INTERNATIONAL STANDARD

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Radiation protection — Performance criteria for radiobioassay

Radioprotection — Critères de performance pour l'analyse radiotoxicologique

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 28218 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This first edition of ISO 28218 cancels and replaces ISO 12790-1:2001, which has been technically revised.

Introduction

In the course of employment, individuals might work with radioactive materials that, under certain circumstances, could be taken into the body. Radiation protection programmes for these individuals can include means for *in vivo* or *in vitro* measurements of radioactive material that has entered the body. The performance criteria required for such measurements usually depend upon the purpose for the radiobioassay measurement, which can include determining the internal human burden of radioactive material, estimating doses and dose commitments, radiation protection management, medical management when appropriate, and providing the necessary data for legal and record-keeping requirements.

Analytical methods for radiobioassay are not currently standardized, but are available in the literature. Guidance on the evaluation of data from the monitoring of workers occupationally exposed to the risk of internal contamination by radioactive substances is provided in ISO 27048 as well as other publications of national and international regulations and guides, the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurement (NCRP), the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Units and Measurements (ICRU). Recommendations of the ICRP, NCRP, IAEA and ICRU, as well as experience with the practical application of these recommendations to the conduct of radiobioassay services and the interpretation and use of radiobioassay results in radiation protection programmes, have been considered in the development of this International Standard.

In addition to superseding ISO 12790-1:2001, this International Standard complements the requirements of ISO 20553. This International Standard develops, expands and applies the principles defined in the aforementioned standards for radiobioassay laboratories. It also provides a consensus on the statistical definitions and formulations of the quantitative performance criteria of decision threshold, detection limit, relative bias and repeatability. These concepts follow the requirements of ISO 11929. In particular, the concept of minimum detectable amount (MDA) used in ISO 12790-1:2001 has been abandoned in favour of detection limit ($y^{\#}$).

Clauses 5 to 8 primarily provide guidance for radiobioassay service laboratories, whereas Clause 9 relates to testing laboratories and provides criteria for performance testing. The information in these clauses provides beneficial insight for service laboratories, for users of the laboratory's services, and for testing laboratories, and it provides a possible basis for an inter-laboratory quality assurance plan.

In this International Standard, the following verbal forms apply:

— “shall” is used to denote a requirement;

— “should” is used to denote a recommendation;

— “may” is used to denote permission (neither a requirement nor a recommendation).

To conform with this International Standard, all radiobioassay needs to be performed in accordance with its requirements, but not necessarily with its recommendations; however, justification needs to be documented for deviations from recommendations.

Radiation protection — Performance criteria for radiobioassay

1 Scope

This International Standard provides criteria for quality assurance and control, and evaluation of performance of radiobioassay service laboratories.

Criteria and guidance for *in vivo* radiobioassay and *in vitro* radiobioassay are given in separate clauses.

The following are within the scope of this International Standard:

— the accuracy of

  — *in vivo* measurements of activity and quantities of selected important radionuclides in test phantoms, and

  — *in vitro* measurements of activity and quantities of selected important radionuclides in test samples;

— minimal requirements for detection limit;

— minimum testing levels and testing ranges;

— requirements for reporting radiobioassay results by service laboratories;

— quality assurance in service laboratories;

— quality control in service laboratories;

— protocol for reporting test evaluations by service laboratories to the testing laboratory;

— default procedures when the service laboratory customer does not specify the performance criteria;

— applications of $y^{\#}$ for different methods (see Annexes A and B).

The following are not within the scope of this International Standard:

— detailed radiochemical methods for separating radionuclides from biological samples;

— detailed procedures for *in vivo* and *in vitro* radioactivity measurements;

— biokinetic data and mathematical models for converting radiobioassay results into dose (dose assessment);

— procedures for the preparation and distribution of test samples and phantoms by the testing laboratories.

2 Normative references

The following referenced documents are 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.

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 5725-3, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99, ISO 5725-1, ISO 5725-2, ISO 5725-3 and the following apply.

3.1
accuracy
characteristic of an analysis or determination that ensures that both the bias and repeatability of the resulting quantity remain within specified limits

3.2
activity
number of spontaneous nuclear disintegrations per unit time

3.3
aliquot
〈*in vitro* radiobioassay〉 representative portion of a whole

3.4
appropriate blank
uncontaminated sample, unexposed person or phantom that is ideally identical in physiochemically and radiologically significant ways with the sample, person or phantom to be analysed

3.5
background
ambient signal response recorded by measurement instruments that is independent of radioactivity contributed by the radionuclides concerned

3.6
bias
systematic error of the indication of a measuring instrument

3.7
freedom from bias
ability of a measuring instrument to give indications free from systematic error

3.8
blind testing
testing of capabilities when the service laboratory is not aware that they are being tested for conformance

