# TECHNICAL REPORT

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# Conformity assessment — Guidelines and examples of a scheme for the certification of processes

*Évaluation de la conformité — Lignes directrices et exemples d'un schéma de certification pour les processus*

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# Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso .org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

A process is considered to be a transformation of input into output, as shown in Figure 1. It is a set of interrelated or interacting activities that use inputs to deliver an intended result. The output of a process can be a product, a service, a combination of a product and a service, or another output. In some cases, process certification is used when certification of the output is not feasible or prohibitively expensive. Certification of the process is the only indicator of quality of the output since the output itself is not certified. Schemes for the certification of processes can be developed for different purposes and can ensure the quality of the products or services that the processes produce. Other purposes can include schemes for processes established by regulators to achieve health, safety or environmental outcomes. Certification of processes that are used to develop products and services can facilitate trade, market access, fair competition and customer acceptance at national, regional and international levels.



```
                                                          OUTPUT
                                                            • Product
  ┌──────────┐        ┌──────────┐        ┌─────────────   • Intermediate
  │  INPUT   │  ═══▷   │ PROCESS  │  ═══▷       product
  └──────────┘        └──────────┘              • Service
                                                • other
```
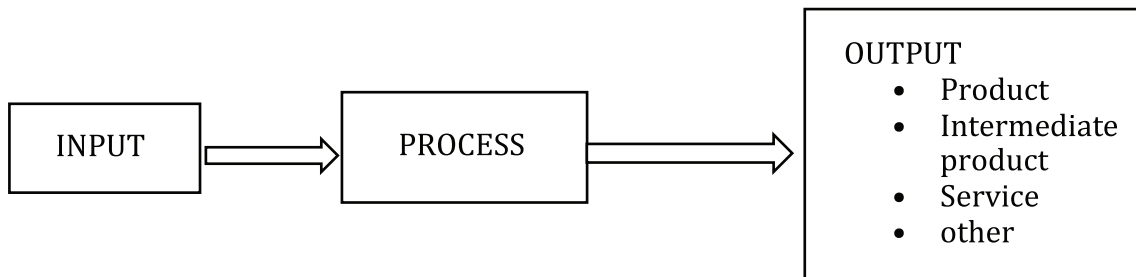
**Figure 1 — Schematic representation of the outputs of a process**

Processes can be for a specific product or service (e.g. welding, non-destructive testing, heat treatment (annealing), surface treatment) or can include complex systems engineering designs for safety and environmental protection, production of goods and large computer software programs. Other examples of processes are food production, agriculture, supply chain, logistics, construction planning and design, and data security and protection. Annex A provides some examples of processes.

Recently, there has been significant growth in new types of sector specific process certification activities, e.g. for information technology, sustainability, social welfare, blockchain technology, nanotechnology, security systems, food safety, chain of custody, smart cities and smart homes. Certification of these processes in emerging markets is being implemented by conformity assessment bodies to ensure quality of the outcomes. The trend of new processes that are emerging will not stop and they will need to be certified to ensure quality.

This document is intended to provide useful information to those involved in certification on the application of ISO/IEC 17067 for processes. It provides guidance on a type 6 scheme, as outlined in ISO/IEC 17067, related to the certification of processes.

In practice, there are many different ways in which certification of processes is operated. There are other measures that scheme owners, in consultation with other interested parties, can adopt, or use in different combinations, to achieve a fit-for-purpose scheme.

In particular, the range of activities used, and the intensity with which they are applied, need to be proportionate to the consequences and likelihood of a process failing to fulfil specified requirements resulting in faulty products or services. Factors such as the particular characteristics of the marketplace, the technology and methods related to the processes also need to be taken into account.

Management system standards based on a quality management system, e.g. ISO 9001, can optionally be used as a basis for evaluation in the certification of processes as part of a scheme for the certification of processes. Various standards for verification and validation of specific elements of the process are also available for certain processes (e.g. for greenhouse gas emission and software development) that can further ensure the quality of the process outputs.

In the context of this document, the assessment of a management system as part of certification of process does not constitute the certification of the management system.

The principal interested parties, who are most affected by the rules, procedures and management of the scheme, are the following:

— the scheme owner;

— the certification body/bodies;

— the process owner;

— the process operator;

— users of the products and services (outputs) produced by the processes that rely on certification.

NOTE     Where a certification body runs its own scheme, the certification body is the scheme owner.

Other interested parties include, but are not limited to:

— regulatory authorities;

— specifiers, purchasers and users of certified processes;

— conformity assessment bodies, such as testing laboratories, validation and verification bodies and inspection bodies, involved in the certification of processes;

— accreditation bodies and peer assessment groups;

— international certification schemes that facilitate the recognition of certification status from one scheme owner to another;

— organizations that endorse and/or benchmark certification schemes

— consumers (users).

This document provides guidelines accompanied by examples that are used to illustrate ways in which the guidelines can be used, without precluding other approaches as decided by the scheme owner in consultation with the other stakeholders.

# Conformity assessment — Guidelines and examples of a scheme for the certification of processes

## 1 Scope

This document provides guidelines, principles and examples of schemes for the certification of processes.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

ISO/IEC 17067:2013, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17067 and ISO/IEC 17065 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

**3.1**
**process**
set of interrelated or interacting activities which transforms inputs into outputs

Note 1 to entry: A process is considered to be the object of conformity assessment by certification.

Note 2 to entry: In this document, a certification process is a set of activities which deliver a certified process.

[SOURCE: ISO/IEC 17065:2012, 3.5, modified — The original Example and Note to entry have been replaced by Notes 1 and 2 to entry.]

**3.2**
**process operator**
person or organization that operates the *process* (3.1)

Note 1 to entry: The process operator can be the process owner or can be different, e.g. in franchising.

**3.3**
**process owner**
person or organization that defines and owns the *process* (3.1)

# 4 General description of a scheme for the certification of processes

## 4.1 Characteristics of process

The process should be established, with clearly defined boundaries and scope, maintained and documented. The process should be repeatable and the output (e.g. service or product) should be consistent.

NOTE      Processes can be described in terms of the attributes of process title, process purpose and process outcomes.

## 4.2 Development and operation of a scheme

**4.2.1**   General provisions for the development and operation of a scheme for the certification of processes are stipulated in ISO/IEC 17067:2013, Clause 6. This document provides guidance on how those general provisions are implemented in a particular scheme for the certification of processes. Figure 2 provides a schematic representation of the elements of a single process.
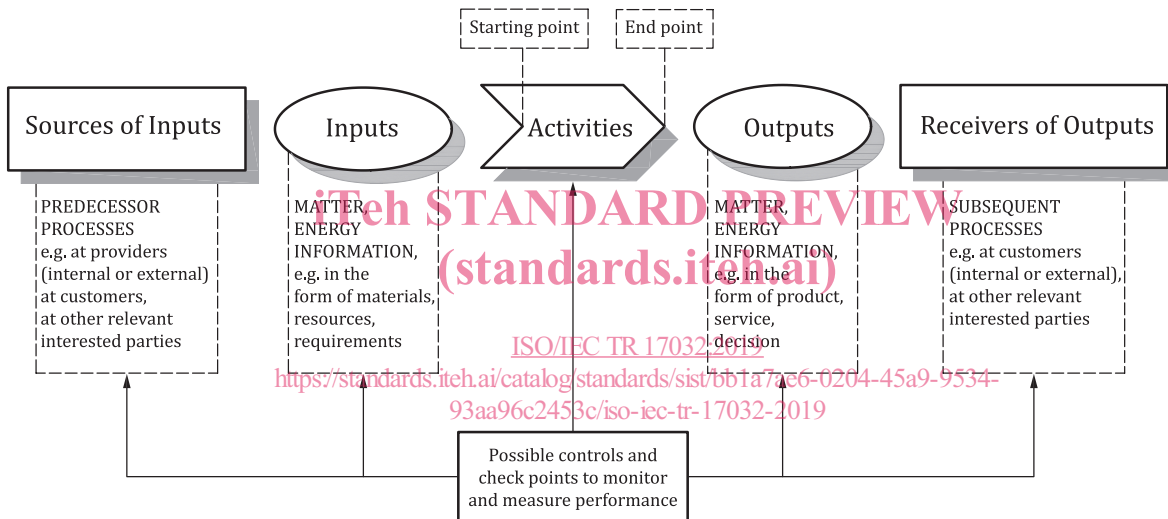


Figure 2 — Schematic representation of the elements of a single process

**4.2.2**   Schemes for the certification of processes can be developed for different purposes, which can include schemes established by industries, sectors or regulators.

NOTE      As an example, the application of conformity assessment methodology to the assessment to process quality characteristics and organizational maturity is described in ISO/IEC 29169.

**4.2.3**   The main parties involved in the operation of the scheme should be:

a)   the scheme owner;

b)   the certification body;

c)   the organization that owns and/or operates the process being certified and that has an agreement with the certification body (client).

## 4.3   Outline of a scheme for the certification of processes

### 4.3.1   Certification of processes

**4.3.1.1**   Certification of processes is a third-party attestation that fulfilment of specified requirements for a process has been demonstrated. Certification of processes is carried out by certification bodies that should conform to ISO/IEC 17065.

**4.3.1.2**   Certification of processes is intended to provide confidence to customers, regulators, industry and other interested parties that the organization conducting the process has fulfilled specified process requirements. Specified requirements for processes are generally contained in standards or other normative documents. Certification can apply generally to the process or to specific implementations of the process by an individual or organization. The scheme owner can use a risk-based approach for planning of activities.

**4.3.1.3**   Certification of processes cover a variety of processes, such as welding, non-destructive testing, system design engineering, heat treatment, production monitoring, food production, agriculture, software development, surface treatment services, supply chain, logistics, construction planning and design, and data protection.

NOTE      Annex A provides examples of schemes for the certification of processes.

### 4.3.2   Functional approach

**4.3.2.1**   Schemes for the certification of processes should consider the functional approach as described in ISO/IEC 17000. In ISO/IEC 17065, the term "evaluation" is defined as a combination of "selection and determination".

**4.3.2.2**   The functional approach consists of the following:

— **selection**, which includes planning and preparation activities in order to collect or create all the information and input needed for the subsequent determination function;

— **determination**, which can include conformity assessment activities such as testing, measuring, inspection, monitoring, assessment of the process, verification and validation, and auditing to provide information regarding the requirements for the process as input to the review and attestation functions;

— **review**, which means consideration of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements;

— **decision** on certification as a conclusion based on the results of review, that fulfilment of specified requirements has or has not been demonstrated;

— **attestation**, which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated;

— **surveillance** (where specified by the certification scheme), which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

**4.3.2.3**   Whenever certification of processes is performed, a certification scheme is in place and defines specific activities for the elements as described in 4.3.2.2.

## 4.4 Scheme owner

**4.4.1** The scheme owner is a person or organization responsible for developing and maintaining a specific scheme for the certification of processes (see ISO/IEC 17067:2013, 6.3).

The following main types of scheme owners can be identified:

a) certification bodies;

b) organizations that are not certification bodies, such as regulatory bodies, trade associations or other organizations that develop a certification scheme;

c) a group of certification bodies or organizations, perhaps in different countries, that can together set up a certification scheme.

NOTE 1    A group of certification bodies or organizations can establish a management structure so that the scheme can operate effectively.

NOTE 2    The publication of a process standard or a standard relating to a conformity assessment scheme for a process by a national, regional or international standards body or standards development organization (SDO) does not make it a scheme owner. This does not preclude the standards body or SDO from being a scheme owner in addition to being a standards body or SDO.

**4.4.2** The scheme owner should:

— be a legal entity or part of a legal entity;

NOTE 1    A governmental scheme owner is deemed to be a legal entity on the basis of its governmental status.

— take responsibility for the objectives, the content and the integrity of the scheme;

— implement operational controls to protect the confidentiality of information provided by the parties involved in the scheme;

— evaluate and manage the risks/liabilities arising from its activities;

NOTE 2    Evaluating risks does not imply risk assessments as outlined in ISO 31000.

— understand the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis;

— ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects;

— document the content of the scheme;

— have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities, i.e. arrangements should be appropriate (e.g. for the range of activities and schemes undertaken and in the geographic regions in which the scheme operates);

— have the financial stability and resources required for it to fulfil its role in the operation of the scheme;

— set up a structure for the management of the scheme;

— maintain the scheme and provide guidance when required.

## 4.5 Engagement of interested parties

**4.5.1** When developing a scheme, the scheme owner should have a clear understanding of the objectives of the scheme and the assumptions that underlie the need for, and the acceptance of, the scheme. To assist in this, the scheme owner should be inclusive, identify and invite interested parties and seek their opinions and define the type of their participation in scheme development.

**4.5.2**   Before developing the specific content of the scheme, the interested parties should agree on the following:

— confirmation of the ownership;

— confirmation of the governance and decision-making mechanisms that might or might not provide for direct involvement of interested parties;

— confirmation of the underlying business and funding model;

— providing an outline for monitoring and periodic review of the scheme.

**4.5.3**   Once developed, the scheme owner should ensure that information about the scheme is made publicly available upon request to ensure transparency, understanding and acceptance.

**4.5.4**   The scheme owner should ensure that the scheme is regularly reviewed, including confirmation that:

— it is fulfilling its objectives, in accordance with a process that includes interested parties;

— it is operated by competent, consistent and impartial certification bodies;

— it is delivering the results in an effective manner according to the specified requirements.

## 4.6   Scheme management

### 4.6.1   Scheme documentation

The scheme owner should create, control and maintain adequate documentation for the operation, maintenance and improvement of the scheme. The documentation should specify the rules and the operating procedures of the scheme, and in particular the responsibilities for governance of the scheme.

### 4.6.2   Reporting to the scheme owner

When reporting to the scheme owner is required (e.g. by certification bodies), the content and frequency of reporting should be defined. Such reporting can be for the purpose of scheme improvement, for control purposes and for monitoring the extent of conformity by process operators.

### 4.6.3   Outsourcing

If the scheme owner outsources all or part of the management of the scheme to another party, it should have a legally binding contract defining the duties and responsibilities of both parties. A governmental scheme owner can outsource management of the scheme by regulatory provisions.

### 4.6.4   Scheme integrity programme

The scheme owner should implement and perform a programme (e.g. validation audit, surveillance or other checks) to ensure scheme objectives are being fulfilled which can include monitoring certification bodies activities.

### 4.6.5   Review of scheme operation

The scheme owner should define a process for reviewing the operation of the scheme on a periodic basis in order to confirm it is meeting its objectives and to identify aspects requiring improvement, taking into account feedback from interested parties. The review should include provisions for ensuring that the scheme requirements are being applied in a consistent manner.