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Radiological protection — Monitoring and internal dosimetry for specific materials —

Part 1: Inhalation of uranium compounds

Radioprotection — Contrôle et dosimétrie interne des éléments spécifiques —
Partie 1: Inhalation de composés d'uranium

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

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Foreword

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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 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.

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.

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

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

3.12
annual dose
committed effective dose resulting from all intakes occurring during a calendar year

Note 1 to entry: The term “annual dose” is not used to represent the dose received in a year from all preceding intakes.

3.13
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 International Standard, the integration time is 50 years following any intake.

3.14
equivalent dose
product of the absorbed dose and the radiation weighting factor for the specific radiation at this point

3.15
committed equivalent dose
time integral of the equivalent dose rate in a particular tissue or organ following intake of radioactive material into the body of a reference person

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

3.16
excretion function
function describing the fraction of an intake excreted per day after a given time has elapsed since the intake occurred

3.17
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

3.18
intake
<process> act or process of taking radionuclides into the body by inhalation or ingestion or through the skin

3.19
intake
<quantity> activity of a radionuclide taken into the body in a given time period or as a result of a given event

3.20
***in vitro* analyses**
indirect measurements
analyses that include measurements of radioactivity 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.

3.21
***in vivo* measurements**
direct measurements
measurement of radioactivity present in the human body carried out using detectors to measure the radiation emitted

Note 1 to entry: Normally, the measurement devices are whole-body or partial-body (e.g. lung, thyroid) counters.

3.22
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 International Standard distinguishes four different categories of monitoring programmes, namely *confirmatory monitoring programme* (3.23), *routine monitoring programme* (3.24), *special monitoring programme* (3.25) and *task-related monitoring programme* (3.26), as well as two different types of monitoring, namely *individual monitoring* (3.27) and *workplace monitoring* (3.28), which feature in each category.

3.23
confirmatory monitoring programme
monitoring programme carried out to confirm assumptions about working conditions

EXAMPLE Monitoring programme carried out to confirm that significant intakes have not occurred.

3.24
routine monitoring programme
monitoring programme associated with continuing operations and intended to demonstrate that working conditions, including the levels of individual dose, remain satisfactory and meet regulatory requirements

3.25
special monitoring programme
monitoring programme performed to quantify significant exposures following actual or suspected abnormal events

3.26
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

3.27
individual monitoring
monitoring 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

3.28
workplace monitoring
monitoring using measurements made in the working environment

3.29
monitoring interval
period between two consecutive times of measurement

3.30
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

3.31
quality control
part of quality assurance intended to verify that systems and components correspond to predetermined requirements

3.32
quality management
all activities of the overall management function that determine the quality policy, objectives and responsibilities, and that implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system

3.33
investigation level
level of dose, exposure or intake at or above which investigation has to be made in order to reduce the uncertainty associated with the dose assessment

3.34
recording level
level of dose, specified by the employer or the regulatory authority, at or above which values of dose received by workers are to be entered in their individual records

3.35
reference level
value of measured quantities above which some specified action or decision should be taken

3.36
retention function
function describing the fraction of an intake present in the body or in a tissue, organ or region of the body after a given time has elapsed since the intake occurred

3.37
scattering factor
geometric standard deviation of the lognormal distribution of bioassay measurements

3.38
time of sampling
<*in vitro* analysis> time at which the biological sample (e.g. urine, faeces) was provided by the individual concerned, i.e. the end time of the collection period

3.39
time of measurement
<*in vivo* analysis> time at which the measurement begins

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 for an integration period of 50 years
$e(50)$	Dose coefficient: committed effective dose per unit intake
f_1	Gastro-intestinal uptake factor
I	Intake
$m(t_i)$	Predicted value of the measured quantity at time, t_i, for unit intake (excretion or retention function at time, t_i, 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)
M_i	Measurement value at time, t_i
M_c	Critical value
ΔT	Duration of the monitoring interval (in days)
$\Delta T/2$	mid-time of the monitoring interval (in days)

$E(t)$ Value of the excretion function at time t (day) after a unit intake

$R(t)$ Value of the retention function at time t (day) after a unit intake

A_{DL} Detection limit

4.2 Abbreviated terms

AMAD Activity median aerodynamic diameter

CRM Certified reference material (ISO 28218)

DAC Derived air concentration

DIL Derived investigation level

DL Annual dose limit = 0,02 Sv

DRL Derived recording level

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

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

LOAEL Lowest-observed-adverse-effect level

MRL Minimal risk level

NOAEL No-observed-adverse-effect level

PAS Personal air sampler

RPE Respiratory protective equipment

SAS Static air sampler

TRS Transfer reference standard (ISO 28218)

U-nat Uranium compound with natural isotopic composition

WHO World Health Organization

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-233 and U-232 are also included. This International Standard describes four different isotopic compositions 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[20]

	U-238		U-235		U-234		Total alpha activity	Alpha activity ratio U-234/ U-238
	Isotopic composition by mass	Total alpha activity	Isotopic composition by mass	Total alpha activity	Isotopic composition by mass	Total alpha activity		
	%	%	%	%	%	%	Bq/g	
U-nat	99,275	48,26	0,72	2,25	0,0055	49,49	2,56E+04	1,03
DU	99,799	83,45	0,2	1,07	0,0010	15,48	1,49E+04	0,186
LEU	96,471	14,78	3,5	3,45	0,02884	81,78	8,12E+04	5,54
HEU	6,41	0,042	92,8	3,92	0,79	96,04	1,89E+06	2282

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 inhalation 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 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. 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 deposition and particle transport data obtained from the ICRP Human Respiratory Tract Model[8] and the ICRP systemic model for uranium[10]; deposition and particle transport parameters are assumed by ICRP to be independent of the chemical form inhaled.

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, and to quantify the likely intake of radioactive material and the resulting committed effective dose received. Decisions about the need for monitoring and the design of the monitoring programme should be made in the light of such a risk assessment, as described in ISO 20553.

Routine monitoring is performed to quantify normal exposures, i.e. where there is no evidence to indicate that acute intakes have occurred but where chronic exposures cannot be ruled out. Routine monitoring programmes assume that working conditions and the risks of intake remain reasonably constant. The design of this type of programme of regular measurements is heavily dependent on the level of the annual dose, which shall be readily and reliably quantified. The level should be well below legally relevant limits, accounting for uncertainties; for example, in activity measurement and dose assessment. If the level is too high, intakes representing considerable fractions of dose limits could be overlooked, while a low value may result in unnecessary efforts at low exposures.

Special monitoring is performed to quantify significant exposures following actual or suspected abnormal events. In comparison to routine monitoring, the time of intake is usually much better known and additional information may be available, which helps to reduce the uncertainty of assessment. The purposes of dose assessment in such cases include

— assistance in decisions about countermeasures (e.g. decorporation therapy),

— compliance with legal regulations, and

— help to improve conditions in the workplace.

In most cases, special monitoring is performed individually. In cases where there is reason to suspect that exposure limits could be exceeded, it may be appropriate to extend the measurements in order to determine individual retention and excretion functions and biokinetic model parameters.

Confirmatory monitoring may be required to check the assumptions underlying the procedures previously selected. It may consist of workplace or individual monitoring, e.g. as occasional measurements to investigate the potential accumulation of activity in the body.

Task-related monitoring applies to a specific operation. The purpose and the dose criteria for carrying out task-related monitoring are identical to those for routine monitoring.

Individual monitoring gives information needed to assess the exposure of a single worker by measuring individual body activities, excretion rates or activity inhaled (using personal air samplers, see 8.2).

Workplace monitoring, which includes *collective monitoring*, provides exposure assessments for a group of workers assuming identical working conditions, i.e. risks of intake as well as all factors influencing the resulting doses. It is mainly used in cases where individual monitoring is not appropriate and it may also be needed in those cases where individual monitoring is not sufficiently sensitive. In some cases results of workplace monitoring are needed to support individual dose assessments (e.g. air monitoring may provide information on the time of an intake).

Factors determining the extent of a monitoring programme are

— the magnitude of likely exposures,

— the requirement to identify accidental exposure events, and

— the need to assess the effectiveness of respiratory protective equipment (RPE).

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 is prevalent when uranium content in the kidney exceeds 3 μg g^{-1} (retrospective) and for radiological hazard 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, particularly lung retention and excretion kinetics. 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 on particle deposition and transport associated with the respiratory tract 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 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 respiratory tract and outdated definitions of the specific activity of uranium, is doubtful. 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 inhaled, inadequate information on the pattern of exposure and an inappropriate choice of the monitoring interval.

The toxicity of uranium varies according to its chemical form, isotopic composition and route of exposure. On the basis of the toxicity of different uranium compounds in animals, it was concluded that the relatively more water-soluble compounds were the most potent renal toxicants. The less water-soluble compounds were of moderate-to-low renal toxicity, and the insoluble compounds had little potential to cause renal toxicity but could cause pulmonary toxicity when exposure was by inhalation.

Uranium is unique among the elements because it presents both a chemical and a radiological hazard. For soluble uranium compounds, with a U-235 enrichment by mass no greater than 3 %, limits on intake