Radiological protection - Monitoring and internal dosimetry for specific materials - Part 2: Ingestion of uranium compounds (ISO 16638-2:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 16638-2:2022 sisaldab Euroopa standardi EN ISO 16638-2:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 16638-2:2022 consists of the English text of the European standard EN ISO 16638-2:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.08.2022.	Date of Availability of the European standard is 03.08.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16638-2

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English Version

Radiological protection - Monitoring and internal dosimetry for specific materials - Part 2: Ingestion of uranium compounds (ISO 16638-2:2019)

Radioprotection - Contrôle et dosimétrie interne des éléments spécifiques - Partie 2: Ingestion de composés d'uranium (ISO 16638-2:2019)

Strahlenschutz - Überwachung und interne Dosimetrie für bestimmte Stoffe - Teil 2: Ingestion von Uranverbindungen (ISO 16638-2:2019)

This European Standard was approved by CEN on 24 July 2022.

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

Ref. No. EN ISO 16638-2:2022 E

European foreword

The text of ISO 16638-2:2019 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 16638-2:2022 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 February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

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.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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

Endorsement notice

The text of ISO 16638-2:2019 has been approved by CEN as EN ISO 16638-2:2022 without any modification.

Annex G
(informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN-CENELEC national member.

This European Standard does not fall under any Directive/Regulation of the EU.

In the relevant CEN-CENELEC countries, these A-deviations are valid instead of the respective provisions of the European Standard until the national situation causing the A-deviation has changed.

Clause	Deviation
General	Germany Incorporation monitoring in Germany is legally regulated by the German Guidelines on physical radiation protection control for determination of the body dose part 2: Determination of the body dose of internal exposition (incorporation monitoring) of January 12, 2007 Regarding the measurements and the quality control described in this clauses shall comply with the guideline on physical radiation protection control for determination of the body dose part 2: Determination of the body dose of internal exposition (incorporation monitoring) of January 12, 2007
11.3	Germany Measurement uncertainties as described in this clause are legally not taken into account in Germany.

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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.

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

A list of all the parts in the ISO 16638 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In the course of employment, individuals may work with radioactive materials that, under certain circumstances, could be taken into the body. Protecting workers against the risks of incorporated radionuclides needs monitoring for potential intakes and/or quantifying actual intakes and exposures. Internal radiation exposure caused by the contamination of radioactive substances results in doses, which cannot be measured directly. Decisions should be made regarding which methods, techniques, frequencies, etc., to select in order to measure and assess these doses. The criteria for determining the design of a monitoring programme, i.e. its requirements, methods and schedule, usually depends on legislation, the purpose of the overall radiation protection programme, the probabilities of potential radionuclide intakes and the characteristics of the materials handled.

For these reasons, four International Standards addressing monitoring programmes (ISO 20553), laboratory requirements (ISO 28218), dose assessments (ISO 27048) and special cases of inhalation of uranium compounds (ISO 16638-1) have been developed and can be applied in a straightforward manner to many radionuclides for accreditation purposes.

This document has been developed to address the specific issue of monitoring and internal dosimetry for ingestion of uranium compounds. It contributes to harmonizing the practices in the monitoring of occupationally exposed persons while remaining complementary to ISO 16638-1. Occupational intakes solely by ingestion are rare however they may need to be considered in some circumstances, for example; external contamination of the mouth or lips; in cases of poor working practices such as food being eaten in contamination areas. Intakes by ingestion can also occur alongside inhalation depending on the circumstances of the event. Monitoring and dose assessment for intakes by inhalation (ISO 16638-1) are covered in a separate document and would take precedence over the requirements for assessing intakes by ingestion. However, the monitoring requirements are very similar. Uranium is both radiologically and chemically toxic. Hence, the scientific bases of current occupational exposure standards are reviewed in addition to radiation exposure limits.

This document describes the need for a monitoring and internal dosimetry programme for the different compounds of uranium in case of a risk of ingestion and offers guidance on its design. The design of the workplace, the work practices and hygiene practices followed and the protective equipment worn, may all be essential in controlling exposure to this risk. The development of this document has taken into account recommendations from international expert bodies and persons with international experience of the practical application of its recommendations in radiological protection programmes. Its application facilitates the exchanges of information between authorities, supervisory institutions and employers.

Radiological protection — Monitoring and internal dosimetry for specific materials —

Part 2: Ingestion of uranium compounds

1 Scope

This document specifies the minimum requirements for the design of professional programmes to monitor workers exposed to a risk of ingestion to uranium compounds. This document establishes principles for the development of compatible goals and requirements for monitoring programmes and dose assessment for workers occupationally exposed to internal contamination. It establishes procedures and assumptions for risk analysis, monitoring programmes and the standardized interpretation of monitoring data in order to achieve acceptable levels of reliability for uranium and its compounds. It sets limits for the applicability of the procedures in respect to dose levels above which more sophisticated methods need to be applied.

This document addresses those circumstances when exposure could be constrained by either radiological or chemical toxicity concerns.

This document addresses, for ingestion of uranium and its compounds, the following items:

a) purposes of monitoring and monitoring programmes;

b) description of the different categories of monitoring programmes;

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

d) information that is collected for the design of a monitoring programme;

e) procedures for dose assessment based on reference levels for special monitoring programmes;

f) criteria for determining the significance of monitoring results;

g) uncertainties arising from dose assessment and interpretation of bioassays data;

h) reporting/documentation;

i) quality assurance;

j) record keeping requirements.

It is not applicable to the following items:

a) detailed descriptions of measuring methods and techniques for uranium;

b) modelling for the improvement of internal dosimetry;

c) potential influence of counter-measures (e.g. administration of chelating agents);

d) investigation of the causes or implications of an exposure;

e) dosimetry for inhalation exposures and for contaminated wounds.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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*

ISO 15189, *Medical laboratories — Requirements for quality and competence*

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

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
absorption
movement of material to blood regardless of mechanism

Note 1 to entry: Absorption generally applies to the uptake into blood of soluble substances and material dissociated from particles.

3.2
activity
number of spontaneous nuclear disintegrations per unit time

Note 1 to entry: The activity is stated in becquerels (Bq), i.e. the number of disintegrations per second.

3.3
clearance
the action that results in the movement of radioactive material from the site of deposition in tissues and organs

Note 1 to entry: This action can be natural or induced by therapeutic means.

Note 2 to entry: The clearance rate is the rate at which this occurs.

3.4
contamination
radioactive substances on surfaces or within solids, liquids or gases (including the human body), where its presence is unintended or undesirable, or the process giving rise to its presence in such places