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

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National foreword

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

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see http://patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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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.

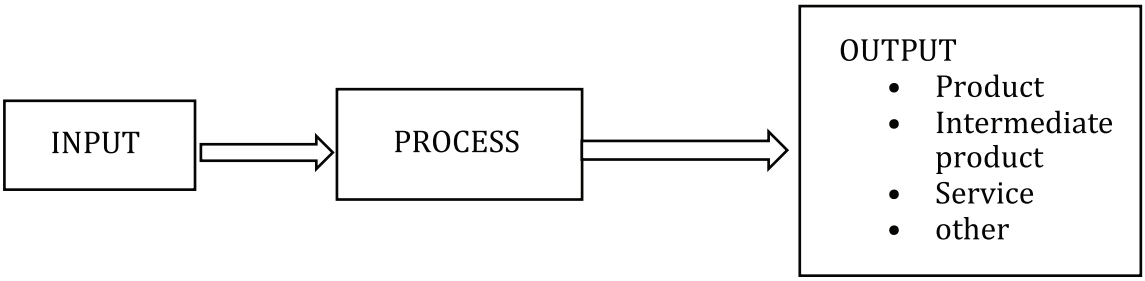

Figure 1 — Schematic representation of the outputs of a process

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.

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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.

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TECHNICAL REPORT **ISO/IEC TR 17032:2019(E)**

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)

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