SLOVENSKI STANDARD
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Radiološka zaščita - Ocena odmerka doze za spremljanje stanja delavcev glede notranje izpostavljenosti sevanju (ISO 27048:2011)

Radiation protection - Dose assessment for the monitoring of workers for internal radiation exposure (ISO 27048:2011)

Strahlenschutz - Dosisermittlung für die Überwachung der inneren Strahlungsbelastung von beruflich strahlenexponierten Personen (ISO 27048:2011)

Radioprotection - Estimation de la dose interne dans le cadre de la surveillance des travailleurs en cas d'exposition aux rayonnements (ISO 27048:2011)

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Radiation protection — Dose assessment for the monitoring of workers for internal radiation exposure

Radioprotection — Estimation de la dose interne dans le cadre de la surveillance des travailleurs en cas d'exposition aux rayonnements

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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 organisations, 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 standardisation.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 27048 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

Introduction

The doses resulting from internal radiation exposure arising from contamination by radioactive substances cannot be measured directly. Workers are monitored by making systematic measurements of activity concentrations in air, activity in the body or excretion rates (see ISO 20553). The quantitative interpretation of such measured activities requires well-defined models and data describing the behaviour of radioactive substances in the human body. Such models and comprehensive data are provided by the International Commission on Radiological Protection (ICRP). The practical use of these models, however, requires assumptions to be made regarding the circumstances of an intake event (either known or assumed) such as information on the chemical and physical characteristics of the radioactive material to which the individual was exposed and the length of the time interval between intake and measurement.

In the case of an abnormal event leading to significant intake of a radioactive substance an exhaustive investigation may be justified to assess the internal dose as reliably as possible. The procedure to be applied in such a situation strongly depends on the individual case and is less amenable to standardisation. However, when monitoring workers, the great majority of measurements indicate minor, if not negligible, exposures. For these cases, while it is important to ensure the reproducibility of dose assessments, it is also important to optimise the effort and cost involved in making the interpretation.

Various intercomparison studies have revealed that, in spite of the availability of scientific support in the form of International Atomic Energy Agency (IAEA)[1][2][3][4][5] and ICRP[6][7][8][9][10][11][12][13][14][15][16] recommendations, the actual application of identical models and data by different laboratories often results in dose assessments differing by orders of magnitude. There is, therefore, a need to lay down standard procedures for assessing internal doses using exposure data, body activities or excretion rates, in order to achieve consistency and reliability in the assessment of doses.

This International Standard should improve the reproducibility of dose assessments while ensuring that the level of effort required for data interpretation is commensurate with the seriousness of the exposure. It should enable the exchange of consistent dosimetric information among laboratories and authorities, including across international borders. It is expected that it form the basis for certification, accreditation or approval in this field, for which there is a growing demand.

Radiation protection — Dose assessment for the monitoring of workers for internal radiation exposure

1 Scope

This International Standard specifies the minimum requirements for the evaluation of data from the monitoring of workers occupationally exposed to the risk of internal contamination by radioactive substances. It presents procedures and assumptions for the standardised interpretation of monitoring data, in order to achieve acceptable levels of reliability. Those procedures allow the quantification of exposures for the documentation of compliance with regulations and radiation protection programmes. Limits are set for the applicability of the procedures in respect of the dose levels above which more sophisticated methods will have to be applied.

This International Standard addresses the following:

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

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

c) criteria for determining the significance of monitoring results;

d) interpretation of workplace monitoring results;

e) uncertainties arising from sampling, measurement techniques and working conditions;

f) the special topics of

   1) interpretation of multiple data arising from different measurement methods at different times,

   2) handling data below the decision threshold,

   3) rogue data, and

   4) calculation of doses to the embryo/foetus and infant;

g) reporting/documentation;

h) quality assurance.

It is not applicable to the following:

— dosimetry for litigation cases;

— modelling for the improvement of internal dosimetry;

— the potential influence of decorporation measures (e.g. administration of chelating agents);

— the investigation of the causes or implications of an exposure;

— dosimetry for contaminated wounds.

2 Normative references

The following referenced documents are indispensable for the application 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/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, *Radiation protection — Performance criteria for radiobioassay*

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 and ISO 5725-3 and the following apply.

3.1
absorption
absorption characterised by its rate in the deposited material and which, depending on the material, is denoted as being of type F, M or S

3.1.1
absorption type F
deposited materials that have high (fast) rates of absorption into body fluids from the respiratory tract

3.1.2
absorption type M
deposited materials that have intermediate (moderate) rates of absorption into body fluids from the respiratory tract

3.1.3
absorption type S
deposited materials that have low (slow) rates of absorption into body fluids from the respiratory tract

3.2
activity
number of spontaneous nuclear disintegrations per unit time

NOTE The activity is stated in becquerels (Bq), i.e. the number of disintegrations per second.

3.3
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 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.

3.4
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 The *clearance rate* is the rate at which this occurs.

3.5
contamination
activity of radionuclides present on surfaces, or within solids, liquids or gases (including the human body), where the presence of such radioactive material is unintended or undesirable

3.6
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 will not exceed a predefined dose level

3.7
decision threshold
fixed 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

NOTE The decision threshold is the critical value of a statistical test for the decision between the hypothesis that the physical effect is *not* present and the alternative hypothesis that it *is* present. When this value is exceeded by the result of an actual measurement, this is taken to indicate that the hypothesis should be rejected. The statistical test shall be designed such that the probability of wrongly rejecting the hypothesis (error of the first kind) is at most equal to a given value, α.

3.8
detection limit
smallest true value of the measurand which is detectable by the measuring method

NOTE The detection limit is the smallest true value of the measurand which is associated with the statistical test and hypothesis according to ***in vivo* measurement** (3.14) by the following characteristics: if, in reality, the true value is equal to or exceeds the detection limit, the probability of wrongly not rejecting the hypothesis (error of the second kind) shall be at most equal to a given value, β.

3.9 Doses[17]

3.9.1
annual dose
committed effective dose resulting from all intakes occurring during a calendar year

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

3.9.2
committed effective dose
time integral of the equivalent dose rate over an integration period, which, in the context of this International Standard, is 50 years following any intake

3.9.3
effective dose
sum of weighted equivalent doses in all tissues and organs of the body

3.10
excretion function
fraction of an intake excreted per day after a given time has elapsed since the intake occurred

3.11
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

3.12
intake
activity of a radionuclide taken into the body in a given time period or as a result of a given event

3.13
***in vitro* analyses**
indirect measurements
analyses including measurements of radioactivity present in biological samples taken from an individual

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

3.14
***in vivo* measurement**
direct measurements
measurement of radioactivity present in the human body carried out using detectors to measure the radiation emitted

NOTE Normally, the measurement devices are whole-body or partial-body (e.g. lung, thyroid) counters.

3.15
monitoring
measurements made for the purpose of assessment or control of exposure to radioactive material and the interpretation of the results

NOTE This International Standard distinguishes four different *categories* of monitoring programmes, namely **confirmatory monitoring programme** (3.15.1.1), **routine monitoring programme** (3.15.1.2), **special monitoring programme** (3.15.1.3), and **task-related monitoring programme** (3.15.1.4), as well as two different *types* of monitoring, namely **individual monitoring** (3.15.2.1) and **workplace monitoring** (3.15.2.2), which feature in each category.

3.15.1 Categories of monitoring programme

3.15.1.1
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.

3.15.1.2
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 to meet regulatory requirements

3.15.1.3
special monitoring programme
monitoring programme performed to quantify significant exposures following actual or suspected abnormal events

3.15.1.4
task-related monitoring programme
monitoring programme related to a specific operation, to provide information on a specific operation of limited duration, or following major modifications applied to the installations or operating procedures, or to confirm that the routine monitoring programme is suitable

3.15.2 Types of monitoring

3.15.2.1
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

3.15.2.2
workplace monitoring
monitoring using measurements made in the working environment

3.16
monitoring interval
period between two consecutive times of measurement

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

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

3.19
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

3.20
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

3.21
reference level
investigation level or recording level

3.22
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

3.23
scattering factor
geometric standard deviation of the lognormal distribution of bioassay measurements

3.24
time of measurement
⟨*in vitro* analysis⟩ time at which the biological sample (e.g. urine, faeces) was taken from the individual concerned

3.25
time of measurement
⟨*in vivo* analysis⟩ time at which the measurement begins

4 Symbols and abbreviated terms

α	probability of falsely claiming the presence of activity in a sample
β	probability of falsely claiming the absence of a component in a sample
D_v	annual committed effective dose (Sv) such that lower doses may be discounted for the purpose of the monitoring programme (maximum value: 0,1 mSv)
E_v	level of annual dose (Sv) such that lower doses may be considered negligible for the purpose of the monitoring programme (maximum value: 0,1 mSv)
$E(50)$	committed effective dose
$e(50)$	dose coefficient: committed effective dose per unit intake
f_A	gastro-intestinal uptake factor
I	intake
$L_i(I)$	likelihood function
$m(t)$	predicted value of the measured quantity at time, t, for unit intake (excretion or retention function at time, t_i, for unit intake)
$m_c(t)$	predicted value of the quantity measured after a period of t 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
n	in routine monitoring, number of monitoring intervals in a calendar year, i.e. $365/\Delta T$
P	activity to be measured (*in vitro* or *in vivo*) corresponding to all known, already documented intakes
N	number of measurements below the decision threshold
K_{SF}	scattering factor of the monitoring method applied
ΔT	duration of the monitoring interval (in days)
t_m	time of the current measurement
t_i	time of the assumed intake
y^*	decision threshold

5 Derivation of critical values for routine monitoring programmes

Critical values, M_c — the maximum value for the result of a single measurement where the corresponding extrapolated annual dose will not exceed a predefined dose level — shall be derived for each routine monitoring programme. This dose level shall be set such that lower doses may be considered negligible (i.e. reported as zero dose). For measurement results below M_c, there is no need to evaluate the intake or dose explicitly: the dose may be regarded as insignificant. The measured value (if above the decision threshold) shall be recorded in order to document the fact that the measurement was carried out and to provide information to support any possible future reassessment of dose.

The annual committed effective dose, D_v, selected as the dose level for the derivation of M_c shall not exceed 0,1 mSv, unless required differently in national law.

The critical value, M_c, for an individual routine monitoring programme depends on

— the monitoring interval determined in accordance with ISO 20553, and

— the distribution and retention in the body or the excretion rate from the body of the contaminant.

Critical values may be calculated for air concentrations provided that these calculations are based on a realistic assessment of the air concentration in the breathing zone of the worker.

Assuming a single acute intake at the midpoint of the monitoring interval, M_c for a routine monitoring programme can be calculated using Equation (1):

$$M_c = \frac{D_v \times m(\Delta T/2)}{e(50)} \times \frac{\Delta T}{365} \quad (1)$$

where

D_v is the level of annual dose (Sv) such that lower doses may be discounted for the purpose of the monitoring programme;

$m(\Delta T/2)$ is, for *in vitro* measurements, the value of the excretion function at time $\Delta T/2$ (days) after a unit intake, and, for *in vivo* measurements, the value of the retention function at time $\Delta T/2$ (days) after a unit intake;

$e(50)$ is the dose coefficient: the committed effective dose per unit intake for inhalation (appropriate absorption type).

Equation (1) is based on the assumption that only one radionuclide is incorporated. For mixtures of radionuclides, typical isotope ratios (weighted by the dose coefficients) shall be applied to reduce M_c.

Critical values, M_c for D_v = 0,1 mSv for each *in vitro* and *in vivo* measurement are given in Tables 1 to 5 for the selected radionuclides and the monitoring intervals defined in ISO 20553 for a routine monitoring programme.

The fact that nuclides and critical values are listed in Tables 1 to 5 does not imply that the corresponding measurement method alone is adequate for routine monitoring. For some of the nuclides, actual detection limits do not fulfil the requirements of ISO 20553. Data for these nuclides are provided to give a numerical basis for decisions on whether the monitoring method is appropriate. The measurements for which numbers are given may supplement other monitoring procedures, e.g. workplace monitoring.