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Radiological protection — Monitoring and internal dosimetry for specific materials —

Part 2: Ingestion of uranium compounds

Radioprotection — Contrôle et dosimétrie interne des éléments spécifiques —
Partie 2: Ingestion de composés d'uranium

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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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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

3.5
decision threshold
value of the estimator of the measurand which, when exceeded by the result of an actual measurement using a given measurement procedure of a measurand quantifying a physical effect or quantity, it is decided that the physical effect or quantity is present

Note 1 to entry: Otherwise, this effect is assumed to be absent.

3.6
detection limit
smallest true value of the measurand which ensures a specified probability of being detectable by the measurement procedure

3.7
committed effective dose
sum of the products of the committed organ or tissue equivalent doses and the appropriate tissue weighting factors

Note 1 to entry: In the context of this document, the integration time is 50 years following any intake.

Note 2 to entry: The committed effective dose is expressed in Sievert (Sv).

3.8
excretion function
function describing the fraction of an intake excreted per day after a given time has elapsed since the intake occurred

Note 1 to entry: The excretion function is expressed in becquerels per day (Bq/d).

3.9
event
any unintended occurrence, including operating error, equipment failure or other mishap, the consequences or potential consequences of which are not negligible from the point of view of protection or safety

3.10
intake
activity (3.2) of a radionuclide taken into the body in a given time period or as a result of a given *event* (3.9)

Note 1 to entry: The intake is expressed in becquerels (Bq).

3.11
in vitro analyses
analyses that include measurements of radionuclides present in biological samples taken from an individual

Note 1 to entry: These include urine, faeces and nasal samples; in special monitoring programmes, samples of other materials such as blood and hair may be taken.

3.12
monitoring
measurements made for the purpose of assessment or control of exposure to radioactive material and the interpretation of the results

Note 1 to entry: This document distinguishes three different categories of monitoring programmes, namely *confirmatory monitoring programme* (3.13), *special monitoring programme* (3.14) and *task-related monitoring programme* (3.15), as well as one type of monitoring, namely *individual monitoring* (3.16), which features in each category.

3.13
confirmatory monitoring programme
monitoring programme carried out to confirm assumptions about working conditions and that a routine monitoring programme for dose assessment purposes is not required

3.14
special monitoring programme
monitoring programme performed to quantify suspect significant exposures following an *event* (3.9)

3.15
task-related monitoring programme
monitoring programme related to a specific operation, or providing information on a specific operation of limited duration, or following major modifications applied to the installations or operating procedures, or confirming that the routine monitoring programme is suitable

3.16
individual monitoring
monitoring (3.12) by means of equipment worn by individual workers, by measurement of the quantities of radioactive materials in or on the bodies of individual workers, or by measurement of radioactive material excreted by individual workers

3.17
quality assurance
planned and systematic actions necessary to provide adequate confidence that a process, measurement or service satisfy given requirements for quality such as those specified in a licence

3.18
quality control
part of *quality assurance* (3.17) intended to verify that systems and components correspond to predetermined requirements

3.19
reference level
value of measured quantities above which some specified action or decision should be taken

3.20
scattering factor
geometric standard deviation of the lognormal distribution of bioassay measurements

4 Symbols and abbreviated terms

4.1 Symbols

D_v committed effective dose due to annual intake (Sv) such that lower doses may be discounted for the purpose of the monitoring programme

$E(50)$ committed effective dose (Sv) for an integration period of 50 years

$e(50)$ dose coefficient: committed effective dose per unit intake ($Sv \cdot Bq^{-1}$), for an integration period of 50 years

f_A alimentary tract transfer factor, fraction of activity entering the alimentary tract that is absorbed from the gut in the absence of both radioactive decay losses and endogenous input to the tract

I intake in Bq (3.13)

$m(t_i)$ predicted value of the measured quantity (Bq/d/Bq = d^{-1}) at time, t_i, for unit intake (excretion or retention function, for unit intake)

$m_c(t_i)$ predicted value of the quantity measured after a period of t_i, days of a chronic unit intake per day (excretion or retention function at time, t_i, for chronic unit intake per day)

4.2 Abbreviated terms

CRM certified reference material (see ISO 28218[2])

DU depleted uranium (uranium with an assay of U-235 that is lower than its content in natural uranium)

HEU high enriched uranium (uranium with an assay of U-235 equal to or more than 20 %)

IARC International Agency for Research on Cancer

ICRP International Commission on Radiological Protection

LDH lactate dehydrogenase

LEU low enriched uranium (uranium with an assay of U-235 from the natural level to 20 %)

LOAEL lowest-observed-adverse-effect level

NOAEL no-observed-adverse-effect level

TRS transfer reference standard (see ISO 28218[2])

U-nat uranium compound with natural isotopic composition

5 Purpose and need for monitoring programmes

Uranium compounds are considered a mixture of three major isotopes: U-234, U-235 and U-238; but in certain cases U-236, U-233 and U-232 are also included. This document describes four different isotopic compositions, as examples, representing natural (U-nat), depleted (DU), low (LEU) and high (HEU) enriched uranium forms (see Table 1) based on their typical uranium isotopic compositions encountered in the nuclear industry. Specific isotopic compositions should be used if available.

Table 1 — Isotopic composition of natural uranium (U-nat), depleted uranium (DU), low enriched uranium (LEU) and high enriched uranium (HEU), by mass and total uranium alpha activities, based on specific activity values in ICRP 107[12]

	U-238		U-235		U-234			
	Isotopic composition by mass	Total alpha activity	Isotopic composition by mass	Total alpha activity	Isotopic composition by mass	Total alpha activity	Total alpha activity	Alpha activity ratio U-234/U-238
	%	%	%	%	%	%	Bq/g	
U-nat	99,275	48,26	0,72	2,25	0,005 5	49,49	2,56E+04	1,03
DU	99,799	83,45	0,2	1,07	0,001 0	15,48	1,49E+04	0,186
LEU	96,471	14,78	3,5	3,45	0,028 84	81,78	8,12E+04	5,54
HEU	6,41	0,042	92,8	3,92	0,79	96,04	1,89E+06	2287

The general population is exposed to ubiquitous uranium in the environment with ingestion of food and drinking water being the primary contributors to body burden. In industry, uranium can be present in a variety of chemical forms, often in association with other radionuclides. In general, there is insufficient high-quality data regarding ingestion by workers to be able to determine the absorption parameters for uranium and, therefore, describe the biokinetics of the material which would form the base for assessing radiological or chemical constraints or optimising monitoring procedures. However, the absorption data can be obtained from animal studies designed specifically to calculate the material specific absorption parameters in a range of industrial materials. The relative importance of chemical and radiological toxicities of ingested uranium depends on the degree of enrichment of U-235 (and U-234), the compound solubility, and the chemical speciation. In order to recommend material-specific dose coefficients and predict the biokinetics of uranium in humans, the absorption parameter values obtained from the animal studies are combined with human physiology data obtained from the ICRP human alimentary tract model (HATM)[10] and the ICRP systemic model for uranium[8].

The purpose of monitoring in general is to verify and document that the worker is protected adequately against risks from radionuclide intakes and the protection complies with legal requirements. Therefore, monitoring forms part of the overall radiation protection programme. The programme starts with an assessment to identify work situations in which there is a risk of internal contamination of workers by ingestion, and to quantify the likely intake of radioactive material and the resulting committed effective dose received.

Work-related ingestion of uranium compounds can occur after ingestion of contaminated food or beverages; by transfer of contamination by hand-to-mouth or object-to-mouth contact; and by the more passive but more direct mechanism of deposition of contaminants around the mouth and into the oral cavity. Intakes by ingestion can be controlled through effective hand washing and cleaning or minimized with occupational hygiene recommendations of no food and no drink consumption in the workplace and by wearing individual protective equipment. Exposures by ingestion would not be expected under normal circumstances and hence there is no requirement for a routine monitoring programme. Work-related accidental ingestion can occur as a result of poor work practices and lack of personal hygiene. Decisions about the need and the design of the monitoring programme should be made in the light of such a risk assessment with mainly special or confirmatory or task-related individual monitoring. Factors determining the extent of a monitoring programme are the magnitude of likely exposures and the requirement to identify accidental exposure events.

In order to improve both risk assessment and management of uranium, there is a need for adapted exposure limit values. The process of setting exposure limits begins with a careful analysis of toxicological studies with relevant conditions of exposure, which is compared with actual exposure. The final value takes into account the risk, as well as practical and economic constraints. Protective values are regularly revised and modified depending on: new research, new risk assessment or improvement of detection limits following new instrumental analysis methods. The toxicity of uranium varies according to its chemical form and isotopic composition. Absorption rates differ with the solubility of the compound. Those limits need to take into account both chemical and radiological risks. Most regulatory bodies agree that uranium chemical toxicity requires consideration when the uranium content in the kidney exceeds 3 $\mu g \cdot g^{-1}$ (retrospective) and regarding radiological hazards when the annual effective dose is above 6 mSv (prospective).

Judgements on the efficacy and accuracy of monitoring programmes depend on detailed information about the biokinetics of uranium. Generally, this information is not available from human exposures. It is often based on biokinetic data predicted by combining material-specific absorption parameter values, obtained from animal or in vitro studies, with human data and on the systemic behaviour of uranium. The ICRP have long considered it appropriate to use such material-specific parameters rather than default parameters. For all uranium compounds, large errors in the assessment of intake can occur in the absence of material specific biokinetic data for the chemical form ingested.

For uranium and its compounds, the risk analysis shall be based both on consideration of its chemical toxicity and its radiation toxicity. The validity of currently recommended limits for uranium, which were derived from judgemental decisions on nephrotoxicity, simplistic biokinetic models of the human alimentary tract and outdated definitions of the specific activity of uranium, is doubtful.

