

# Product Design and Manufacturing Conformance Certification

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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](mailto: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 17](#)), 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 that 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,<sup>1</sup> *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.

<sup>1</sup> International Organization for Standardization, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, [www.iso.org](http://www.iso.org).