ICS 13.280 SLOVENSKÁ TECHNICKÁ NORMA Október 2024

STN	**Radiačná ochrana** **Všeobecné požiadavky na skúšky výkonnosti biologickej metódy *in vivo* (ISO 23588: 2023)**	**STN** **EN ISO 23588** 40 1421

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/24

Obsahuje: EN ISO 23588:2024, ISO 23588:2023

139189

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 23588

July 2024

ICS 13.280

English Version

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

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

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

This European Standard was approved by CEN on 7 July 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 23588:2024 E

Contents

Page

European foreword..... 3

European foreword

The text of ISO 23588:2023 has been prepared by Technical Committee ISO/TC 85 “Nuclear energy, nuclear technologies, and radiological protection” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 23588:2024 by Technical Committee CEN/TC 430 “Nuclear energy, nuclear technologies, and radiological protection” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 23588:2023 has been approved by CEN as EN ISO 23588:2024 without any modification.

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)

COPYRIGHT PROTECTED DOCUMENT

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 ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Planning ... **2**
4.1 Determination of the type of proficiency test ... 2
4.2 Choice of measurement tasks ... 3
4.3 Selection of radionuclides ... 3
4.4 Selection of activity ranges ... 3
4.5 Choice of phantom ... 4
4.6 Announcement of the proficiency test ... 4

5 Preparation of phantoms and sources ... **5**
5.1 Preparation of phantoms ... 5
5.2 Preparation of sources ... 5
5.3 Quality assurance ... 5

6 Conducting the proficiency test ... **5**
6.1 General ... 5
6.2 Preparation of the phantom at the participant's facility ... 6
6.3 Measurement of the phantom by the participants ... 6
6.4 Reporting protocol ... 6

7 Data analysis and evaluation of results ... **7**
7.1 General ... 7
7.2 Determination of the assigned value ... 7
7.3 Calculation of the performance scores ... 8
7.4 Report ... 8

Annex A (informative) **Example schedule for a proficiency test** ... **9**

Annex B (informative) **Example measurement tasks** ... **10**

Annex C (normative) **MTL for in vivo radiobioassay performance testing** ... **11**

Annex D (informative) **Examples of phantoms** ... **12**

Bibliography ... **13**

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.

INTERNATIONAL STANDARD ISO 23588:2023(E)

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*