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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)

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Contents

Page

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 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

— the statistical analyses that are used to determine the performance of participants in the proficiency test.

4.1.2 The organizer shall draft a schedule for the proficiency test. Annex A provides an example timeline for a proficiency test.

4.2 Choice of measurement tasks

4.2.1 The organizer shall decide which radionuclides, or groups of radionuclides, shall be included in the test based upon the objectives of the proficiency test. The choice of the body region to be tested, either whole-body or a particular organ such as the lung or thyroid, should be relevant to those radionuclides based on a particular exposure scenario (inhalation, ingestion, wound) and their biokinetics inside the body. ISO 28218 and Annex B provide details of appropriate body regions to be tested for various categories of radionuclides under certain exposure scenarios.

4.3 Selection of radionuclides

4.3.1 The radionuclides used in the test shall be selected from the list provided in ISO 28218:2010, Table 1 or Annex C in accordance with the group of radionuclides and type of in vivo measurement being tested.

4.3.2 The organizer may choose to use surrogate radionuclides instead of the primary radionuclide of interest based on practical considerations such as half-life in relation to the timescale of the proficiency test, external dose incurred during preparation and use, ease of production, and shipping, and expense.

NOTE Ba-133 (or Ba-133 and Cs-137) can substitute for I-131 in regularly performed proficiency tests, and I-125 can be replaced by I-129 for economic reasons. Because of the multiplicity of their emission lines, Ba-133 and Eu-152 are also used as reference radionuclides.

4.3.3 The purpose of the proficiency test should also be considered when choosing radionuclides. For proficiency test schemes where it is not necessary to identify the radionuclide and only a result in terms of activity is required, the radionuclides used should be those commonly encountered. Proficiency tests where there is a requirement to identify individual nuclides may use more complex mixtures.

4.3.4 More than one nuclide may be included in a phantom. Generally, K-40 should be included because it is always present in the human body and often the only radionuclide detected in routine measurements.

In principle any gamma emitter that has emissions of sufficient yield may be considered for use in a proficiency test if it can be prepared, measured, transported, and has no other restrictions on its use. But the organizer should consider the measurement capabilities of the potential participants in the test. For example, if there will be both germanium-based and sodium iodide detectors, it may be necessary to include tasks that are applicable to both types of detector.

4.4 Selection of activity ranges

4.4.1 For schemes involving accredited dosimetry laboratories, the minimum testing levels shall be those provided in ISO 28218:2010, Table 1 or Annex C.

4.4.2 The distribution of the radionuclides in the phantom should be homogenous for basic proficiency tests.

4.4.3 For other schemes, the activity present in the phantom may be determined by the organizer dependent upon the purpose of the test. The least sensitive type of system likely to participate should be considered when determining the testing activity, but this may not be the deciding factor.

4.4.4 For proficiency tests involving instruments not specifically designed for in vivo monitoring but used in emergency response, the activity may be related to a dose criterion that is of interest.

4.4.5 The activities in a radionuclide mixture should be based on the emission probabilities of the main gamma lines.

4.5 Choice of phantom

4.5.1 The phantom shall be appropriate to the measurement tasks (see Annexes B and D for examples).

4.5.2 The phantom should be based on the ICRP reference individual (ICRP 89)[6]. A male and/or female (adult) phantom, an intermediate phantom derived from these, or a group of age-dependent phantoms may be used. For partial body activity distributions, the organizer should use a phantom that is suitable for the specific partial body measurement task.

4.5.3 Where proficiency tests are carried out over many years, the organizer should consider including one type of phantom consistently throughout the performance test rounds. The nuclides and activity ranges in this phantom should also be maintained throughout different rounds.

4.5.4 Phantoms used for calibration at photon energies below 100 kiloelectron volts (keV) shall be constructed of tissue equivalent material and shall be anthropomorphic. For photon energies above 100 keV, acceptable phantoms may be made from other materials. See Annex D for examples of phantoms.

NOTE With regards to handling and radiation protection aspects, phantoms containing sealed or solid radioactive sources are preferable to phantoms containing unsealed sources or radionuclides in liquid form.

4.6 Announcement of the proficiency test

4.6.1 The proficiency test shall be announced sufficiently in advance of the measurement campaign to give interested laboratories time to consider their application.

4.6.2 The description of the proficiency test shall be sufficiently detailed to enable an interested laboratory to decide whether to apply. It should include information about:

— the type of proficiency test, for example, sequential (round-robin) or measurement audit (single);

— the phantom geometry (whole-body, thyroid, lung);

— the quantity to be determined (organ activity, whole-body activity);

— the range of gamma radiation energies in which the participants can be expected to detect or measure gamma radiation;

— specific measurement conditions that shall be followed by the participants (e.g. measurement time) or that influence settings of the measurement facility (e.g. activity distribution);

— the method of the evaluation of results;

— significant dates in the test schedule.

4.6.3 If appropriate, the organizer should state whether the proficiency test meets any national regulatory requirements.

4.6.4 In some tests, it may be appropriate to announce only the quantity (organ activity, whole-body activity) to be determined without additional information (e.g. to test the capability of the laboratories to identify radionuclides).

4.6.5 The organizer should provide details about participation fees and other administrative requirements.

5 Preparation of phantoms and sources

5.1 Preparation of phantoms

5.1.1 The transmission and scatter characteristics of the phantom should be similar to those for the body as described in ICRU 44[7].

5.1.2 Where several phantoms are used as part of the same round of a proficiency test, they shall be manufactured of the same material. The density of a single phantom shall not vary by more than 5 % from the mean density for all the phantoms in the round.

5.2 Preparation of sources

5.2.1 The organizer shall use sources whose activity is traceable to a national standard, where possible. If sources whose activity is not traceable to a national standard are used, special requirements for the evaluation of the results should be applied. The organizer shall also have a documented process and quality program for the preparation of the sources.

If it is not possible or economically not justified to get a calibration certificate for the final sources, special rules may be applied. In such a case it may be reasonable to purchase a radionuclide solution with an appropriate calibration certificate, which is traceable to applicable national or international standards, to produce 'self-made' sources for the phantoms using calibrated scales and pipettes maintaining traceability. Appropriate quality control checks should be performed on the sources produced. These processes shall be documented.

5.2.2 Where more than one phantom is prepared, the activity of the phantoms should be measured and be within 5 % of the reference activity or the mean activity of all the phantoms.

5.2.3 Solid sources (e.g. rod sources used in brick phantoms) can be purchased from a third party or be produced by the organizer of the proficiency test. See 5.2.1 for requirements regarding the traceability of the sources. The total activity of the set of sources should be reported with an expanded uncertainty (two standard deviations, $k = 2$) of less than 5 %. The homogeneity of the activity of the individual sources shall be determined, for example by gamma-ray measurements. The standard deviation of the activities of the individual sources should not exceed 5 %.

5.3 Quality assurance

The organizer shall physically examine the phantom(s) prior to and after the testing round to determine whether any degradation of the phantom(s) has occurred. The organizer shall also determine that the activity in the phantom(s), corrected for half-life, is unchanged at the end of the testing round.

6 Conducting the proficiency test

6.1 General

6.1.1 The organizer shall communicate requirements that affect one or more participants of a proficiency test no later than one month after establishing the requirements.

6.1.2 The organizer and participants shall co-operate to ensure that any legislative requirements regarding the conduct of the test, such as shipping and security of the phantom, are fulfilled.