Product Design and Manufacturing Conformance Review

API [designation-type TBD] PTV-PC
FIRST EDITION, [month][year]
Introduction

This standard has been developed to be utilized when product specifications, recommended practices, or jurisdictional requirements call for independent verification, validation, and/or manufacturing assurance. A manufacturing organization can elect to follow this standard independently or an end-user may require 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 assure the product’s integrity and reliability.

The objective of API Product Verification and Product Conformance is to provide confidence to all interested parties that a product fulfills specified requirements. The value of certification is the degree of confidence and trust that 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 API Product Type Verification and Product Conformance Certification include, but are not limited to the following:

- the clients of the certification bodies;
- the customers of the organizations whose products are certified;
- governmental authorities;
- non-governmental organizations;
- consumers and other members of the public.

Implementation of the API Product Type Verification and Product Conformance process will:

- eliminate duplication of product conformance verification efforts;
- facilitate approval of product designs through a transparent process acceptable to multiple customers;
- facilitate and accelerate regulatory approval; and
- provide a consistent approach and defined scope for effective and efficient, independent verification API Product Type Verification and Product Conformance activities.

The API Product Verification and Product Conformance process is intended to provide assurance that the client’s design meets a set of specified requirements, which may include:

- API Product Specification or other industry standards;
- Functional specification or Technical specification;
- Material selection and qualification to meet functional or technical specification;

The supporting element to the product conformity assessment is the Product Conformance manufacturing assessment to provide assurance that the product can be produced consistently in compliance with the design conformity assessment documentation. This can be achieved by the assessments/auditing of the manufacturing facility implementation/execution of quality management process and periodic confirmation of the facility’s capability to manufacture the product consistently and conformance with the design requirements and the client’s quality plans and ITPs (Inspection and Test Plans).
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1 Scope

1.1 Coverage

The scope of this document is to define the necessary processes for API Product-Type Verification and Product Conformance. This document defines the process for an independent certification body (IPTCO) to evaluate an API Product Design and perform subsequent conformance assurance for the manufactured product to assure the design requirements are met. As part of this process, this document defines the requirements for the competence, consistent operation and impartiality of the independent party who performs these activities as a certification body evaluating and certifying API Products.

This document is intended to be utilized when product specifications, recommended practices, the client’s customer, or regulatory requirements call for independent product verification, validation, and/or manufacturing assurance. When a client obtains an independent API Product Type Verification and Product Conformance Certification of a product that is acceptable to all stakeholders, there is no need to repeat the process provided the activities follow the requirements of this document and were performed by an accredited IPTCO.

1.2 API Product Type Verification and Product Conformance Certifications

An API Product Type Verification Certification states that the design of a product type is in conformity with specified requirements. The certificate is valid for a specified period of time.

An API Product Conformance Certification states that a manufactured product is in conformity with specified design and fabrication requirements. The Product Conformance Certification is issued for a manufactured product and states conformity with the specified requirements at the time of issue of the certificate.

2 Normative References

The following referenced document is indispensable for the application of this document.

ISO/IEC 17000, Conformity assessment – Vocabulary and general principles

3 Terms, Definitions, and Abbreviations

3.1 Terms and Definition

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following shall apply. When identical terms are defined in ISO/IEC 17000 and this document, the following definitions shall apply.

3.1.1 client

the organization that is responsible to an independent certification body for ensuring that products, processes or services meet and, if applicable, continue to meet, the certification requirements.

Note The term “client” (3.1.1) as used in this document refers to the organization who is the “customer” of the IPTCO to obtain product certification including API Product Type Verification and / or Product Conformance.

3.1.2 scope of certification
description of:
— The product(s),
— The applicable certification scheme (i.e., Product Type Verification and / or Product Conformance)
— The standard(s) and other normative document(s) (including date of publication / edition) to which the product(s) has been judged to comply.

for which the certification is granted.
3.1.3 conformity assessment
demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

3.1.4 third-party conformity assessment activity
conformity assessment activity that is performed by a person or body that is independent of the person or organization that provides the object, and of user interests in that object.

Note “object” is used to encompass any particular material, product, installation, process, system, person, or body to which conformity assessment is applied.

3.1.5 conformity assessment system
rules, procedures and management for carrying out conformity assessment.

3.1.6 customer
person or organization that could or does receive a product or a service that is intended for or required by this person or organization.

Note The term “customer” as used in this document refers to the organization that receives a product that has been certified for a client by an IPTCO.

3.1.7 design acceptance criteria (DAC)
Defined limits placed on characteristics of materials, products, or services established by the organization, customer, and / or applicable specifications to achieve conformity to the product design.

3.1.8 design validation
Process of proving a design by testing to demonstrate conformity of the product to design requirements.

Note: Design validation can include one or more of the following (this is not an all-inclusive list):

a) Prototype tests,
b) Functional and / or operational tests of production products,
c) Tests specified by industry standards and / or regulatory requirements
d) Field performance tests and reviews.

3.1.9 design verification
Process of examining the result of design and development output to determine conformity with specified requirements.

Note Design verification activities can include one or more of the following (this is not an all-inclusive list):

a) Confirming the accuracy of design results through the performance of alternative calculations,
b) Review of design output documents independent of activities of design and development,
c) Comparing new designs to similar proven designs.

3.1.10 evaluation
combination of selection and determination functions of conformity assessment activity.

3.1.11 product
output of an organization that can be produced without any transaction taking place between the organization and the customer.
3.1.12 **procedure**
specified way to carry out an activity or a process.

3.1.13 **process**
set of interrelated or interacting activities that use inputs to deliver an intended result.

Note Whether the “intended result” of a process is called *output, product or service* depends on the context of the reference.

3.1.14 **product requirement**
requirement that relates directly to a product as specified in product standards and / or normative documents and, developed as part of the product design by the client.

3.1.15 **scope of certification**
description of:
- The product(s), process(es) or service(s);
- The applicable certification scheme, and
- The standard and other normative document(s) (including date of publication) to which the product(s), process(es) or service(s) has been judged to comply.

for which certification is granted.

3.1.16 **product requirement**
requirement that relates directly to a product as specified in product standards and / or normative documents and, developed as part of the product design by the client.

3.1.17 **service**
output of an organization that with at least on activity necessarily performed between the organization and the customer.

3.1.18 **specified requirements**
need or expectation that is stated.

Note Specified requirements may be stated in normative documents such as regulations, product standards and technical specifications.

3.1.19 **COMPETENCE** – Ability to apply knowledge and skills to achieve intended results (ISO 9000-2015)

3.2 **Abbreviated Terms**
- IPTCO Independent Product Type Conformance Organization
- ITP Inspection and Test Plan
- NDE Non-Destructive Examination
- PTC Product-Type Certification
- QMS Quality Management System
4 Application

4.1 General

4.1.1 Initial Application

The IPCO shall require the client to complete and submit an application (Harish: Need to develop standard form for consistency and legal) (See section ???) to begin the PDCC process to provide the information necessary to perform the service.

The following information is considered necessary for the application:

- The client’s name and physical address;
- The product(s) to be certified;
- significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations
- Client’s current QMS status and internationally QMS standard used for QMS.
- the client’s office/plant information for which application being submitted,
- information concerning all outsourced/sub-contracted processes used by the applicant that will affect conformity to requirements;
- the API standards and/or other normative documents for which the client is seeking certification;
- Details of any special or additional requirements (if any/as applicable)
- all other information needed to perform design review. Details per Section 5.3.2, in accordance with the relevant certification requirements,

4.1.2 Application Review

The IPCO shall review the application information to ensure that:

- The applicant information and the product information is sufficient to conduct the certification process;
- Differences in understanding between the certification body and the client are resolved and there is an agreement on the standards and other normative documents that will be applied;
- The scope of the certification being applied for by the applicant is clear.
- The resources are available to perform all evaluation and certification activities;
- The IPCO has the competence and capability to perform the certification activities.

The IPCO shall have a process to identify when the client’s request for certification includes a type of product or normative document with which the IPCO has no experience. The IPCO shall decline to accept the application if it lacks any competence or capability for the product being submitted for certification.

4.1.3 Final Evaluation Overview Reviews

The IPCO shall assign appropriate personal to review all the documentation, data, and results pertaining to the evaluation (e.g., Product Design Evaluation, Facility Manufacturing Capability and Conformance Evaluations). Only personnel who were not involved in the initial evaluation activities shall be assigned to perform evaluation overview reviews. Recommendations for PDCC decisions shall be based on the Evaluation Overview Review.
4.1.4 Certification Determination and Decision

The IPCO shall assign at least one individual to make the final certification recommendation which shall be based on all information related to the evaluation(s) and the final evaluation overview review. The certification decision shall be made by a person or group (e.g., a committee) which has not been involved in the review process.

If the decision is made not to grant certification to the client, the IPCO shall notify the client of that decision and identify the reasons for the decision.

4.1.5 Certification Documentation

The IPCO shall issue the client formal PDCC documentation that lists

a) The name and address of the IPCO;

b) The date the certification is granted;

c) The name and address of the client;

d) The type and scope of the certification;

e) The term or expiration date of certification if certification expires after an established period of time;

f) Reviewed technical specification

g) Applicable technical specification

h) Any other information as required by the IPCO.

4.1.6 Register of Certified Products

The IPCO shall maintain a listing of certified products in a register that contains as a minimum:

a) Identification of the product;

b) The standards, specifications, and any other normative documents certified to;

c) The name and address of the client;

d) The scope of the certification and the validity period and / or stipulations.

4.2 Evaluation and Assessment Requirements

The IPTCO shall maintain a documented procedure for evaluation and assessment activities to ensure all necessary arrangements are suitably managed. The IPTCO shall assign personnel to perform each evaluation task required to provide API Product Type-Verification and Product Conformance Certificate for which the client has applied. The IPTCO shall ensure all necessary information and / or documentation is made available for performing the evaluation tasks (including design and development review and / or facility manufacturing capability and conformance evaluations).

A report of the evaluation(s) shall be provided to the client identifying all nonconformities and details as requested by the client. If one or more nonconformities have been identified and if the client expresses interest in continuing the certification process, the IPTCO shall provide information regarding additional evaluation tasks needed to verify that the nonconformities have been corrected.
Figure 1 – API Product Evaluation and Assessment Approval Workflow
5 Independent Product Type Conformance Organization

5.1 General

5.2 Contractual and Legal

5.2.1 Independent Product Type Conformance (IPTC) Organization

The independent Product Type Conformance Organization shall be a legally established entity such that the IPTCO is responsible for its conformance assessment activities.

Organization Qualifications:

1. Established legal entity
2. Management System
3. Have a formal competence system
4. Organizational structure with enough qualified resources to comply with the requirements and perform the duty
5. Shall have adequate arrangement to safeguard the confidentiality of information obtained during services
6. Shall no commercial interest or shall be independent of any part of an organization having direct commercial interest in the products to be Type Conformed
7. The staff shall be free of any commercial, financial or/and other pressure that may influence their judgement or the result of their work
8. IPTCO requirements shall be performed impartially and shall not be compromised by commercial or financial pressures. Risks to impartiality shall be identified on a regular basis. Risks shall include those that arise from the IPTCO’s activities, its relationships (including the relationships of its personnel with the client). Excluding the compensation for services.
9. IPTCO should not have or appear to have an organizational conflict of interest with client.
   a. (copy from ASME Chapter 5-1.1.10)

5.2.2 IPTCO Agreement

The IPTCO shall maintain a legal agreement for the provision of its certification services to its clients. The IPTCO shall ensure that the IPTCO Agreement requires the client comply with the following requirements:

a) Continually fulfil the certification requirements including implementing required changes when they are issued by the IPTCO;

b) Ensure the certified product continues to conform to the certified requirements

c) Make necessary arrangements for
--- the IPTCO’s evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s) and personnel, and

--- for the investigation of complaints;

d) Makes advertising claims regarding Product Type-Verification and Conformance Certification by the IPTCO consistent with the scope of certification;

e) Does not use its Product Type-Verification and Conformance Certification in a manner so as to bring the IPTCO into disrepute and does not make any misleading or unauthorized statements regarding its Product Type-Verification and Conformance Certification;

f) Upon suspension or withdrawal of Product Type-Verification and Conformance Certification, discontinues its use of all advertising that contains any reference to the Product Type-Verification and Conformance;

g) If the client provides copies of the Product Type-Verification and Conformance Certification documents to others, the documents shall be reproduced in their entirety or as specified by the IPTCO.

h) Maintain a record of all complaints made known to the client relating to compliance with certification requirements and make these records available to the IPTCO when requested; and

--- Take and record appropriate action(s) in response to complaints and any nonconformities found in products that affect compliance with the requirements of the Product Type-Verification and Conformance Certification

i) Notify the IPTCO of changes that may affect its ability to conform to the Product Type-Verification and Conformance Certification

5.2.3 Use of Product Type Verification and Conformance Certificates

The IPTCO shall ensure control over the ownership, use and display of Product Type-Verification and Conformance Certifications. Misleading or incorrect use of Product Type-Verification and Conformance Certifications shall be corrected.

5.3 Organizational Structural Requirements

The IPTCO activities shall be structured and managed to ensure impartiality. The IPTCO shall document its organizational structure and define the responsibilities and authorities of all personnel performing product type-verification and conformance activities. The IPTCO shall identify individuals or group of individuals having responsibility and authority for:

a) Development of operational policies and procedures: applicable

b) Management of the implementation of the policies and procedures; - applicable

c) Development of certification requirements; - not applicable

d) Performance of evaluation activities (including design evaluation and manufacturing evaluation); - applicable

e) Decisions on issuance of deliverable (Product Type Conformance?); - need to define what the deliverable is.

f) Providing response(s) to complaints and appeals; - applicable

g) Personnel evaluation and competence - applicable

h) Management system. - applicable
5.4 Personnel Requirements

5.4.1 General
The IPTCO shall employ or have access to an adequate number of competent personnel to conduct all the operations of the Product Type-Verification and Conformance program. The personnel shall be competent for the functions they perform, including product design reviews and/or manufacturing assessments.

5.4.2 Competence of Personnel

5.4.2.1 General
The IPTCO shall maintain a documented procedure for the management of personnel competency for all personnel involved in the IPTCO evaluation and PTC process. The procedure shall define:

a) The criteria required to ensure the competence of personnel for each function in the process. - applicable
b) The process and requirements necessary to recruit, select, and establish the competency of personnel. - applicable
c) The training required and provide, as necessary, the required training on conformance processes, requirements, methodologies, activities and other relevant requirements. - applicable
d) Document that the personnel have the required competencies for the duties and responsibilities they undertake - applicable
e) formally authorize and appraise the performance of certification body personnel; - applicable
f) maintain records each point listed above. - applicable

Note: The expectation is that personnel are experienced "qualified experts" for the specific product (i.e., equipment assembly or component) and/or QA/QC process(es) that the IPTCO reviews and provides Product Type-Verification and Conformance Certification for.

5.4.2.2 Personnel Qualification Requirements – Design Review

IPTCO personnel (Inspector, Reviewer, and Supervisor) performing design reviews shall meet the following requirements:

Inspector and Reviewer:

a) Bachelor’s degree or higher in Engineering, technology, science or mathematics from a recognized institute
b) Working knowledge of: applicable API standards and specifications, applicable interpretations and reference codes and standards
c) Min 5 years of relevant experience on the product(s) i.e., equipment assembly(ies) and component(s)
d) Documented training and continued relevant education
e) Identified and qualified by the organization reviewer is associated with to perform the review

Supervisor:

a) Bachelor’s degree or higher in Engineering, technology, science or mathematics from a recognized institute
b) Working knowledge of: applicable API standards and specifications, applicable interpretations and reference codes and standards
c) Min 10 years of relevant experience on the product(s) i.e., equipment assembly(ies) and component(s)
d) Documented training and continued relevant education

e) Identified and qualified by the organization supervisor is associated with

5.4.2.3 Personnel Qualification Requirements – Fabrication and Manufacturing Assessment

IPTCO personnel (Inspector, Reviewer, and Supervisor) performing fabrication and manufacturing assessments shall meet the following requirements:

Inspector and Reviewer:

a) Inspector shall have knowledge of quality assurance requirements and shop and field procedures and performances

b) Ability to monitor and evaluate shop and field procedures and performance

5.4.3 Personnel Qualification Records

Records of the relevant qualifications, training and experience of each member of the personnel involved in the evaluation and product type process shall be maintained by the IPTCO. Records shall be maintained by the IPTCO for a minimum of five (5) years after the date each individual ceases to work for the IPTCO.

Records shall be kept up to date with the following:

a) name and address;

b) organization affiliation and position held;

c) list of the product(s) i.e., equipment assembly(ies) and component(s) and / or QA/QC process(es), e.g., QMS Auditor / Lead Auditor, NDE disciplines, and Inspection Techniques the individual is competent to evaluate;

d) educational qualification and professional status;

e) experience and training;

f) the assessment of competence;

g) professional qualifications and certifications held;

h) date of most recent updating of records;

i) performance appraisal;

j) authorizations held within the IPTCO.

Records shall be signed and dated by the authorized IPTCO individual reviewing and accepting the individual’s record file(s) to attest the employee or contractor is deemed as competent for the specific product(s) and / or QA/QC process(es) the individual is qualified to perform.

5.4.4 Contract with the personnel

The IPTCO shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to:

a) comply with the rules defined by the certification body, including those relating to confidentiality (7.5.4) and independence from commercial and other interest;

b) declare any prior and/or present association on their own part, or on the part of their employer, with:

1) a supplier or designer of products, or

2) a provider or developer of services, or

3) an operator or developer of processes to the evaluation or certification of which they are to be assigned; and
c) reveal any situation known to them that may present them or the certification body with a conflict of interests.

IPTCOs shall use this information as input to identifying risks to impartiality raised by the activities of such personnel or by the organizations that employ them.

**MANAGEMENT OF CHANGE – to add**

5.5 Management system requirements for IPTCO *(Move from Section 9)*

5.5.1 General

The IPTCO shall establish and maintain a management system that ensures the consistent fulfillment of the requirements. The IPTCO's management system shall conform an internationally recognized quality management system standard (e.g., ISO 9001, etc.) and address the following elements as a minimum:

- required management system documentation (e.g. manual, policies, definition of responsibilities, procedures);
- control of documents);
- control of records;
- management review;
- internal audit;
- corrective actions;
- preventive actions.

**To be continued…………**

5.5.2 Duties of IPTCO, Supervisor, Inspector & Reviewer

5.5.2.1 Duties for IPTCO (Agency)

5.5.2.1.1 Qualifications

An Authorized Agency shall be one of the following:

a) a company that has adopted and utilizes API Standards in the daily execution of the entity’s processes for the manufacturing, inspection, and operation of equipment governed by application of API Standards. The entity shall also actively participate in the continued development of API Standards and processes.

b) a company in the business of providing “third party” inspection services.

The company shall have:

a) recognition from a government entity to perform inspection and design examinations for equipment governed under API Standards with specific focus on safety and functionality.
   - The company shall be a registered entity within the same city, state, province, or country as the government entity that is providing the recognition.

b) accreditation or certification under a recognized accreditation or certification scheme that is found acceptable by API
   - The scope of activity on the certificate shall identify the performance of inspections and design examinations for related products governed by API or similar national or international recognized standards.
   - The certificate shall be valid and in good standing.
   - The company shall have undergone at least one accreditation or certification renewal cycle.
c) appropriate levels of financial support or liability insurance

5.5.2.1.2 Agency Duties

The Agency shall perform the duties specified in a) through h) below:

a) Provide Inspectors, Reviewers, and Supervisors to participate in related surveys of API Certified facilities performing manufacturing and design functions for which they provide Inspection services.

b) Maintain qualified Inspectors, Reviewers and Supervisors to monitor the performance and to audit the activities at shops and field sites for which inspection agreements have been made, in accordance with the requirements of X.X.X.X.

c) Assure proper execution of responsibilities. In particular, the Agency shall

1) establish and implement an internal program which shall provide assurance that its employees holding the positions of Inspector, Reviewer, and Supervisor perform work in accordance with the requirements of API XXXX. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout the life term of any agreement covering inspections required by API XXXX, in accordance with the program. The program shall provide for indoctrination and training of personnel performing such activities, as necessary, to ensure that suitable proficiency and competencies are achieved and maintained.

2) provide instructions in writing to Inspectors, Reviewers and their Supervisors, specifying their respective duties and responsibilities.

3) provide instructions in writing to Inspectors and Reviewers requiring them to immediately contact their Supervisor whenever the Inspector or Reviewer is unable to readily resolve any question concerning API specification compliance, manufacturing procedure, or quality assurance provision or its implementation. Instructions should be included as a reminder to the that he has both the authority and the duty to refuse to sign any Data Reports involving nonconformance with the API Standards.

4) conduct annual planned audits of activities Supervisors to verify compliance with the provisions of the API Standard. The audit shall be performed by appropriately trained personnel, in accordance with a written procedure or checklist. Audit results shall be documented and reviewed by management. Follow-up action, including re-audit of deficient areas, shall be taken where indicated to ensure that necessary corrective action is completed.

5) establish and implement a written policy to ensure levels of Inspector and Reviewer activity commensurate with the scope of the API Audit requirements.

d) Provide certification for each Inspector, Reviewer, and Supervisor to be performing work under the provisions of the API Code to ensure that the Inspectors, Reviewers, and Supervisors meet the required experience and training requirements specified in X.X.X.X. Certification and documentation of qualifications shall be retained by the employer and shall be made available for review by the jurisdictional authorities and the API Audit Team, upon request.

e) Maintain a record of Certificate Holders' shop and field sites where Inspectors and Reviewers assigned to him by his Agency for supervision are performing API Type Approval inspection activities. Agency shall track & record the dates of visits to such locations and outcomes of the Audit.

f) Verify to API that the audits required by g) have been carried out.

g) When requested by API, perform follow-up activities on Certificate Holders for which they provide Audit services.

h) When an Agency enters into a contract with a manufacturing or designer facility, the duties of the agency shall include the requirements of 1) through 6) below.

1) Notify the API Audit department and the applicable enforcement authority when entering into an agreement with an API approved manufacturing or designer facility.

2) Notify the API approved manufacturing and/or design facility and the applicable enforcement authority whenever an agreement with an Owner is terminated.

3) Provide qualified Inspectors, Reviewers and Supervisors to participate in the interview of the API approved manufacturing and/or design facility for which they provide audit services.
4) Provide qualified Inspectors, Reviewers and Supervisors to review and accept any proposed modification to the Owner’s Quality Assurance Manual or procedure.

5) Ensure periodical audits of the API approved manufacturing or designer facility Quality Assurance Program and the results are reported to API manufacturing and/or design facility for review and determination as to whether the Type Approval Certificate shall be renewed.

6) Ensure at least once each year, the Agency performs an audit of the API approved manufacturing and/or design facility activities to verify that the procedures are being followed and that records exist to support continue certification.

5.5.2.2 Duties of Supervisor

5.5.2.2.1 Duties

The Supervisor shall perform the duties specified in a) through g) below:

a) Maintain a record of those Inspectors and Reviewers assigned and a description of their assignments.

b) Verify the accuracy and completion of audits carried out by Inspectors and Reviewers assigned by Agency under his management. Supervisor shall ensure data that tracks & records the dates of visits to such locations and outcomes of the Audit are disseminated to the Agency and other related stakeholders.

c) Assist in maintaining the competency of the Inspectors and Reviewers to an acceptable level through periodic arrangement of panel discussions of work-related topics, written communications of unique problems and their solution, informal question and answer discussion sessions, and other means he deems suitable. The Supervisor shall ensure that documentation of such activities are accurately recorded in the Agency’s documentation system.

d) The Supervisor shall be responsible for the technical performance of the Inspector and Reviewer(s) assigned to him. He shall report in writing to his management significant nonconforming activities that are reported to him or that he observed on the part of the Inspector and Reviewer, following full investigation of such activities.

e) Audit the performance of each Inspector and Reviewer as specified below.
   1) The audit shall be performed at least once each year at approximately 12-month intervals and at additional
   2) times as requested by the Inspector and Reviewer.
   3) The audit shall take place at a shop or field site on location.
   4) The Supervisor shall be accompanied by the Inspector and Reviewer during the audit.
   5) An audit is not required if the has not been engaged in API inspection activity within the last 12 months.

f) The audit required by 4.6.2.2.1 e) shall be recorded in writing, containing the status of each item audited and a brief description of the objective evidence reviewed to evaluate the duty being audited.

g) Confirm the corrective action has been verified by the Inspector and Reviewer to ensure compliance with the applicable API Standard requirements at the shops and sites which have been assigned by the Supervisor.

5.5.2.3 Duties for Inspector and Reviewer

5.5.2.3.1 Qualifications

The Inspector and Reviewer shall be selected and designated as such by his employer. The Inspector and Reviewer shall have the qualifications specified in a) through h).

a) The Inspector and Reviewer shall have completed and passed training and certification to conduct audits of API approved manufacturing and/or design facility in accordance with API XXXX.

b) The Inspector and Reviewer shall have a working knowledge of applicable API Standards Sections, and other applicable reference codes and standards.

c) The Inspector and Reviewer shall have knowledge of quality assurance requirements and shop and field procedures and processes.
d) The Inspector and Reviewer shall have the knowledge and ability to evaluate and monitor shop and field procedures and performance.

e) The Inspector and Reviewer shall have demonstrated the ability to perform shop and field inspections to the satisfaction of the Agency employing the individual.

f) The Inspector and Reviewer shall have a satisfactory degree of experience, knowledge, and background to conduct the inspection of equipment, consistent with the complexity of the assignment.

g) The Inspector and Reviewer shall have knowledge of the requirements for quality assurance records.

5.5.2.3.2 Performance of Inspector and Reviewer Duties

The audit must be performed in conformance with API XXXX Section XXX and documented in accordance Section XXX and shall provide evidence of the satisfactory performance of the duties as specified in the applicable Sections of the API standard.

6 Product Design Conformance Assessment Evaluation

6.1 General

The IPCO shall maintain a documented procedure for design verification and validation review to be conducted in accordance with applicable API specification, standards, or recommended practices as applicable.

Scope of IPCO under this standard is to verify the product is in conformance with the identified API Publication. When API publication does not have any established requirements Alternative Analysis methods should be followed to perform design review.

The IPCO shall assign personnel to perform each design review task required to provide API Product Design Conformance Certificate (PDCC) for which the client has applied. The IPCO shall ensure all necessary information and / or documentation is made available for performing the review (including design and development review and / or facility manufacturing capability and conformance reviews).

A report/document of the review(s) shall be provided to the client identifying all nonconformities and details as requested by the client. If one or more nonconformities have been identified and if the client expresses interest in continuing the certification process, the IPCO shall provide information regarding additional evaluation tasks needed to verify that the nonconformities have been corrected.

Once all nonconformity has been resolved a final certificate shall be issued by IPCO to applicant as required in section 4.3.5...???

6.2 Engineering Methods

The design verification review may be in accordance with other engineering methods from the API publication that can include the client’s design analysis methodology and include whether the methodology is based on an “alternate analysis method” (i.e., equipment designed using alternate analysis other than required by current existing API Publication).

Alternate analysis methods may include:

- ASME Boiler and Pressure Vessel Code (BPVC) Section VIII, Division 2 or Division 3,
- Article KD-4 of ASME Section VIII Div 3,
- API RP 579,
- British Standard (BS) 7910,
- DNV-GL C203, and
- API 17TR8.
• Methodology as specified in BSEE NTL 2019-G03 may be applied as an alternate compliance process.

• Operator Requirements

When IPTCO has perform design review to alternate compliance to existing API Publication requirement certification should clearly list.

Design based on manufacturer’s standards may also be accepted. In such cases, complete details of the manufacturer’s standard and engineering justification are to be submitted for review.

a) The manufacturer will be required to demonstrate 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.

b) Where strain gauge testing, fracture analysis, proof testing or similar procedures form a part of the manufacturer’s design criteria, the procedure and results are to be submitted for review.

c) Historical performance data for systems, equipment or component is to be submitted for justification of designs based on manufacturer’s standards.

d) IPTCO will consider the application of risk-based evaluation for alternative feature for the design, as applicable.

6.3 Product Design Conformance Certification (PDCC) Assessment

6.3.1 General

The client’s product design and development activities shall be conducted in accordance with API Spec Q1 or an internationally recognized Quality Management System Standard and per applicable API Publication and shall include QMS controls for all design development activity for:

a) Design and development planning
b) Design and development inputs
c) Design and development outputs
d) Design and development review
e) Design and development verification and final review
f) Design and development validation and approval, and
g) Design and development changes

The required information and documentation required for review by IPCO shall include design documentation as specified in the applicable API Publication.

6.3.2 Documentation by Client:

The required information and documentation required for review shall include design documentation as specified in the applicable API Publication. Typical documents may include the following:

1. Plant QMS information/certificate
2. Basis of design,
3. Functional description and specification for the product
4. Operating characteristics specification
5. The design drawings for the product or system
6. Assembly/sub-assembly drawings with component list and reference to material specifications
7. Design calculations and governing requirements
   a. Design inputs,
b. Design outputs,

c. Accept/reject criteria

8. FMEA/FMECA for the loads and environment identified in the basis of design; (as applicable)

9. Client Design review records, and

10. Material selection, qualification and testing.

11. Material specifications

12. Validation testing program procedures, details with accept/reject criteria

13. Material test reports for materials used in prototype validation testing

14. Validation testing results

15. Design and development verification and final review records.

16. Inspection and test plan for product (API Quality Control Section or Mfg requirements)

17. Design and Development Planning (including the client's documented procedure to plan and control the design and development of the product),

6.3.3 Design Verification Review

The IPCO assigned to perform the Design Verification Review shall ensure all necessary documentation, drawings, and data are available and provided for review in the manner agreed with the client to ensure confidentiality is maintained of all proprietary information.

In this step the review of a design of the product to determine compliance with the agreed API Publication, technical requirements and the prototype test proposal (as applicable) will be completed. The review of the test proposals is to confirm that testing will adequately demonstrate compliance of the product(s) with the API Publication. The Design Verification Review shall include a review of the client's design verification/validation documentation to verify compliance to applicable API Publication and client specification.

The comments or recommendations resulting from the Review will be advised together with the preliminary conditions and/or limitations that will be applicable to the PDCC.

When the API Publication is silent or requirements are not clear API Request for Interpretation shall be initiated for guidance.

For new product designs or established products used in new applications, where a FMECA or HAZOP has been conducted, the Design Validation Review shall ensure that all potential modes of failure have been identified and the design validation performed to adequately evaluate the equipment for the identified potential modes of failure.

6.3.4 Design Validation Review

The IPCO assigned to perform the Design Validation Review shall ensure all necessary validation test reports and records are available and provided for review in the manner agreed with the client to ensure confidentiality is maintained of all proprietary information. The design validation review shall include review of the design validation and functional testing process and procedures used to validate the performance of the design per applicable API Publication. The review shall include the validation requirements as specified by the API Publication. These may typically include: pressure test(s), load test(s), functional test(s), nondestructive examinations, destructive examinations, life cycle test(s) etc. as applicable per API Publication or other effort and design/functional specification.

The Design Validation Review shall ensure that all potential modes of failure have been identified and the design validation tests performed adequately evaluate the equipment for the identified potential modes of failure.
6.3.5 Issuance of PDCC

To standardize certificate among various IPCO a standardized format shall be used. PDCC certificate shall have sufficient information that can be useful to customer. PDCC certificate shall include as minimum following information:

- Name and address of the client
- Description of product
- Product designation
- Product Type
- Intended Application
- Specified API Publication(s) against which the product conforms to
- Product Ratings – load, pressure, temperature, fluid exposure and combination rating etc.
- Additional environmental tests performed (if applicable)
- Limitations or other conditions applicable for the product
- Design validation/verification detail(s) including accept reject criteria.
- Production site and design site information. (I am clear that the production site is important but not sure why this needs to be on the certificate. Same with the design site location. Should we remove?
- Certificate Number
- Date of Issue
- Date of Expiry – (five year from issue) Confirm with API Legal

All PDCC certificates shall must include the following comments in the section for Limitations or other conditions:

- PDCC does not eliminate the need for normal inspection required by the API Publication

If additional requirement which is above and beyond API Publication requirements being verified those should be clearly listed on certificate in separate section.

7 Product Manufacturing Conformance Assessment

7.1 General

The manufacturing organization receiving the PTC shall implement and maintain a quality management system in conformance with API Q1. The quality management system shall be audited at least annually by a QMS certification body and records of these audits and conformance shall be maintained.

The QMS certification body shall be an organization independent of the manufacturer that has accreditation to ISO 17021.

7.2 Facility Process capability verification

a) Site specific
b) How process verification relates to design
c) Verification methods/requirements
d) Frequency
e) Changes in facility capability
f) Changes in outsourcing activities
7.3 Review monitoring and witness requirements of actual product

7.3.1 Definitions

These definitions are only for the scope of the Product Type certification. These terms are commonly used in the industry and use of these in contractual agreements between manufacturer and customer agreements are outside the scope of this document.

a. Review

b. Monitor

Activities that are periodically checked to confirm conformance. No formal notification of individual activities shall be required. This will be an informal communication between the independent party and the manufacturer to understand how these activities occur.

c. Witness

Requires written notification and must have written documentation from the independent party prior to execution of activity to waive witness point. Where a witness point is waived the results of the activity shall be documented and the independent party shall review the resulting report and documentation of review of the report shall be documented.

d. Hold

Requires written notification and cannot be waived. This is a process stop point to validate results prior to proceeding.

7.3.2 Level of involvement

a. Review of approved Design
   1) Confirm current design is approved per design section.
   2) Review relevant drawings and documents
      - Design shall include all required documents and drawings required to manufacture product including revision.
   3) Quality Plan requirements (when are they required based on the design/component/process criticality). These must be included as part of the design approval.
   4) Design of the current product being manufactured shall be traceable to the currently approved design, including any revisions.

b. Review of facility capability

c. Review of manufacturing records for non-verified activities

d. Develop a monitoring/verification plan in accordance with the established and approved criticality.
   1) Criticality of components and processes must be defined in accordance with risk assessment.
      The defined criticality must conform with any requirements governing the design standards and specification the design. Where no criticality requirements exist in the governing standards the criticality shall be defined by the manufacturer.
   2) Plan must be documented by the manufacturer and revisions to the plan must be maintained and controlled.
   3) Plan shall identify the level of involvement of the independent party involvement for identified critical actives/products (regardless of if the activity or product is performed in house or outsourced)
   4) Verification plan shall address outsourcing of critical processes and components.
5) This shall be integrated in the manufacturer's manufacturing documentation such as Inspection and Test Plans and Quality Plans.
6) Where verified activities fail testing these failures shall be documented and signed off by independent party
7) Matrix?

7.4 Issuing of Review Certification
a. Document the revision of the design that was manufactured
b. Identify the activities verified through document review, monitored or witnessing and activities not verified
c. Identify any approved deviations from the approved design, test plan and/or Quality Plans

8 Changes to Certification

8.1 General
The IPTCO shall maintain a documented procedure to address changes to certification. When the IPTCO’s certification scheme introduces new or revised requirements that affect the client, the IPTCO shall ensure these changes are communicated to all clients. The IPTCO shall verify the implementation of the changes by its clients and shall take actions required to ensure the revised certification process maintains its integrity and stakeholder confidence. The IPTCO shall consider other changes affecting certification, including changes initiated by the client, and shall take the appropriate action(s).

Note Changes affecting certification may include new information related to the fulfillment of certification requirements obtained by the IPTCO after certification has been established.

8.1.1 Actions To Implement Changes
The actions to implement changes affecting certification shall include as applicable:

— Design Verification Review
— Design Validation Review
— Product Manufacturing Conformance Assessment
— Final Evaluation Overview Review
— Certification Determination and Decision
— Revision of certification document(s) to appropriately extend or reduce the scope of certification and/or modify the Product Manufacturing Conformance certification if required.

8.2 Termination, Reduction, Suspension or Withdrawal of Certification

8.2.1 General
The IPTCO shall maintain a documented procedure for handling nonconforming certified product(s) noted as part of surveillance or customer complaints and ensure that the continuation of certification is justified. Depending on the root cause analysis and/or corrective action report analysis, the IPTCO may determine that appropriate actions are required which may include:

— Continuation of certification under conditions specified by the certification body (e.g. increased surveillance);
— Reduction in the scope of certification to remove nonconforming product risks;
— Suspension of the client’s certification pending remedial action by the client;
— Withdrawal of the certification.
8.2.2 Certification Status Information

If certification is terminated, suspended or withdrawn, the IPTCO shall ensure all required certification documents and the client’s registry listing are revised appropriately to ensure they provide no indication that the product continues to be certified.

If a scope of certification is reduced, the IPTCO shall ensure all required certification documents and the client’s registry listing are revised appropriately to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

If certification is suspended, the certification body shall ensure the actions needed to end suspension and restore certification for the product(s) in accordance with the IPTCO’s requirements and any other actions required are communicated to the client. Evaluations required to release the suspension or required by the IPTCO shall be completed in accordance with the IPTCO’s program and procedures.

If product certification is reinstated after suspension, the IPTCO shall ensure all required certification documents and the client’s registry listing are revised appropriately to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall ensure all required certification documents and the client’s registry listing are revised appropriately to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

8.2.3 Records

The IPTCO shall retain records to provide objective evidence that all certification process requirements have been satisfactorily completed. Records shall be maintained as confidential and handled in a manner that ensures confidentiality is maintained. If the IPTCO requires that product undergoes a complete re-evaluation within a determined cycle, records shall be maintained for each product evaluation that is conducted. Records shall be retained electronically for a minimum of ten (10) years after the client stops production of the subject product.

8.3 Complaints and Appeals

8.3.1 General

The IPTCO shall maintain a documented procedure to receive, evaluate and effectively handle complaints and appeals. The IPTCO shall document and track complaints and appeals, as well as the associated actions to effectively resolve them. Upon receipt of a complaint or appeal, the IPTCO shall confirm whether the complain or appeal relates to certification activities provided by the IPTCO and if so shall acknowledge the receipt and outline the actions that are planned to address the complaint or appeal.

8.3.2 Collecting Information

The IPTCO shall obtain and verify all required information (as far as practical) to process the complaint or appeal and to ultimately provide a decision.

8.3.3 Decision

The decision resolving the complaint or appeal shall be reviewed by, made and approved by person(s) not involved in the certification activities related to the complaint or appeal. To ensure there is no conflict of interest, IPTCO personnel (including those performing in a supervisory role) who have provided consultancy for a client or been employed by a client, shall not be involved in the review or approval of the resolution of the complaint or appeal for that client for a minimum period of two years following the end of the consultancy or employment.

The IPTCO shall provide formal notification of the outcome and the end of the complaint and / or appeal process to the complainant / appellant.
8.3.4 Records

The IPTCO shall retain records to provide objective evidence that all complaint and appeal requirements have been satisfactorily completed. Records shall be maintained as confidential and handled in a manner that ensures confidentiality is maintained.

9 Deliverables
Bibliography

[1] API Specification Q1, *Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry*


[5] ASME Boiler and Pressure Vessel Code (BPVC) Section VIII, Division 2 or Division 3,

[6] Article KD-4 of ASME Section VIII Div 3,

[7] API RP 579,

[8] British Standard (BS) 7910,

[9] DNV-GL C203, and

[10] API 17TR8