SLOVENSKI STANDARD
SIST EN ISO 16637:2019

01-september-2019

Radiološka zaščita - Nadzorovanje in notranja dozimetrija za člane osebja, izpostavljene medicinskim radionuklidom kot odprtemu viru sevanja (ISO 16637:2016)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 16637:2019**

ICS:

13.280	Varstvo pred sevanjem	Radiation protection

SIST EN ISO 16637:2019 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16637

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 16637:2019 E

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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of an identical text or by endorsement, at the latest by December 2019, and conflicting national standards shall be withdrawn at the latest by December 2019.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 16637

First edition
2016-02-15

Radiological protection — Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources

Radioprotection — Surveillance et dosimétrie interne des travailleurs exposés lors des utilisations médicales des radioéléments en sources non scellées

Reference number
ISO 16637:2016(E)

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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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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*.

Introduction

In the course of employment, individuals might work with radioactive materials that, under certain circumstances, could be taken into the body. Protecting workers against risks of incorporated radionuclides requires the monitoring of potential intakes and/or the quantification of actual intakes and exposures. The doses resulting from internal radiation exposure arising from contamination by radioactive substances cannot be measured directly. The selection of measures and programmes for this purpose requires decisions concerning methods, techniques, frequencies, etc. for activity measurements and dose assessment. The criteria permitting the evaluation of the necessity of such a monitoring programme or for the selection of methods and frequencies of monitoring usually depend upon the legislation, the purpose of the radiation protection programme, the probabilities of potential radionuclide intakes, and the characteristics of the materials handled.

For these reasons, ISO standards establishing requirements for monitoring programmes (ISO 20553), laboratory requirements (ISO 28218), and dose assessment (ISO 27048) have been developed. These can be applied in a straightforward manner to many workplaces where internal contamination may occur. In order to apply these standards to staff involved in diagnostic or therapeutic uses of radionuclides in medicine, the short effective half-life of radionuclides commonly used for these purposes and the distance between nuclear medicine department and *in vivo* counting facilities or radio-analytical laboratories shall be taken into account. Consequently, guidance on the application of the three International Standards cited above to nuclear medicine staff was requested by a number of countries.

This International Standard establishes criteria to determine whether intake monitoring is required for staff exposed to medical radionuclides as unsealed sources. It also establishes requirements on the design of such monitoring programmes, associated dose assessments, and laboratory requirements. Recommendations of international expert bodies and international experience with the practical application of these recommendations in radiological protection programmes have been considered in the development of this International Standard. Its application facilitates the exchange of information between authorities, supervisory institutions, and employers. This International Standard is not a substitute for legal requirements.

Radiological protection — Monitoring and internal dosimetry for staff members exposed to medical radionuclides as unsealed sources

1 Scope

This International Standard specifies the minimum requirements for the design of professional programmes to monitor workers exposed to the risk of internal contamination via inhalation by the use of radionuclides as unsealed sources in nuclear medicine imaging and therapy departments. It establishes principles for the development of compatible goals and requirements for monitoring programmes and, when adequate, dose assessment. It presents procedures and assumptions for the risk analysis, for the monitoring programmes, and for the standardized interpretation of monitoring data.

This International Standard addresses the following items:

a) purposes of monitoring and monitoring programmes;

b) description of the different categories of monitoring programmes;

c) quantitative criteria for conducting monitoring programmes;

d) suitable methods for monitoring and criteria for their selection;

e) information that has to be collected for the design of a monitoring programme;

f) general requirements for monitoring programmes (e.g. detection limits, tolerated uncertainties);

g) frequencies of measurements;

h) procedures for dose assessment based on reference levels for routine and special monitoring programmes;

i) assumptions for the selection of dose-critical parameter values;

j) criteria for determining the significance of individual monitoring results;

k) interpretation of workplace monitoring results;

l) uncertainties arising from dose assessments and interpretation of bioassays data;

m) reporting/documentation;

n) quality assurance.

This International Standard does not address the following:

— monitoring and internal dosimetry for the workers exposed to laboratory use of radionuclides such as radioimmunoassay techniques;

— monitoring and internal dosimetry for the workers involved in the operation, maintenance, and servicing of PET cyclotrons;

— detailed descriptions of measuring methods and techniques;

— dosimetry for litigation cases;

— modelling for the improvement of internal dosimetry;

