SLOVENSKI STANDARD
oSIST prEN ISO 23588:2024

01-maj-2024

Radiološka zaščita - Splošne zahteve za preskuse strokovne usposobljenosti za radiobioanalizo in vivo (ISO 23588:2023)

Radiological protection - General requirements for proficiency tests for in vivo radiobioassay (ISO 23588:2023)

Strahlenschutz - Allgemeine Anforderungen an Eignungsprüfungen für in vivo Bioassays (ISO 23588:2023)

Radioprotection - Exigences générales concernant les essais d'aptitude pour les mesures d'anthroporadiométrie (mesures in vivo) (ISO 23588:2023)

Ta slovenski standard je istoveten z: **prEN ISO 23588**

ICS:

13.280	Varstvo pred sevanjem	Radiation protection

oSIST prEN ISO 23588:2024 **en,fr,de**

INTERNATIONAL STANDARD

ISO 23588

First edition
2023-02

Radiological protection — General requirements for proficiency tests for in vivo radiobioassay

Radioprotection — Exigences générales concernant les essais d'aptitude pour les mesures d'anthroporadiométrie (mesures in vivo)

Reference number
ISO 23588:2023(E)

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

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO 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 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 Technical Committee ISO/TC 85, *Nuclear energy, nuclear technology, and radiological protection,* Subcommittee SC 2, *Radiological protection*.

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

The direct (in vivo) measurement of radionuclides emitting penetrating radiations (X- and gamma rays) in the body is an important technique in radiological protection. Along with the appropriate biokinetic and dosimetric models, the results can be used to assess doses due to intakes of radionuclides[5]. These measurements and assessments are typically done

— routinely among radiation workers in occupational radiation protection, and

— among members of the public, emergency workers or helpers in a nuclear or radiological emergency.

In vivo monitoring may also be used to identify the level of exposure of an individual in a criticality incident through the measurement of activated body sodium[5].

In vivo measurements may be made by dosimetry laboratories with dedicated facilities, in nuclear facilities using whole-body or partial body scanners, or in hospitals or universities with appropriate equipment. The most common direct (in vivo) methods are whole-body, lung, and thyroid counting.

Participating in performance testing programmes with suitable phantoms is commonly required by national regulatory bodies as part of the accreditation of in vivo dosimetry service laboratories for the validation of bioassay methods. For other facilities making in vivo measurements, such as nuclear facilities, hospitals, and universities, participating in intercomparisons can help monitor the performance, identify problems, and provide education and training opportunities. ISO 28218 provides performance criteria for radiobioassay including in vivo monitoring. The general design requirements and performance characteristics of in vivo measurement instrumentation, including test procedures for performance control, are described in IEC 61582[4].

General requirements on proficiency testing and statistical methods for evaluation are given in ISO/IEC 17043[3] and ISO 13528[2], respectively.

The purpose of this document is to give a fuller set of requirements and recommendations for proficiency test organizers than given in the standards mentioned above, including

— planning and announcement of testing actions,

— selection of radionuclides,

— selection of activities to be used for testing,

— preparation of test sources,

— selection of phantoms,

— measurement of phantoms,

— analysis of results provided by the participants, and

— reporting.

Radiological protection — General requirements for proficiency tests for in vivo radiobioassay

1 Scope

This document specifies general requirements for proficiency tests that are offered to in vivo bioassay measurement facilities operating a whole-body counter (WBC) or partial body counter (PBC) for monitoring of persons.

It specifies minimum requirements for proficiency testing applicable to dosimetry laboratories that have dedicated facilities for in vivo monitoring and where accreditation is required as part of providing the service. It also provides general requirements for proficiency testing that may include a larger group of non-accredited laboratories that may perform measurements as part of worker surveillance or in response to an emergency.

This document covers proficiency tests that involve only the quantification of radionuclides and tests that require the identification of radionuclides and their activity.

This document does not define specific requirements on administrative aspects of proficiency testing, such as shipping and finance, that may be the subject of national or international regulation.

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 28218:2010, *Radiation protection — Performance criteria for radiobioassay*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
activity distribution
information about the spatial distribution of the provided activity in a phantom, to be used as a basis for the choice of an efficiency calibration by the participant

Note 1 to entry: Examples of activity distributions are activity in the whole-body, lung, skull or thyroid.

3.2
attendant
person appointed by the *organizing laboratory* (3.4) to attend the participants during their measurements for the proficiency test

3.3
minimum testing level
MTL
amount of radioactive material that the service laboratory is intended to be able to measure for participation in the performance testing programme, assuming the samples are free of interference from other radionuclides, unless specifically addressed

Note 1 to entry: The MTLs are not intended to be interpreted as the appropriate detection limit required for a specific internal dosimetry programme, but rather as an acceptable minimum testing level for radiobioassay service laboratories based on good measurement practice.

[SOURCE: ISO 28218:2010, 3.18]

3.4
organizer
organizing laboratory
institution or consortium of institutions that provides the proficiency test

3.5
participant
participating laboratory
laboratory whose proficiency is tested as described in this document

3.6
partial body counter
PBC
equipment for the determination of activity in a region of the body

3.7
test result
information about the performance of the individual *participant* (3.5), prepared and dispatched by the *organizer* (3.4)

3.8
whole-body counter
WBC
equipment for the determination of the presence, location and/or amount of radioactivity in the body

[SOURCE: ISO 12749-2:2022[1], 3.4.9]

4 Planning

4.1 Determination of the type of proficiency test

4.1.1 The organizer shall clearly define the purpose of the proficiency test. The purpose should encompass

— the aims of the proficiency test, for example to test the proficiency of accredited dosimetry service laboratories to set criteria or to provide information on the performance of facilities and laboratories that would be used in response to an emergency,

— the radionuclides, or categories of radionuclides, that are the subject of the proficiency test (see Annex B and Annex C),

— the MTLs for these radionuclides, or categories of radionuclides (see Annex C),

— the types of laboratories or facilities that are eligible to participate in the test,

— the type of proficiency test, for example whether it is for a single laboratory to set criteria (measurement audit) or a sequential participation test with a phantom, and