SLOVENSKI STANDARD
oSIST prEN ISO/IEC 17025:2017

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Splošne zahteve za usposobljenost preskuševalnih in kalibracijskih laboratorijev (ISO/IEC DIS 17025:2016)

General requirements for the competence of testing and calibration laboratories (ISO/IEC DIS 17025:2016)

Allgemeine Anforderungen an die Kompetenz von Prüf- und Kalibrierlaboratorien (ISO/IEC DIS 17025:2016)

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais (ISO/IEC DIS 17025:2016)

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DRAFT INTERNATIONAL STANDARD

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General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

ICS: 03.120.20

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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. In the field of conformity assessment, ISO and IEC develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

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).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Agreement on Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO/IEC 17025 was prepared by the *ISO Committee on Conformity Assessment* (CASCO). It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.

The first edition (1999) of this International Standard was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results. ISO/IEC 17025 was aligned with ISO 9001:2000 in 2005. Since then ISO 9001 has been revised twice.

Introduction

This International Standard has been developed with the objective of promoting confidence in the operation of laboratories.

This International Standard contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results.

Laboratories that conform to this International Standard will also operate generally in accordance with the principles of ISO 9001.

This International Standard requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The use of this International Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if laboratories conform to this International Standard.

In this International Standard, 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.

General requirements for the competence of testing and calibration laboratories

1 Scope

1.1 This International Standard specifies the general requirements for the competence, impartiality and consistent operation of laboratories as defined in the standard.

1.2 This International Standard is applicable to all organizations, regardless of the number of personnel, performing laboratory activities (see 3.6).

1.3 Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this International Standard in confirming or recognizing the competence of laboratories.

2 Normative references

The following referenced document is indispensable for the application 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.

JCGM 200:2012, International vocabulary of metrology — basic and general concepts and associated terms (VIM), 3rd edition issued by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions

For the purposes of this document, the following terms and definitions given in ISO/IEC 17000 and JCGM 200:2012 and the following apply[1].

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

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

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

3.1
impartiality
presence of objectivity

Note 1 to entry: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the laboratory.

[1] Where there is more than one definition for the same term, the definitions in ISO/IEC 17000 and JCGM 200:2012 take precedence.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality are freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

[SOURCE: ISO/IEC 17021-1:2015, 3.2]

3.2
complaint
expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO 17000:2004, 6.5 — modified: *conformity assessment body or accreditation body replaced by laboratory and added the term results and removed appeals*]

3.3
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.4
intralaboratory comparison
organization performance and evaluation of measurements or tests on the same or similar items, within the same laboratory, in accordance with predetermined conditions

3.5
proficiency testing
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

[SOURCE: ISO/IEC 17043:2010, 3.7— modified: *the reference to the Annex and notes deleted.*]

3.6
laboratory
body that performs one or more of the following activities:
— calibration
— testing
— sampling, associated with subsequent calibration or testing

3.7
decision rule
a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

4 General requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The laboratory shall ensure the protection of its customers' confidential information and proprietary rights, including protecting the electronic storage and transmission of results.

4.2.2 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

NOTE Legally enforceable commitments can be, for example, contractual agreements.

4.2.3 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.4 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.5 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for all its activities.

NOTE For the purpose of this international standard, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The laboratory shall identify management who have overall responsibility for the laboratory.

5.3 The laboratory shall carry out its activities in such a way as to meet the requirements of this International Standard, its customers, regulatory authorities and organizations providing recognition. The laboratory shall be responsible for activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.4 The laboratory shall define and document the range of laboratory activities for which it conforms with this International Standard. The laboratory shall only claim conformity with this International

Standard for the range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.5 The laboratory shall:

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to assure the consistent application of its activities and validity of the results.

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement; and

e) ensuring the required validity of laboratory activities.

5.7 Laboratory management shall ensure that:

a) the integrity of the management system is maintained when changes to the management system are implemented;

b) communication takes place regarding the effectiveness of the management system and the importance of meeting customer and other requirements.

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities.

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be supervised and competent, and shall work in accordance with the laboratory's management system.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, experience.

6.2.3 The laboratory shall ensure that the personnel have the competence to perform the laboratory activities for which they are responsible and understand the significance of and response to deviations found with regard to the laboratory activities.

6.2.4 The laboratory shall communicate to each person their duties, responsibilities and authorities.

6.2.5 The laboratory shall have procedure(s) and maintain records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring of competence of personnel.

6.2.6 The laboratory shall authorize personnel to:

a) develop, modify, verify and validate methods;

b) perform specific laboratory activities;

c) analyze results, including statements of conformity or opinions and interpretations; and

d) report results.

6.3 Laboratory facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented

6.3.3 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a) access to and use of areas affecting laboratory activities;

b) prevention of contamination, interference or adverse influences on the laboratory activities;

c) effective separation between areas in which there are incompatible laboratory activities.

NOTE Influences that can adversely affect the validity of results include biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration levels.

6.3.5 When the laboratory performs activities at facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this International Standard are met.