INTERNATIONAL STANDARD

ISO 12790-1

First edition
2001-12-01

Radiation protection — Performance criteria for radiobioassay —

Part 1: General principles

Radioprotection — Critères de performance pour l'analyse radiotoxicologique —

Partie 1: Principes généraux

Reference number
ISO 12790-1:2001(E)

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Printed in Switzerland

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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 3.

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 part of ISO 12790 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 12790-1 was prepared by Technical Committee ISO/TC 85, *Nuclear energy*, Subcommittee SC 2, *Radiation protection*.

ISO 12790 consists of the following parts, under the general title *Radiation protection — Performance criteria for radiobioassay*:

— *Part 1: General principles*

— *Part 2: Rationale and specific applications*

Introduction

In the course of employment, individuals may work with radioactive materials that, under certain circumstances, could be taken into the body. Radiation protection programmes include means for direct or indirect measurements or both, of radioactive material that has entered the body. The performance criteria required for such measurements usually depend upon the purpose for the radiobioassay measurement: determining the internal human burden of radioactive material; estimating doses and dose commitments; radiation protection management; medical management when appropriate; and to provide the necessary data for legal and record-keeping requirements. Measurements that are made as part of a routine monitoring programme are usually at a lower minimum detectable amount (MDA) than those to be used for diagnostic purposes. Routine examination measurements may be made less frequently and diagnostic measurements may sometimes require more rapid turn-around times.

Much of the information in this part of ISO 12790 is contained in other internal dosimetry standards for individual radionuclides. This part of ISO 12790 collects, expands, and standardizes the performance criteria contained in the other standards. It also provides a consensus on the statistical definitions and formulations of the quantitative performance criteria of bias, repeatability, accuracy and MDA.

Clauses 4 to 6 were written primarily to provide guidance for radiobioassay service laboratories, whereas clause 5 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 interlaboratory quality assurance plan. Definitions for certain words used in the text are included in clause 2. These definitions are included to give the precise meaning intended. Furthermore, this part of ISO 12790 has created unique terms the definitions of which are given in clause 2.

Radiation protection — Performance criteria for radiobioassay —

Part 1: General principles

1 Scope

This part of ISO 12790 provides criteria for quality assurance and control, evaluation of performance and the accreditation of radiobioassay service laboratories.

Criteria and guidance for direct radiobioassay (*in vivo*) and indirect radiobioassay (*in vitro*) are given in separate clauses of this part of ISO 12790.

This part of ISO 12790 addresses:

a) the accuracy of direct (*in vivo*) measurements of activity and quantities of selected important radionuclides in test phantoms and indirect (*in vitro*) measurements of activity and quantities of selected important radionuclides in test samples;

b) methods for determining the minimum detectable amount;

c) minimum testing levels and testing ranges;

d) requirements for reporting radiobioassay results by service laboratories;

e) quality assurance in service laboratories;

f) quality control in service laboratories;

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

h) default procedures when the service laboratory customer does not specify the performance criteria.

The scope of this part of ISO 12790 does not include:

a) detailed radiochemical methods for separating radionuclides from biological samples;

b) detailed procedures for *in vivo* and *in vitro* radioactivity measurements;

c) metabolic data and mathematical models for converting radiobioassay results into absorbed dose and dose equivalent;

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

Analytical methods for radiobioassay are not currently standardized, but are available in the literature. Guidance for converting radiobioassay results into dose are provided in 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, and experience with the practical application of these recommendations to the conduct of radiobioassay services and the interpretation and use of bioassay results in radiation protection programmes, have been considered in the development of this part of ISO 12790.

2 Terms and definitions

The following terms are of a restricted nature for the purposes of this part of ISO 12790. Terms defined in International Vocabulary of Basic and General Terms in Metrology (ISO publication: 1993, ISBN 92-67 01075-1) and

in application of statistics (ISO 5725-1, ISO 5725-2, ISO 5725-3) are not defined in this part of ISO 12790. A word or term requiring a more precise definition is redefined in this clause even though it was included in one of the aforementioned references.

The word “shall” is used to denote a requirement; the word “should” is used to denote a recommendation; and the word “may” is used to denote permission, neither a requirement nor a recommendation. To conform to this part of ISO 12790, all radiobioassay shall be performed in accordance with its requirements, but not necessarily with its recommendations; however, justification shall be documented for deviations from recommendations.

2.1
accuracy of measurement
characteristics of an analysis or determination that ensures that both the bias and precision of the resulting quantity remain within specified limits

2.2
activity
transition rate stated in becquerels

2.3
aliquot
representative portion of a whole

2.4
appropriate blank
uncontaminated sample, an unexposed person or phantom that is ideally identical in physiochemically and radiologically significant ways with the sample, person or phantom to be analysed

2.5
background
ambient signal response recorded by measurement instruments that is independent of radioactivity contributed by the radionuclides

2.6
bias
systematic error of the indication of a measuring instrument

2.7
freedom from bias
ability of a measuring instrument to give indications free from systematic error

2.8
bioassay
another word for radiobioassay as used in this part of ISO 12790

2.9
blind testing
testing of capabilities when the service laboratory is not aware that they are being tested for conformance

2.10
certified reference material
CRM
reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed and for which each certified value is accompanied by an uncertainty at a stated level of confidence

2.11
coefficient of variation
CV
the quotient of the estimated standard deviation of a series of determinations, x_1, x_2, ... x_i, x_n, of a quantity divided by the arithmetic mean value ($\overline{x}$) of x_i; i.e.

$$\mathrm{CV} = \frac{\sqrt{\dfrac{\sum_{i=1}^{n} (x_i - \overline{x})^2}{(n-1)}}}{\overline{x}}$$

or for a single measurement the quotient of the estimate of the standard deviation divided by the value of the single measurement (synonymous with the relative standard deviation, multiplied by 100 when expressed as percent)

2.12
concentration
the activity or mass per unit volume or per unit mass

2.13
confidence interval
the interval about an estimate of a stated quantity within which the expected value of the quantity is expected to lie (with a specified probability)

2.14
decision level
the amount of a count or final instrument measurement of a quantity at or above which a decision is made that the radionuclide is definitely present

2.15
direct radiobioassay
the measurements of radioactive material in the human body utilizing instrumentation that detects radiation emitted from the radioactive material in the body (synonymous with *in vivo* measurement)

2.16
indirect radiobioassay
measurements to determine the presence of or to estimate the amount of radioactive material in the excreta or in other biological materials removed from the body (synonymous with *in vitro* measurement)

2.17
***in vitro* measurement**
synonymous with indirect bioassay

2.18
***in vivo* measurement**
synonymous with direct bioassay

2.19
measurand
particular quantity subject to measurement

2.20
monitoring
measurement of activity in the whole body, in a region of the body, in material from the body or in the air for reasons related to the estimation of intake of radioactive material

2.20.1
operational monitoring
monitoring related to certain operations

2.20.2
routine monitoring
monitoring carried out at regular intervals during normal operations

2.20.3
special monitoring
monitoring carried out in actual or suspected conditions

2.21
minimum detectable amount
MDA
smallest amount (activity or mass) of a measurand in a sample that will be detected with a probability β of non-detection (Type II error) while accepting a probability α of erroneously deciding that a positive (non-zero) quantity of measurand is present in an appropriate blank sample (Type I error)

2.22
minimum detectable concentration
MDC
minimum detectable amount (MDA) expressed in units of concentration

2.23
minimum testing level
MTL
amount of radioactive material that the service laboratory should be able to measure for participation in the performance testing programme, assuming the sample(s) are free of interference from other radionuclides unless specifically addressed

NOTE The MTLs should not be construed as being the appropriate MDA required for a specific internal dosimetry programme, but rather an acceptable minimum testing level for radiobioassay service laboratories based on good measurement practice.

2.24
MQA plan
measurement quality assurance plan

2.25
phantom
surrogated person or part of a person used for calibration of *in vivo* measurement systems

NOTE A phantom is constructed to allow placement of radionuclides in a geometry approximating internal depositions.

2.26
quality assurance
all those planned and systematic actions necessary to provide adequate confidence that an analysis, measurement, or surveillance programme will perform satisfactorily in service

2.27
quality control
those actions that control the attributes of the analytical process, standards, reagents, measurement equipment, components, system or facility according to predetermined quality requirements

2.28
radiobioassay
measurement of amount or concentration of radionuclide material in the body or in biological material excreted or removed from the body and analysed for purposes of estimating the quantity of radioactive material in the body

2.29
reagent or method blank
contribution of the reagents to the measurement process determined by carrying the reagents through all the operations that are used for the sample

2.30
relative bias
quotient of the bias divided by the expected value

2.31
relative standard deviation
synonymous with coefficient of variation

2.32
repeatability
closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

2.33
reproducibility
closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement

2.34
service laboratory
laboratory performing direct and/or indirect radiobioassay measurements

2.35
standard deviation
s

for a series of n measurements of the same measurand, the quantity s characterizing the dispersion of the results and given by the formula

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \overline{x})^2}{(n-1)}}$$

where

x_i is the result of the ith measurement;

$\overline{x}$ is the arithmetic mean of the n results considered.

2.36
systematic error
mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand

2.37
testing laboratory
laboratory responsible for evaluating the performance of service laboratories in meeting the performance specifications of this part of ISO 12790

2.38
traceability
property of result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

NOTE The unbroken chain of comparisons is called a traceability chain.

2.39
transfer reference standard
TRS
material that contains radionuclide components of interest in chemical and physical forms similar to bioassay specimens, and is used to quantify the amount of activity present in a person or sample measured

NOTE The radionuclides used for the preparation of the TRS are, when possible, related to CRMs. The preparation procedures are verified and documented.

2.40
unbiased
state wherein a measurement of a random variable has zero bias; i.e., if the measured value of the measurement is equal to the expected value of the property being determined

2.41
uncertainty of measurement
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurement

2.42
validation
defining the process of the method capability and determining whether it can be properly applied as intended or a test to determine whether the overall implemented analysis fulfills specified requirements

2.43
verification
act of confirming, substantiating or assuring that an action, condition or goal has been implemented, completed or accomplished according to the specified requirements or a test to prove that a particular step of the analysis fulfills specified requirements

3 Symbols and abbreviated terms

3.1 Symbols

A_{ai} Actual quantity in the test phantom for the ith measurement

A_i Value of the ith measurement in a category being tested

$\dot{B}$ $\dot{B} = B/t$

B_r Relative bias

B_{ri} Relative bias statistic for the ith measurement

C_B Total counts of the appropriate blank (counts)

D Decision level

D_c Decision level expressed in units of radioactivity or quantity of measurand

E Counting efficiency (including correction for self absorption when appropriate) expressed as a fraction, counts per second per becquerel of the measurand

$k_{1-\alpha}$ Abscissa of the standardized normal distribution corresponding to the probability level $1 - \alpha$

K Calibration factor in appropriate units such as counts per second per unit activity

$\dot{K}$ Calibration factor in appropriate units such as counts per second per becquerel