DRAFT INTERNATIONAL STANDARD

ISO/DIS 16637

ISO/TC **85**/SC **2**

Secretariat: **AFNOR**

Voting begins on:
2014-01-15

Voting terminates on:
2014-04-15

Radiological protection — Monitoring and internal dosimetry for staff exposed to medical radionuclides as unsealed sources

Radioprotection — Surveillance et dosimétrie interne des travailleurs exposés lors des utilisations médicales des radioéléments en sources non scellées

ICS: 13.280

Reference number
ISO/DIS 16637:2013(E)

Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

ISO 16637 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

Introduction

In the course of employment, individuals might work with radioactive materials that, under certain circumstances, could be taken into the body. Protecting workers against risks of incorporated radionuclides requires the monitoring of potential intakes and/or the quantification of actual intakes and exposures. The doses resulting from internal radiation exposure arising from contamination by radioactive substances cannot be measured directly. The selection of measures and programmes for this purpose requires decisions concerning methods, techniques, frequencies etc. for measurements and dose assessment. The criteria permitting the evaluation of the necessity of such a monitoring programme or for the selection of methods and frequencies of monitoring usually depend upon the legislation, the purpose of the radiation protection programme, the probabilities of potential radionuclide intakes, and the characteristics of the materials handled.

For these reasons, three ISO standards for the monitoring programmes (20553:2006), for the laboratory requirements (28218:2010), and for the dose assessment (27048:2011) have been developed and can be applied in a straightforward manner to many workplaces where internal contamination may occur. However, their application for the staff involved in the diagnostic or therapeutic use of radionuclides in medicine requires account to be taken of special aspects resulting from the short effective half-times of the nuclides in use and from the distances between department of nuclear medicine and whole body and thyroid counting facilities or laboratories undertaking spectrometry on urine samples. Consequently, guidance for the practical application of the three standards cited above to the nuclear medicine staff was requested by a number of countries.

This International Standard offers guidance for the decision whether a monitoring is required for staff exposed to medical radionuclides as unsealed sources and how it should be designed, for the dose assessment and for the laboratories requirements. Recommendations of international expert bodies and international experience with the practical application of these recommendations in radiological protection programmes have been considered in the development of this International Standard. Its application facilitates the exchanges of information between authorities, supervisory institutions and employers. The International Standard is not a substitute for legal requirements.

Radiological protection — Monitoring and internal dosimetry for staff exposed to medical radionuclides as unsealed sources

1 Scope

This International Standard specifies the minimum requirements for the design of professional programmes to monitor workers exposed to the risk of internal exposure by the use of radionuclides as unsealed sources in nuclear medicine departments and establishes principles for the development of compatible goals and requirements for monitoring programmes and, when adequate, dose assessment. It presents procedures and assumptions for the risk analysis, for the monitoring programmes and for the standardised interpretation of monitoring data.

This International Standard addresses the following items:

a) purposes of monitoring and of 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 assessments and interpretation of bioassays data;

m) reporting/documentation;

n) quality assurance.

This International Standard does not address

— monitoring and internal dosimetry for the workers exposed to laboratory use of radionuclides such as radioimmunoassay techniques;

— monitoring and internal dosimetry for the workers involved in the operation, maintenance and servicing of PET cyclotrons;

— detailed descriptions of measuring methods and techniques;

— dosimetry for litigation cases;

— modelling for the improvement of internal dosimetry;

— the potential influence of medical treatment of the internal contamination;

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

— dosimetry for ingestion exposures.

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

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99, ISO 20553, ISO 28218 and ISO 27048 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

3.2
absorption type F
deposited materials that have high (fast) rates of absorption into body fluids from the respiratory tract

3.3
absorption type M
deposited materials that have intermediate (moderate) rates of absorption into body fluids from the respiratory tract

3.4
absorption type S
deposited materials that have low (slow) rates of absorption into body fluids from the respiratory tract

3.5
activity
number of spontaneous nuclear transformations per unit time

Note 1 to entry: The activity is stated in becquerel (Bq), i.e. the number of transformations 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
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

3.8
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

3.9
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

3.10
detection limit
smallest true value of the measurand which is detectable by the measuring method

3.11
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.

3.12
committed effective dose
sum of the products of the committed organ or tissue equivalent doses and the appropriate tissue weighting factors. In the context of this International Standard, the commitment period (integration time following the intake) is taken to be 50 years

3.13
effective dose
sum of the products of the committed organ or tissue equivalent doses and the appropriate tissue weighting factors

3.14
excretion function
fraction of an intake excreted per day after a given time has elapsed since the intake occurred

3.15
event = incident
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

3.16
intake
activity of a radionuclide taken into the body in a given time period or as a result of a given event

3.17
***in vitro* analyses**
indirect measurements
analyses including 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.

3.18
***in vivo* measurement**
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.

3.19
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 five different *categories* of monitoring programmes, namely **routine monitoring programme** (3.20), **task-related monitoring programme** (3.21), **triage monitoring programme** (3.22), **special monitoring programme** (3.23), and **confirmatory monitoring programme** (3.24).

Note 2 to entry: This International Standard distinguishes two different *types* of monitoring, namely **individual monitoring** (3.25) and **workplace monitoring** (3.26), which feature in each category.

3.20
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

3.21
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

3.22
triage monitoring programme
monitoring programme consist of frequent measurements performed in the nuclear medicine centres that does not enable one to calculate a dose but to verify that a given threshold of potential intake is not surpassed

3.23
special monitoring programme
monitoring programme performed to quantify significant exposures following actual or suspected abnormal events

3.24
confirmatory monitoring programme
monitoring programme carried out to confirm assumptions about working conditions, for example that significant intakes have not occurred

3.25
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

3.26
workplace monitoring
monitoring using measurements made in the working environment

3.27
monitoring interval
period between two consecutive times of measurement

3.28
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

3.29
quality control
part of quality assurance intended to verify that systems and components correspond to predetermined requirements

3.30
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

3.31
reference level
investigation level or recording level

3.32
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

3.33
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
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

3.35
scattering factor
geometric standard deviation of the lognormal distribution of bioassay measurements

3.36
time of measurement
⟨*in vitro* analysis⟩ time at which the biological sample (e.g. urine, faeces) was taken from the individual concerned

3.37
time of measurement
⟨*in vivo* analysis⟩ time at which the measurement begins