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