construction; conditions under which the product operates; any other normative references (such as applicable API product specifications or other industry specifications); and/or other limitations that can affect the design and development are contained in the technical product specifications (TPS). The functional specifications are typically gathered by the end-user of the product and communicated to the manufacturer to use during product development and manufacture. The manufacturer will further develop technical specifications for the product intended for manufacturing.

C.2 The information and documentation necessary for review may include:

a) manufacturer QMS information/certificate, including API Monogram License or APIQR certificate or other registrations (i.e., API Q1 or equivalent, as applicable);

b) design and development planning (including the manufacturer's documented procedure to plan and control the design and development of the product);

c) the basis of design, including the loads and environment;

d) functional specifications and technical specifications for the product;

e) the operating characteristics specification;

f) design drawings for the product or system;

g) assembly/sub-assembly drawings with component list and reference to material specifications;

h) design calculations and governing requirements:

   i. design inputs;

   ii. design outputs;

   iii. accept/reject criteria;

i) design and development verification and final review records;

j) risk assessment [e.g., failure modes and effects analysis (FMEA)/failure modes, effects, and criticality analysis (FMECA) or HAZOP (as applicable)];

k) manufacturer design review records;

l) material specifications;

m) material selection, qualification, and testing;

n) validation testing program procedures, details with accept/reject criteria, and results;

o) material test reports for materials used in prototype validation testing.

Annex D
(informative)

Design Verification

D.1 General

The intent of this annex is for the ITCO to review design verification and validation used in defining the performance of these products and to certify that these methods are acceptable. These verification methods are found in API standards, other recognized industry standards (ISO, ASTM, ASME, etc.), and manufacturers' technical specifications.

D.2 Alternative Methods

When the design verification method described in the TPD is not defined by an API or other industry standard, the ITCO shall determine if the method used to certify conformance to the TPS satisfies specified requirements.

Alternate analysis methods may include the following:

a) ASME BPVC, Section VIII, Division 2 or 3;

b) API 579;

c) BS 7910;

d) API 17TR8;

e) API 17TR7;

f) methodology as provided in BSEE NTLs 2019-G02 and 2019-G03;

g) end-user methods and requirements;

h) manufacturer's methods and requirements;

i) manufacturer's technical specifications that have been validated;

j) other recognized industry documents that have been validated.

D.3 Additional Requirements and Considerations

D.3.1 When the design analysis is based upon the manufacturer's technical specification, details of the manufacturer's standard and engineering justification shall be available for review and clearly referenced on the certificate.

D.3.2 The manufacturer shall demonstrate to the certificate requestor and the ITCO by way of testing or analysis that the design criteria employed results in a level of safety consistent with that of a recognized standard or code of practice.

D.3.3 Where strain gauge testing, fracture analysis, proof testing, or similar procedures from the manufacturer's design criteria are used, the procedure and results shall be reviewed by the ITCO.

D.3.4 Historical performance data for systems, equipment, or components shall be reviewed for justification of designs based on manufacturer's standards.

D.3.5 The application of risk-based evaluation for the design may be used.

D.4 ITCO Design Verification and Validation Review Process

The steps for the ITCO review are outlined below.

a) Review preparation:

1) Determine the overview/scope/background for the review.

2) Identify the product configuration (system or independent product): well control system, well-head system, BOP stack, capping stack, riser system, single-equipment (ram BOP, tree valves), etc.

3) Identification of applicable standard(s)/specifications used in the design.

4) Identification of any new technology introduced in the design.

5) Identification of additional requirements (user or regulatory): HPHT, regulatory requirements, customer requirements, regional/geographic requirements, operational periodic checks, or maintenance requirements.

6) Develop stage-review process and communication methods to be used between the ITCO and the designer and between the ITCO and the requestor.

7) Identification and assignment of the personnel necessary for the review and verification of the review.

b) Performing the review (confirm the following are met):

1) Inputs defined as required.

i) Customer-specified requirements (functional specification and operating conditions).

ii) Technical requirements:

— environmental requirements (e.g., fluids and temperature);

— system operational requirements;

— design performance capacity/envelope(s).

iii) statutory or regulatory requirements.

iv) design methodology, assumptions, and formulae documentation.

2) Design verification has been performed per the following requirements.

i) Design calculation results:

— acceptance criteria (stress, strain, fatigue, survival limits, etc.);

— material properties (minimum yield, ultimate tensile strength, maximum hardness, fracture toughness, Charpy values, elongation, elastomeric properties, etc.);

— analysis methods (elastic, plastic, fracture mechanics, etc.; refer to 6.3.2).

NOTE FEA process verification methodology is provided in Annex E.

ii) Manufacturing documents with technical requirements:

— standard drawing requirements with tolerances;

— material specifications;

— process control specifications and instructions, i.e., welding, cladding, coating, NDE, etc.;

— addressing deviations (design changes, nonconformances) from standard requirements;

— specified acceptance criteria, including tolerances.

iii) Quality plan, when available [examples include product quality plan (PQP), inspection and test plan (ITP), manufacturing process specification (MPS), process control plan (PCP), and quality activity plan (QAP), etc.].

iv) Allowances for installation, monitoring, and maintenance requirements of the product.

v) Identification of impact from risk analysis.

vi) Design verification conforms to the following:

— design outputs verified as meeting the technical requirements;

— design outputs verified as meeting customer requirements;

— design outputs verified as meeting statutory and regulatory requirements.

3) Design validation has been performed in accordance with the following:

i) Identification of required testing.

— Prototype tests, functional and/or operational tests of production products, tests specified by industry standards and/or regulatory requirements.

— When design validation by scaling is applied to a design under review by ITCO, ensure that scaling is allowed by and has been used on the design in accordance with the applicable API equipment specification or other relevant technical specification(s), including reviewing of records of the specific validation data/evidence previously collected and being used in support of validation of the new design.

ii) Identification of alternative validation methods, as applicable when standards are not available.

EXAMPLE — Validation of the design method: Model predictions (i.e., stress or thermal FEA, fatigue analysis, fracture mechanics, etc.) shall be validated by measurements and testing. Validation of FEA should follow ASME V&V 10–2006.

Historical validation processes may remain valid if they are documented, demonstrated as technically sound, and meet the equipment design requirements and service conditions.

iii) Additional validation requirements (material characterization, etc.), as applicable.

Material characterization: temperature, corrosion, fatigue, stress-corrosion cracking, hydrogen-induced cracking (HIC), erosion/corrosion, other corrosion mechanism, etc.

iv) Confirm validation requirements have been met.

v) Final verification of review process and issuance of PDCC.

Annex E
(informative)

Finite Element Analysis Process (FEA) Verification Methodology

The following questions are intended to support the process of conducting ITCO reviews of finite element analysis (FEA) reports to achieve the goal of model verification, as applicable. The questions, which apply primarily to a static structural analysis, include a number of checks that can help demonstrate that the FEA is properly performed and is free from potential errors. Since most of these checks cannot be performed without direct access to the FEA model and results files, it is best that responses to these questions (when applicable) are documented by the FE analyst in the FEA report. If the responses are not clear in the report, it is the responsibility of the ITCO reviewer to request clarification from the FE analyst to ensure that the FEA is properly performed.

1) Have applicable industry standards requirements been met (when available)?

2) Have key model dimensions (e.g., diameters, thicknesses) been verified against the part final machine drawing dimensions as specified in the report (including applicable fabrication tolerances and metal loss allowances)? Are plots of the FE model, with coordinates of select nodes and key dimensions, added to the report?

3) Have the material properties specified in the model (e.g., tensile and thermal properties) been verified against the values stated in the report? Are input files that include material models or stress strain curves used in the FEA included in the report?

4) Are boundary conditions properly defined in the model and documented?

5) Have reaction forces/moments been checked to verify proper application of loads, and have they been documented?

6) Is the analysis performed with linear or nonlinear geometry properly documented? Were the effects on nonlinear geometry considered in the elastic-plastic analysis? (Reference: ASME BPVC VIII-Div. 3/KD-231.1)

7) Has the impact of stabilization factors/forces added to achieve convergence been evaluated and documented?

8) Are pressure end-loads included in the model and has proper application been verified and documented?

9) Are preloads/pretension included in the model and has proper application been verified and documented?

10) Has the use of proper stress-strain curve used in the model been verified and documented?

11)A re appropriate allowable stresses used for normal, extreme, and survival conditions, and have they been documented?

12) Have stress and strain plots been provided with proper filters to show high-,stressed and critical areas of the components, and h ocumented?

13) Is proper temperature and de-rating of material properties used in the model and documented?

14) Is proper elastic modulus, Poisson's ratio, thermal expansion coefficient, and other material properties properly used in the model?

15) Is friction accounted for in the model, and has the proper friction coefficient been used and documented?

16) Are stress concentration and amplification factors properly defined and have proper reference sections been used and documented?

17) Is proper fatigue methodology and load histograms used and documented?

18) When combined bending, tension, and pressure loads are present, have both tension and bending side of the components' stress levels been evaluated and documented?

19) Has load separation of components and its impact on seals, fatigue, etc., been evaluated and documented?

20) Has justification for the choice and suitability of the element types used in the analysis been provided and documented?

21) Have mesh sensitivity studies been performed and mesh refinement suitability been justified and documented?

22) Has the application of loads (including thermal, preload, etc.) with regard to their location, magnitude, and direction, been illustrated on a plot of the FE model and documented?

23) Have the applied constraints, with regard to their location, magnitude, and direction, been illustrated on a plot of the FE model and documented?

24) Have the errors and warning messages been reviewed and reconciled (including those associated with meshing, analysis, stabilization, and results)?

25) Are the deformation and stress levels similar to real-life applications (i.e., consistent with the constraints and loads applied in the analysis)?

26) Have some results been verified against hand calculations and/or test results?

27) Has there been any model calibration with testing performed and documented to validate the FEA model?

28) If contact elements and surfaces are used, have separate checks been performed to verify the accuracy/acceptability of their performance, and have they been documented?

29) If seal analysis is performed, have the acceptance criteria been provided and documented?

30) In non-metallic materials were used in the analysis, have the non-metallic properties been provided and documented?

Bibliography

[1] API Recommended Practice 579, *Fitness-for-Service*

[2] API Technical Report 17TR8, *High-pressure High-temperature Design Guidelines*

[3] API Technical Report 17TR7, *Verification and Validation of Subsea Connectors*

[4] ASME *Boiler and Pressure Vessel Code* (BPVC),[2] Section VIII, *Rules for Construction of Pressure Vessels Division 2—Alternative Rules*

[5] ASME *Boiler and Pressure Vessel Code* (BPVC), Section VIII, *Rules for Construction of Pressure Vessel; Division 3—Alternative Rules for Construction of High Pressure Vessels*

[6] BS 7910,[3] *Guide to methods for assessing the acceptability of flaws in metallic structures*

[7] BSEE NTL 2019-G02,[4] *Guidance for Information Submissions Regarding Proposed High Pressure and/or High Temperature (HPHT) Well Design, Completion, and Intervention Operation*

[8] BSEE NTL 2019-G03, *Guidance for Information Submissions Regarding Site Specific and Non-Site Specific HPHT Equipment Design Verification Analysis and Design Validation Testing*

[9] ISO 13879, *Petroleum and natural gas industries — Content and drafting of a functional specification*

[10] ISO 13880, *Petroleum and natural gas industries — Content and drafting of a technical specification*

[11] ISO 17000, *Conformity assessment — Vocabulary and general principles*

[12] ISO 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

[13] ISO/IEC 17065,[5] *Conformity assessment — Requirements for bodies certifying products, processes and services*

[14] ISO/IEC 17067, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

[15] ISO 23605, *Technical product specification (TPS) — Application guidance — International model for national implementation*

[16] ISO/IEC 17029:2019, *Conformity assessment — General principles and requirements for validation and verification bodies*

[17] ISO/IEC 17020:2012, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[2] American Society of Mechanical Engineers, Two Park Avenue, New York, NY 10016, www.asme.org.

[3] BSI, 12950 Worldgate Drive, Suite 800 Herndon, VA 20170, www.bsigroup.com.

[4] Bureau of Safety and Environmental Enforcement, U.S. Department of the Interior, 1849 C Street, NW, Washington, DC 20240, www.bsee.gov.

[5] International Electrotechnical Commission, 3 rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland, www.iec.ch.

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