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Second edition
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Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures

Biologie médicale — Exigences relatives à la compétence des laboratoires d'étalonnage utilisant des procédures de mesure de référence

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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 ISO documents 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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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 15195:2003), which has been technically revised.

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The main changes compared to the previous edition are as follows:

— inclusion of ISO/IEC 17025:2017 as a normative reference;

— removal of clauses that duplicate requirements in ISO/IEC 17025:2017;

— reorganization of this document so that it follows the structure of ISO/IEC 17025:2017.

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

The general requirements for the competence of calibration laboratories are specified in ISO/IEC 17025:2017 for testing and calibration laboratories. This document refers to the additional aspects for the competence of calibration laboratories in the field of laboratory medicine where such "calibration laboratories" are usually denoted as "reference measurement laboratories".

The results produced by medical laboratories should be traceable to reference materials and/or reference measurement procedures of higher order, whenever these are available. This is necessary to allow transferability of measurement results in patient samples irrespective of the place and time of measurement.

The metrological level of the results provided by calibration laboratories should be appropriate to support medical laboratories to fulfil medical requirements. The specific requirements of medical laboratories are addressed in ISO 15189.

Calibration laboratories should implement reference measurement procedures and produce results of measurement that are accurate and traceable to national or international primary reference materials when such are available. Whenever possible, traceability should be established to a reference material which forms an embodiment of the SI unit (ISO 17511).

The calibration laboratory should provide traceable values on reference materials supplied by customers to the highest available level of reference measurement procedures or reference materials.

In many instances, properties of biological materials cannot be expressed in SI units because the molecular structure of their analytes is not exactly known and can be different in a reference material from that in a native sample of human origin (e.g. state of glycosylation of a protein).

Even if the value for a property of a biological material is not traceable to an SI unit, each step of a reference measurement procedure (e.g. gravimetry, volumetry, thermometry, potentiometry) should have values that are traceable to the respective SI unit.

The traceability concept, including its applicability and limitations are described in detail in ISO 17511.

The requirements described in this document and in ISO/IEC 17025:2017 are prerequisites for calibration laboratories to perform their tasks adequately.

This document may form a basis for the accreditation of a calibration laboratory that applies for recognition of the performance of a reference measurement procedure.

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