

Protección radiológica. Vigilancia y dosimetría interna para miembros del personal expuestos a radionucleidos médicos como fuentes no selladas (ISO 16637:2016) (Ratificada por la Asociación Española de Normalización en julio de 2019.)

UNE-EN ISO 16637:2019

Protección radiológica. Vigilancia y dosimetría interna para miembros del personal expuestos a radionucleidos médicos como fuentes no selladas (ISO 16637:2016) (Ratificada por la Asociación Española de Normalización en julio de 2019.)

Radiological protection - Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources (ISO 16637:2016) (Endorsed by Asociación Española de Normalización in July of 2019.)

Radioprotection - Surveillance et dosimétrie interne des travailleurs exposés lors des utilisations médicales des radioéléments en sources non scellées (ISO 16637:2016) (Entérinée par l'Asociación Española de Normalización en juillet 2019.)

En cumplimiento del punto 11.2.5.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de documento normativo español UNE al documento normativo europeo EN ISO 16637:2019 (Fecha de disponibilidad 2019-06-12)

Este documento está disponible en los idiomas oficiales de CEN/CENELEC/ETSI.

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE.

La correspondiente versión oficial de este documento se encuentra disponible en la Asociación Española de Normalización (Génova 6 28004 MADRID, www.une.org).

Las observaciones a este documento han de dirigirse a:

Asociación Española de Normalización

Génova, 6
28004 MADRID-España
Tel.: 915 294 900
info@une.org
www.une.org

© UNE 2019

Prohibida la reproducción sin el consentimiento de UNE.

Todos los derechos de propiedad intelectual de la presente norma son titularidad de UNE.

EUROPEAN STANDARD

EN ISO 16637

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2019

ICS 13.280

English Version

Radiological protection - Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources (ISO 16637:2016)

Radioprotection - Surveillance et dosimétrie interne des travailleurs exposés lors des utilisations médicales des radioéléments en sources non scellées (ISO 16637:2016)

Strahlenschutz - Überwachung und interne Dosimetrie für Personal, das durch medizinische Radionuklide aus offenen Quellen exponiert wurde (ISO 16637:2016)

This European Standard was approved by CEN on 8 March 2019.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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

Contents	Page
European foreword.....	3

European foreword

The text of ISO 16637:2016 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 16637:2019 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 December 2019, and conflicting national standards shall be withdrawn at the latest by December 2019.

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.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16637:2016 has been approved by CEN as EN ISO 16637:2019 without any modification.

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Symbols and abbreviated terms	5
5 Purpose and need for monitoring programmes in nuclear medical diagnosis and therapy 6	
5.1 General.....	6
5.2 Assessment of the level of likely exposures.....	6
5.3 Monitoring programmes.....	7
5.3.1 General.....	7
5.3.2 Confirmatory monitoring programmes.....	7
5.3.3 Routine monitoring programmes.....	8
5.3.4 Triage monitoring programmes.....	8
5.3.5 Task-related monitoring programmes.....	8
5.3.6 Special monitoring programmes.....	8
5.3.7 Implementation of a monitoring programme.....	9
6 Common radionuclides	10
7 Reference levels	10
8 Routine monitoring programmes	11
8.1 General aspects.....	11
8.2 Individual monitoring.....	12
8.3 Methods and monitoring intervals.....	12
9 Triage monitoring programmes	13
10 Special Monitoring programmes	13
10.1 General aspects.....	13
10.2 Workplace monitoring.....	14
10.3 Individual monitoring.....	14
11 Confirmatory monitoring programmes	15
11.1 General aspects.....	15
11.2 Workplace monitoring.....	15
11.3 Individual monitoring.....	15
12 Measurement techniques and performance criteria	15
12.1 General.....	15
12.2 Measurements performed in a laboratory specialised for radiobioassay.....	16
12.2.1 <i>In vitro</i>	16
12.2.2 <i>In vivo</i>	16
12.2.3 Quality assurance and quality control for bioassay laboratories.....	16
12.3 Measurements performed in nuclear medicine service.....	17
13 Procedure for the assessment of exposures	17
13.1 Interpretation of individual monitoring data for dose assessment.....	17
13.1.1 General.....	17
13.1.2 Dose assessment based on routine monitoring.....	17
13.1.3 Dose assessment based on special monitoring.....	17
13.2 Software tools.....	22
13.3 Uncertainties.....	22
13.4 Quality assurance of the assessment process.....	22
14 Reporting and documentation	23

14.1	Reporting results for <i>in vitro</i> measurements.....	23
14.2	Reporting results for <i>in vivo</i> measurements.....	23
14.3	Documentation of the dose assessment.....	24
Annex A (informative) IAEA Safety Guide RS-G-1.2 “decision factor”.....		25
Bibliography.....		27

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.