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Conformity assessment — General requirements for the competence of proficiency testing providers

Évaluation de la conformité — Exigences générales concernant la compétence des organisateurs d'essais d'aptitude

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 or www.iec.ch/members_experts/refdocs).

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This document was prepared by the ISO Committee on Conformity Assessment (CASCO), in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 1, *Criteria for conformity assessment bodies*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/IEC 17043:2010), which has been technically revised.

The main changes are as follows:

— harmonization with ISO/IEC 17025:2017, including technical requirements and structure;

— harmonization with ISO 13528:2022 in terms of terminology;

— incorporation of requirements from ISO/CASCO PROC 33;

— inclusion of the requirement that testing activities, calibration activities and proficiency testing item production conform to the relevant requirements of appropriate ISO conformity assessment standards;

— deletion of Annex C and revision of Annexes A and B.

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 and www.iec.ch/national-committees.

Introduction

Proficiency testing (PT) is widely recognized as an essential tool for demonstrating the competence of conformity assessment bodies. PT can provide evidence of competence and it can be an indicator of an underlying or emerging problem. This document is intended to promote confidence in the operations of PT providers. It contains requirements for PT providers to enable them to demonstrate that they operate competently and can generate valid evaluations of participant performance.

PT involves the use of interlaboratory comparisons for the evaluation of laboratory performance. The definition of "interlaboratory comparison" (see 3.4) broadens the use of both the terms "laboratories" and "measurements or tests" for the purposes of this document to include all types of conformity assessment bodies and their activities, respectively. The term "method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

There are many different purposes for interlaboratory comparisons, which can be addressed by PT schemes, including but not limited to:

a) evaluation of the performance of laboratories for specific measurements, tests, calibrations, examinations, inspections or sampling;

b) identification of problems in laboratories that, for example, can be related to measurement or test methods, effectiveness of training and supervision of personnel, or calibration of equipment;

c) establishment of the effectiveness of measurement or test methods and the comparability of measurement or test results;

d) provision of additional confidence to users of measurement or test results;

e) identification of differences in measurement or test results;

f) education of participating laboratories based on the outcomes of such comparisons;

g) validation of measurement uncertainty claims.

For the following types of interlaboratory comparisons, the term PT does not usually apply because laboratory competence must be established in advance, in order to ensure the validity of measurements or tests as well as the metrological traceability of assigned values:

h) evaluation of the performance characteristics of a measurement or test method (often described as collaborative trials);

i) assignment of values to reference materials;

j) support for statements of the equivalence of measurements of National Metrology Institutes (NMIs), or their Designated Institutes (DIs) through "key and supplementary comparisons", conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated Regional Metrology Organizations (RMOs).

It is recognized that interlaboratory comparisons for purposes h), i) and j) can contribute to independent demonstrations of laboratory competence. The requirements of this document can be applied to many of the technical planning and operational activities for these interlaboratory comparisons.

This document also requires PT providers to plan and implement actions to address risks and opportunities, based on their experience. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative events. The PT provider is responsible for deciding which risks and opportunities to address.

The need for ongoing confidence in laboratory performance is essential not only for laboratories and their customers but also for other interested parties, such as regulators, accreditation bodies and other organizations that specify requirements for laboratories. Most of the requirements in this document apply to those evolving areas, especially regarding management, planning and design, personnel,

assuring validity of results and performance evaluations, confidentiality and other aspects, as appropriate.

This document is intended to provide a consistent basis for all interested parties to determine the competence of organizations that provide PT.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.