



SLOVENSKI STANDARD
SIST EN ISO 16638-1:2017
01-december-2017

**Radiološka zaščita - Nadzorovanje in notranja dozimetrija za posebne materiale -
1. del: Inhalacija uranovih spojin (ISO 16638-1:2015)**

Radiological protection - Monitoring and internal dosimetry for specific materials - Part 1:
Inhalation of uranium compounds (ISO 16638-1:2015)

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Radioprotection - Contrôle et dosimétrie interne des éléments spécifiques - Partie 1:
Inhalation de composés d'uranium (ISO 16638-1:2015)

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Radiological protection - Monitoring and internal dosimetry for specific materials - Part 1: Inhalation of uranium compounds (ISO 16638-1:2015)

Radioprotection - Contrôle et dosimétrie interne des éléments spécifiques - Partie 1: Inhalation de composés d'uranium (ISO 16638-1:2015)

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

The text of ISO 16638-1:2015 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 16638-1:2017 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of an identical text or by endorsement, at the latest by April 2018, and conflicting national standards shall be withdrawn at the latest by April 2018.

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.

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INTERNATIONAL
STANDARD

ISO
16638-1

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**Radiological protection —
Monitoring and internal dosimetry
for specific materials —**

**Part 1:
Inhalation of uranium compounds**

iTeh STANDARD PREVIEW
*Radioprotection — Contrôle et dosimétrie interne des éléments
spécifiques —
(standards.iteh.ai)
Partie 1: Inhalation de composés d'uranium*

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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).

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*.

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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 requires monitoring potential intakes and/or quantifying actual intakes and exposures. The doses resulting from internal radiation exposure arising from contamination by radioactive substances cannot be measured directly. Decisions have to 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, three International Standards addressing monitoring programmes (ISO 20553:2006), laboratory requirements (ISO 28218:2010) and dose assessments (ISO 27048:2011) have been developed and can be applied in a straightforward manner to many radionuclides. However, for a number of specific materials, the practical application of these International Standards is complex and further guidance may be required, e.g. for accreditation purposes.

This International Standard has been developed to address the specific issue of monitoring and internal dosimetry for inhalation of uranium compounds, which reflects

- the growing interest in nuclear energy production and the associated increase in uranium mining and fuel production,
- the large variation of isotopic compositions of the uranium compounds that may be encountered in the workplace, and
- the importance of taking into account both the chemical and the radiological risks arising from exposures to uranium.

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It contributes to harmonizing the practices in the monitoring of occupationally exposed persons while remaining complementary to ISO 20553:2006, ISO 28218:2010 and ISO 27048:2011.

This International Standard describes the need for a monitoring and internal dosimetry programme for the different compounds of uranium and offers guidance on its design. Its development 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 1: Inhalation of uranium compounds

1 Scope

This International Standard specifies the minimum requirements for the design of professional programmes to monitor workers exposed to uranium compounds. It 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 standardised 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 have to be applied.

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

This International Standard addresses, for uranium and its compounds, 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 monitoring results;
- k) interpretation of workplace monitoring results;
- l) uncertainties arising from dose assessment and interpretation of bioassays data;
- m) reporting/documentation;
- n) quality assurance;
- o) record keeping requirements.

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It is not applicable to the following items:

- a) monitoring of exposure due to uranium progeny, including radon;
- b) detailed descriptions of measuring methods and techniques for uranium;
- c) dosimetry for litigation cases;
- d) modelling for the improvement of internal dosimetry;
- e) potential influence of counter-measures (e.g. administration of chelating agents);
- f) investigation of the causes or implications of an exposure;
- g) dosimetry for ingestion exposures and for contaminated wounds.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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

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 20553:2006, *Radiation protection — Monitoring of workers occupationally exposed to a risk of internal contamination with radioactive material*

ISO 28218:2010, *Radiation protection — Performance criteria for radiobioassay*

ISO 27048:2011, *Radiation protection — Dose assessment for the monitoring of workers for internal radiation exposure*

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

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.

3.1 absorption

movement of material into blood regardless of mechanism, which generally applies to the dissociation of particles and the uptake into blood of soluble substances and material dissociated from particles

3.2**absorption Type F**

deposited materials that have high (fast) rates of absorption into body fluids from the respiratory tract

[SOURCE: ICRP 66]

3.3**absorption Type M**

deposited materials that have intermediate (moderate) rates of absorption into body fluids from the respiratory tract

[SOURCE: ICRP 66]

3.4**absorption Type S**

deposited materials that have low (slow) rates of absorption into body fluids from the respiratory tract

[SOURCE: ICRP 66]

3.5**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.

3.6**activity median aerodynamic diameter
AMAD**

value of aerodynamic diameter such that 50 % of the airborne activity in a specified aerosol is associated with particles smaller than the AMAD and 50 % of the activity is associated with particles larger than the AMAD

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Note 1 to entry: The aerodynamic diameter of an airborne particle is the diameter that a sphere of unit density would need to have in order to have the same terminal velocity when settling in air as the particle of interest.

3.7**clearance**

net effect of the biological processes by which radionuclides are removed from the body or from a tissue, organ or region of the body

Note 1 to entry: The clearance rate is the rate at which this occurs.

3.8**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

3.9**critical value**

maximum value for the result of a single measurement in a monitoring programme where it is safe to assume that the corresponding extrapolated annual dose does not exceed a predefined dose level

3.10**decision threshold**

fixed or *a posteriori* value of the measurand by which, when exceeded by the result of an actual measurement of a measurand quantifying a physical effect, it is decided that the physical effect is present

3.11**detection limit**

smallest true value of the measurand that is detectable by the measuring method