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

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National foreword

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Radiological protection — Monitoring and internal dosimetry for staff members 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

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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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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*.

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 activity 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, ISO standards establishing requirements for monitoring programmes (ISO 20553), laboratory requirements (ISO 28218), and dose assessment (ISO 27048) have been developed. These can be applied in a straightforward manner to many workplaces where internal contamination may occur. In order to apply these standards to staff involved in diagnostic or therapeutic uses of radionuclides in medicine, the short effective half-life of radionuclides commonly used for these purposes and the distance between nuclear medicine department and *in vivo* counting facilities or radio-analytical laboratories shall be taken into account. Consequently, guidance on the application of the three International Standards cited above to nuclear medicine staff was requested by a number of countries.

This International Standard establishes criteria to determine whether intake monitoring is required for staff exposed to medical radionuclides as unsealed sources. It also establishes requirements on the design of such monitoring programmes, associated dose assessments, and laboratory 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 exchange of information between authorities, supervisory institutions, and employers. This International Standard is not a substitute for legal requirements.

INTERNATIONAL STANDARD ISO 16637:2016(E)

Radiological protection — Monitoring and internal dosimetry for staff members 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 contamination via inhalation by the use of radionuclides as unsealed sources in nuclear medicine imaging and therapy departments. It 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 standardized interpretation of monitoring data.

This International Standard addresses 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 individual 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 the following:

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

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

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

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 20553, ISO 28218 and ISO 27048 and the following apply.

3.1
absorption
movement of material to blood regardless of mechanism, generally applied to dissociation of particles and uptake into blood of soluble substances and material dissociated from particles

3.2
absorption type F
as defined by ICRP, deposited materials that have high (fast) rates of *absorption* (3.1) into body fluids from the respiratory tract

3.3
absorption type M
as defined by ICRP, deposited materials that have intermediate (moderate) rates of *absorption* (3.1) into body fluids from the respiratory tract

3.4
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.

3.5
activity median aerodynamic diameter
AMAD
value of aerodynamic diameter such that 50 % of the airborne *activity* (3.4) 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.

3.6
contamination
activity (3.4) 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

3.7
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

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

3.9
annual dose
committed effective dose (3.11) resulting from all *intakes* (3.14) 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.

3.10
committed equivalent dose
sum of the products of the total doses absorbed by an organ or a tissue from radiation types, integrated over the commitment period following the *intake* (3.14) of a radionuclide, and the appropriate radiation weighting factors

3.11
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 commitment period [integration time following the *intake* (3.14)] is taken to be 50 years.

3.12
excretion function
function describing the fraction of an *intake* (3.14) excreted per day after a given time has elapsed since the intake occurred

3.13
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

3.14
intake
activity (3.4) of a radionuclide taken into the body in a given time period or as a result of a given event

3.15
***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* (3.21), samples of other materials, such as blood and hair, may be taken.

3.16
***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.

3.17
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* (3.18), *task-related monitoring programme* (3.19), *triage monitoring programme* (3.20), *special monitoring programme* (3.21), and *confirmatory monitoring programme* (3.22).

Note 2 to entry: This International Standard distinguishes two different *types* of monitoring, namely, *individual monitoring* (3.23) and *workplace monitoring* (3.24).

3.18
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

3.19
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* (3.18) is suitable

3.20
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* (3.14) is not surpassed

3.21
special monitoring programme
monitoring programme performed to quantify significant exposures following actual or suspected abnormal events

3.22
confirmatory monitoring programme
monitoring programme carried out to confirm assumptions about working conditions, for example, that significant *intakes* (3.14) have not occurred

3.23
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

3.24
workplace monitoring
monitoring using measurements made in the working environment

3.25
monitoring interval
period between two consecutive times of measurement

3.26
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

3.27
quality control
part of *quality assurance* (3.26) intended to verify that systems and components correspond to predetermined requirements

3.28
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* (3.27), *quality assurance* (3.26), and quality improvement within the quality system

3.29
reference level
investigation level (3.30) or *recording level* (3.29)

3.30
recording level
level of dose, exposure, or *intake* (3.14) 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

3.31
investigation level
level of dose, exposure, or *intake* (3.14) at or above which investigation has to be made in order to reduce the uncertainty associated with the dose assessment

3.32
retention function
function describing the fraction of an *intake* (3.14) present in the body or in a tissue, organ, or region of the body after a given time has elapsed since the intake occurred

3.33
scattering factor
geometric standard deviation of the lognormal distribution of bioassay measurements

3.34
time of measurement
<*in vivo* analysis> time at which the measurement begins

4 Symbols and abbreviated terms

A_{DL}	Value of the activity detection limit (in becquerel) for routine measurements
AMAD	Activity median aerodynamic diameter
B	Breathing rate of worker ($m^3 \cdot h^{-1}$)
C_m	Airborne concentration of radionuclide ($Bq \cdot m^{-3}$)
DL	Detection limit
$E(50)$	Committed effective dose accumulated for an integration period of 50 years following an unit intake (Sv)
$e(50)$	Dose coefficient i.e. committed effective dose accumulated for an integration period of 50 years following a unit intake ($Sv \cdot Bq^{-1}$)
$m(t)$	Predicted value of the measured quantity at time, t, for unit intake (excretion or retention function at time t for unit intake)
I	Intake (Bq)
IAEA	International Atomic Energy Agency

ICRP	International Commission on Radiological Protection
ΔT	Duration of the monitoring interval between two measurements in a routine monitoring programme (in days)
T_{work}	Time spent by the worker in the radioactive atmosphere (h)

5 Purpose and need for monitoring programmes in nuclear medical diagnosis and therapy

5.1 General

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, it forms part of the overall radiation protection programme, which should start with an assessment to identify work situations in which there is a risk of radionuclide intake by workers, and to quantify the annual likely intake of radioactive material and the resulting committed effective dose. Decisions about the need for monitoring and the design of the monitoring programme should be made in the light of such a risk assessment.

5.2 Assessment of the level of likely exposures

It is necessary to assess the likely magnitude of exposures without taking into account personal protective measures. If available, this assessment can be done on the basis of results of earlier monitoring programmes (individual or workplace monitoring) and/or on measurements performed at the workplace to characterize the radiological conditions.

In nuclear medicine, workers can be contaminated by inhalation of volatile compounds (mainly radioiodine) or aerosols. As a result, individual monitoring for internal contamination may be necessary for those workers who regularly work with large activities of volatile radioactive materials.[1]

In order to assess the level of likely exposures, quantification of airborne contamination should be performed in departments where I-131 is used in large amount, i.e. for therapy or where aerosols are used for pulmonary inhalation examination.

To assess the risk of I-131 inhalation, air sampling should be performed in areas where there is a potential for airborne radioactivity. These areas may include the following:

— hot laboratory;

— radioiodine treatment rooms and adjacent areas;

— facility radioactive waste and effluent storage areas.

For a specific radionuclide, the likely committed effective dose due to airborne radioactivity for a worker can be calculated by

$$E\left(50\right) = \frac{I \times e(50)}{0,001} \tag{1}$$

where

$E(50)$	is the committed effective dose for the radionuclide (mSv);
I	is the intake for the radionuclide (Bq);
$e(50)$	is the dose coefficient ($Sv \cdot Bq^{-1}$) for inhalation of the radionuclide and;
0,001	is a conversion factor from Sv to mSv.

Values for $e(50)$ shall be taken from ICRP 68[2] or, for radiopharmaceuticals used as aerosols, from ICRP 53[3] and following addenda. For iodine radioactive isotopes, a vapour form should be assumed unless material-specific information suggesting a particulate form is available.

The likely intake can be calculated by

$$I = B \times T_{\text{work}} \times C_{\text{m}} \tag{2}$$

where

B is the mean breathing rate of a sedentary worker (1,2 $m^3 \cdot h^{-1}$);

T_{work} is the time spent by the worker in the radioactive atmosphere (h) and;

C_{m} is the airborne concentration of the radionuclide ($Bq \cdot m^{-3}$).

If no other reliable information is available or may be obtained from workplace and/or individual measurements, the criteria suggested by IAEA Safety Guide RS-G-1.2[4] and presented in Annex A, can be used to determine whether an internal monitoring program is needed for nuclear medicine workers[5][6][7].

5.3 Monitoring programmes

5.3.1 General

Factors determining the need for a monitoring programme are the following:

— the magnitude of likely exposures;

— the need to recognize incorporation events;

— the need to assess the effectiveness of protective equipment.

A monitoring programme can include individual and/or workplace monitoring. These two types of monitoring provide different information.

— 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).

— Workplace monitoring, either by air monitoring or by measurements of the surface contamination, helps to assess the potential for internal exposure of workers through inhalation and provides information on the risk of contamination for setting up individual monitoring programmes for workers. It complements individual monitoring, since it provides useful indicators for predicting doses and for establishing protective measures for the operation.

As stated in ISO 20553, a monitoring programme for internal contamination is required if the worker is occupationally exposed and the assessed dose contribution from intakes of radionuclides is likely to be significant and is recommended if the level of the likely annual committed effective dose exceeds 1 mSv.

For workers exposed to medical radionuclides as unsealed sources in nuclear medicine departments, different categories of monitoring programmes can be implemented depending on the risk assessment: confirmatory monitoring programmes, triage monitoring programmes, routine or task-related monitoring programmes, and special monitoring programmes, following an incidental intake.

5.3.2 Confirmatory monitoring programmes

Confirmatory monitoring, which consists of workplace and/or individual monitoring performed occasionally or at regular intervals, should be required to check the assumptions about exposure conditions underlying the procedures selected, e.g. the effectiveness of protection measures. Recorded data should be periodically reviewed as they can demonstrate the need for triage, routine, or task-

related monitoring. The time of implementation should be during the process identified as the highest risk of internal exposure.

Confirmatory monitoring is not intended to quantify doses. However, it can be used to review the risk of contamination and the estimation of the likely dose and, following this review, it can demonstrate the need to implement a routine or triage monitoring programme.

5.3.3 Routine monitoring programmes

Routine monitoring programmes are performed to quantify exposures where there is the possibility either of undetected accidental intakes or of chronic intakes. The basis for routine monitoring programmes is the assumption that working conditions, and thus risks of intake, remain reasonably constant. The design of such a programme of regular measurements strongly depends on the level of the annual dose the quantification of which is ensured. This level should be well below legally relevant limits; its definition should take into account uncertainties, for example, in activity measurement and dose assessment. If this level is too high, intakes representing considerable fractions of dose limits could be overlooked, whilst a low value can cause the expenditure of unnecessary efforts at low exposures.

5.3.4 Triage monitoring programmes

Triage monitoring programmes rely on frequent individual screening measurements performed at the workplace by local staff using standard laboratory instrumentation to detect whether potential intake has occurred. Screening measurements, in contrast with *in vivo* or *in vitro* measurement performed in the frame of a routine monitoring programme, do not enable the calculation of an accurate or precise absorbed dose but can be used to determine whether a dose threshold is exceeded. If the screening threshold is exceeded, *in vivo* or *in vitro* radiobioassays are performed in order to confirm internal contamination and to quantify the incorporated activity for dose assessment.

5.3.5 Task-related monitoring programmes

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

In nuclear medicine, task-related monitoring programmes are required in the case of a new diagnostic or therapeutic protocol and operations of limited duration to provide data for dose assessment and for the radiation protection optimisation process. This is also necessary after major modifications have been applied to the installations or operating procedures. The general requirements set out in 8.1 for routine monitoring programmes shall be applied to task-related monitoring programmes. In contrast to routine monitoring programmes, more information can be available about the circumstances of an intake event, especially relating to the time between measurement and the intake.

The objectives of a task-related monitoring programme and the way it is organized, including the basis for interpreting the results, shall be documented.

5.3.6 Special monitoring programmes

Special monitoring programmes are performed to quantify significant exposures following actual or suspected abnormal events (by example, the spill of a radiopharmaceutical solution) or in case of a positive screening during triage monitoring. Therefore, in comparison to routine monitoring programmes, the time of intake is usually much better known, and additional information can be available, which helps to reduce the uncertainty of assessment. The purposes of dose assessment in such cases include assisting in decisions about countermeasures (e.g. decorporation therapy), compliance with legal regulations, and aiding decisions for the improvement of conditions at the workplace. In most cases, special monitoring programmes are performed individually. In cases where there is reason to suspect that the annual effective dose limit could be exceeded, it can be appropriate to extend the measurements in order to derive individual-specific retention and excretion functions and biokinetic model parameters.

5.3.7 Implementation of a monitoring programme

A detailed flowchart is proposed as Figure 1 to contribute to the implementation of monitoring programmes. This flowchart presents the monitoring programmes to apply following three starting points corresponding to different situations:

1) the commissioning of a new nuclear medicine facility or the review of an existing facility;

2) the development of a new protocol (by example for a new radiopharmaceutical);

3) the suspicion of an incidental contamination.

Periodic review of the monitoring programmes shall be conducted, taking into account the recorded data (internal contamination measurements results and, when performed, assessed doses).

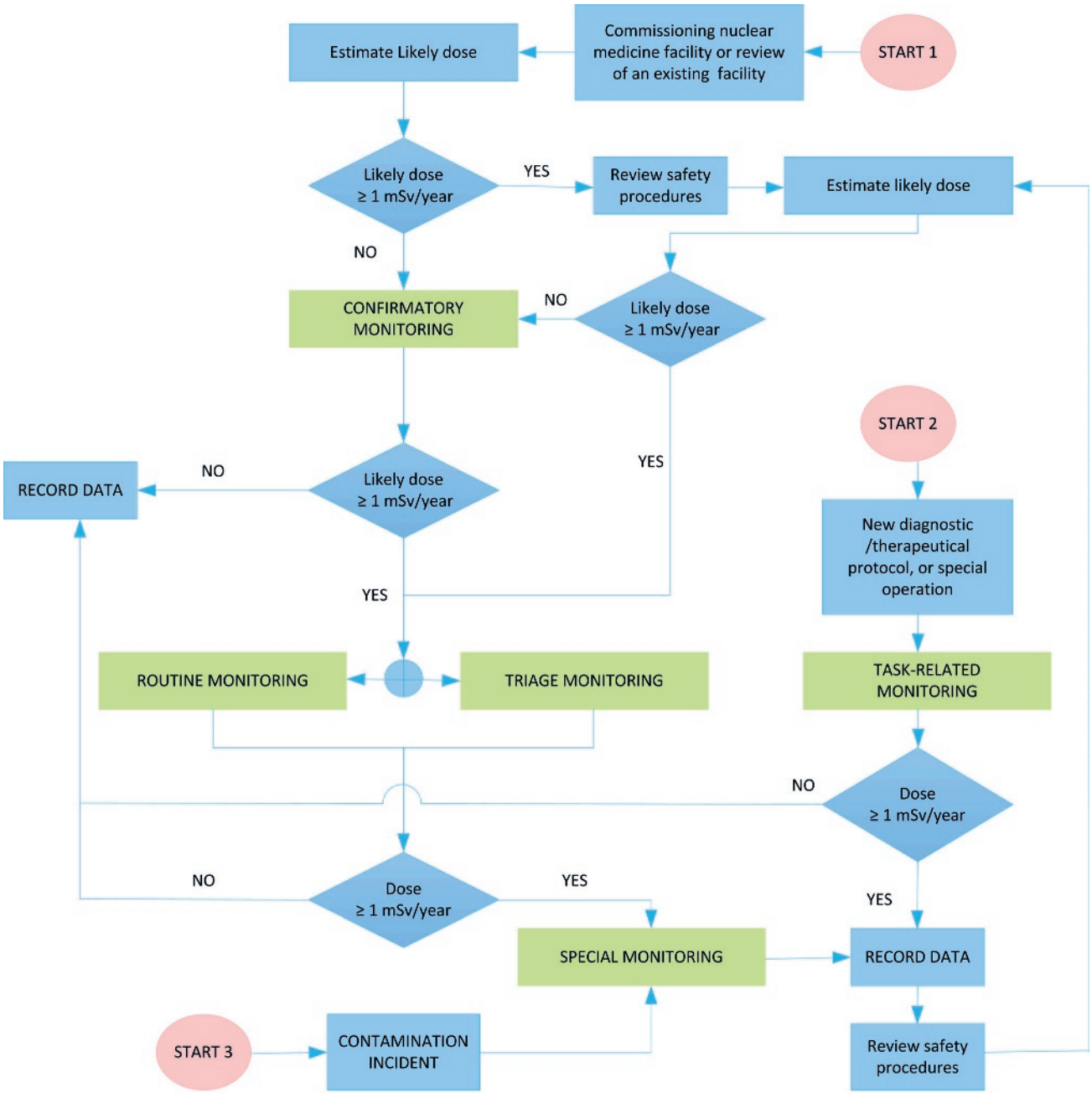

Figure 1 — Flowchart for the implementation of monitoring programmes

6 Common radionuclides

Most of the radionuclides used in nuclear medicine have short half-lives (Table 1). For diagnostic use, the emitted energy shall be deposited in the gamma camera scintillator, with minimal absorption by the tissue. On the contrary, for therapeutic use, the energy shall be deposited in the tissue. Therefore, radionuclides with γ or β+ decay are used for imaging and radionuclides with α or β- decays are used for therapeutic purposes.

Table 1 — Most commonly used radionuclides in nuclear medicine

Radionuclides	Half-life[a]	Main emissions
C-11	20,39 m	β+, γ[i]
O-15	122,24 s	β+, γ[i]
F-18	109,77 m	e-, β+, γ[i]
Ga-67	3,26 d	e-, X, γ
Ga-68	67,71 m	β+, γ[i],γ
Sr-89	50,53 d	β-, γ
Y-90	64,10 h	β-
Tc-99m	6,02 h	e-, X, γ
In-111	2,80 d	e-, X, γ
I-123	13,27 h	e-, X, γ
I-131	8,02 d	e-, β-, X, γ
Sm-153	46,50 h	e-, β-, X, γ
Er-169	9,40 d	β-, γ
Lu-177	6,65 d	β-, γ
Re-186	3,72 d	e-, β-, X, γ
Re-188	17,00 h	e-, β-, X, γ
Tl-201	72,91 h	e-, X, γ
Ra-223	11,43 d	α, β-, X , γ

[a] According to ICRP 107.[8]

γ[i] Annihilation photons.

7 Reference levels

Reference levels are the values of quantities above which a particular action or decision shall be taken. The purpose of setting these levels is so that unnecessary, non-productive work can be avoided and resources can be used where they are most needed. Reference levels include the recording level, above which a dose assessment has to be recorded, lower values being ignored; and the investigation level, above which the exposure estimates have to be confirmed by additional investigations (see Table 2).

NOTE The scope of this International Standard does not include the investigation of the causes or implications of an exposure or intake.

The recording level shall be set at a value corresponding (having regard to the length of the monitoring interval) to an annual dose no higher than 5 % of the annual dose limit. The investigation level shall be set at a value corresponding to an annual dose no higher than 30 % of the annual dose limit.

Table 2 — Reference levels for monitoring internal exposures (ISO 20553)

Level	Meaning
Recording level	The recording level is the level of dose, exposure, or intake at or above which dose assessments have to be recorded in the individual exposure records. It shall be set at a value corresponding to an annual dose no higher than 5 % of the annual dose limit. Results falling below this level may be shown as "below recording level".
Investigation level	The investigation level is a 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. The level shall be set at a value corresponding to an annual dose no higher than 30 % of the annual dose limit.

8 Routine monitoring programmes

8.1 General aspects

Measurements in a routine monitoring programme are made at pre-determined times and are not related to any known intake events. Decisions therefore have to be made in advance, concerning methods, frequencies, and the underlying biokinetic models. For the evaluation of measured values in terms of intakes, it also is necessary to make assumptions concerning the time interval between intake and measurement.

The following general requirements shall be observed when specifying a routine monitoring programme:

— the consequences resulting from an unknown time interval between intake and measurement shall be limited, so that

  — on average, over many monitoring intervals, doses are not underestimated, and

  — the maximum underestimate of the dose resulting from a single intake does not exceed a factor of three;

— the detection of all annual exposures that can exceed 1 mSv shall be ensured;

— at least two measurements shall be performed annually.

The maximum overestimation is in nearly all cases greater than the maximum underestimation. The constraint on the maximum underestimation of a single intake does not exclude a considerable overestimation.

These requirements together with the assumptions about the pattern of intake and the sensitivity of the selected methods of measurement determine the frequency of the routine measurements.

In nuclear medicine, routine monitoring based on individual measurements should be considered for staff members involved routinely in the treatment of patients with significant quantities of I-131.

For this purpose, *in vivo* thyroid measurements can be performed in a radiobioassay laboratory or in the nuclear medicine department using gamma camera[9] or thyroid probe[10][11].

The objectives of a monitoring programme and the way it is to be organized shall include the basis for interpreting the results. The monitoring programme shall be reviewed by means of a confirmatory monitoring programme after any major modifications have been made to the installation, to operations, or to the regulatory requirements.

8.2 Individual monitoring

Individual monitoring of radionuclides can be made by *in vivo* measurements or *in vitro* analyses, by taking continuous air samples using individual air-sampling devices or by a combination of all these methods. The selection depends on a number of factors, such as the following:

— radiation emitted by the radionuclide and its progeny;

— decay rate of the radionuclide;

— retention in the body or excretion rate from the body of the radionuclide as a function of the time between intake and measurement;

— biokinetics, organ deposition and excretion pathway of the radionuclide;

— technical feasibility of measurement.

8.3 Methods and monitoring intervals

The duration of time interval (ΔT, in day) between two measurements in a routine monitoring programme depends on the retention and excretion of the radionuclide, the sensitivity of the available measurement techniques and the uncertainty that is acceptable when estimating annual intake and committed effective dose,

This time intervals given in the following formulae comply with the two requirements:

— the detection of all annual exposures that can exceed 1 mSv shall be ensured [Formula (3)];

— The maximum potential underestimation shall not exceed a factor of three; assuming that a single intake occurred in the middle of the monitoring interval [Formula (4)].

$$e\left(50\right)\times\frac{A_{\mathrm{DL}}}{m(\Delta T)}\times\frac{365}{\Delta T}\leq 1\,\mathrm{mSv} \tag{3}$$

$$\frac{m\left(\frac{\Delta T}{2}\right)}{m(\Delta T)}\leq 3 \tag{4}$$

where

$e(50)$ is the dose coefficient for inhalation (committed effective dose accumulated for an integration period of 50 years following a unit intake);

$m(t)$ is the predicted value of the measured quantity at time t, for unit intake (excretion or retention function at time t for unit intake);

ΔT is the of time interval (days) between two consecutive measurements in a routine monitoring programme;

A_{DL} is the value of the detection limit for routine measurements.

For the routine monitoring of I-131, thyroid measurement is the preferred method, and the maximum time interval between the thyroid measurements derived from the principles laid down above is 15 d, following the assumptions considered in ISO 20553:

— ICRP 66[12] respiratory tract model for inhalation;

— iodine retention and excretion functions defined by ICRP 78[13];

— acute intake by inhalation at the mid-point of the monitoring interval. This is a reasonable assumption for chronic intakes, and, on average, it prevents the underestimation of intakes;

— with DL values of routine measurements as from ICRP 78. In facilities where the DL of the counting instrument significantly differ from the value given in ICRP 78 (100 Bq), a specific routine monitoring frequency should be determined.

When thyroid measurements cannot be performed, an alternative is to perform urine *in vitro* analyses with the same maximum time interval, i.e. 15 d knowing that for urine monitoring, the 1 mSv detection level may not be achieved. Tolerance on the time interval should not exceed 2 d.

In a routine monitoring programme, the detection of all annual exposures that can exceed 1 mSv shall be ensured as stated above. For the monitoring of I-131 intake with a time interval of 15 d, under the above assumptions, the activities measured that, if detected in each monitoring interval, correspond to an annual committed effective dose of 1 mSv are the following:

— for *in vivo* thyroid measurement: 300 Bq;

— for *in vitro* urine measurements: 0,4 Bq/d.

9 Triage monitoring programmes

Individual routine monitoring as defined above may not be feasible for radionuclides with a half-life shorter than that of I-131. In this case, when the likely dose determined following the method described in 5.2 is above 1 mSv/year, a possibility is to implement triage monitoring in the nuclear medicine department and in case of positive result, to initiate *in vivo* counting or *in vitro* urinalysis in a radiobioassay service laboratory in order to evaluate the committed effective dose, $E(50)$ [14].

Triage monitoring is based on frequent screening measurements performed at the workplace by local staff using standard laboratory instrumentation. The procedure can consist in the following[14]:

— frequent measurements with a calibrated dose rate monitor placed in front of the abdomen for radionuclides with very short physical half-lives (≤6 h), such as Tc-99m (daily measurements) and those used in positron emission tomography imaging, i.e. C-11, F-18, and Ga-68 (half-daily measurements). For O-15, the triage measurement may be performed following the detection of air contamination by an alarm;

— measurements with a hand contamination monitor immediately after use for pure beta emitters, i.e. Y-90, as well as beta emitters with low-intensity gamma rays, i.e. Sm-153, Lu-177, Re-186, and Re-188;

— measurements by a calibrated surface contamination monitor placed in front of the thyroid for I-123 or with a lung monitor or a calibrated dose rate monitor located in front of the thorax for Ga-67, In-111, and Tl-201. The measurements' frequency should be determined for each radionuclide depending on the detection limit of the detector.

Workplace monitoring including measurements of surface contamination can also be performed as part of a triage monitoring programme.

10 Special Monitoring programmes

10.1 General aspects

Special monitoring programmes refer to measurements made when intake is suspected following an event and shall be conducted to provide data for the following:

— dose assessment required for estimating risk and determining the need for any treatment;

— radiological protection optimization process.

In contrast to routine monitoring programmes, special monitoring programmes can reveal more information about the circumstances of an intake event, especially relating to the time between the measurement and the intake.

The objectives of a special monitoring programme and the way it is organized, including the basis for interpreting the results, shall be documented.

10.2 Workplace monitoring

Air monitoring and surface contamination monitoring can be used to characterize the localization of the radioactive contamination.

10.3 Individual monitoring

The goal of special individual monitoring is to ensure that any intake is detected at an early stage and that the associated committed doses are evaluated. Special monitoring programmes are investigative; they are usually based on a suitable combination of *in vivo* measurements and *in vitro* analyses in association with the appropriate biokinetic model.

— *In vivo* measurement: The radionuclide content of the body is quickly available and gives an indication whether a significant intake has occurred.

— *In vitro* analysis: Usually, a reliable dose assessment on the basis of urinary analysis requires a 24 h sample; but in the case of special monitoring programmes, it can be helpful to collect "spot samples".

Table 3 summarizes recommended methods for individual monitoring; it does not take into account the effects of treatment that can be undertaken to reduce the committed effective dose.

Table 3 — Recommended methods for special monitoring programmes after inhalation

Radionuclide/ material	*In vitro* analyses		*In vivo* measurements	
	Urine sample		Organ	
	Spot	24 h	WB	Thyroid
F-18	+		++	
Ga-67	+		++	
Sr-89		++		
Y-90		++		
Tc-99m		+	++	
In-111			++	
I-123		+		++
I-131		+		++
Sm-153		+	++	
Er-169		++	+	
Lu-177		+	++	
Re-186		+	++	
Re-188		+	++	
Tl-201		+	++	
Ra-223		++		
++ = Recommended. + = Supplementary (helpful but not mandatory). WB = Whole Body.				

In case of suspected incorporation of[18]FDG, *in vivo* brain monitoring of F-18 is effective to detect levels below the 1 mSv if the measurement is performed up to 1 d after the event[15].

C-11 and O-15 are not listed due to their very short half-life (see Table 1), however contamination by C-11 can be detected by *in vivo* measurements performed very rapidly after the intake event.

11 Confirmatory monitoring programmes

11.1 General aspects

Confirmatory monitoring programmes are required to check the assumptions about exposure conditions underlying the procedures selected, e.g. the effectiveness of protection measures. It may consist of workplace or individual monitoring. Periodic measurements can be made to ensure that working conditions are satisfactory. In association with the Radiation Protection Officer, the results of workplace monitoring (wipe tests and air sample measurements) and contamination measurements made on individuals can be compared and the radiation protection system modified if necessary. By example, confirmatory monitoring can demonstrates the need to implement a routine or triage monitoring programme.

11.2 Workplace monitoring

Workplace monitoring is related to the nature of the radionuclides and the type of work undertaken. It may consist of airborne activity measurements or surface wipe test.

Workplace monitoring should include measurements of airborne activity when extensive use is made of volatile materials or radioactive gases (by example large amount of I-131 or Tc-99m-labelled aerosols), and measurement of surface contamination in the workplace.

In the presence of a relatively high radiation background, the direct detection of significant levels of surface contamination may not be possible, and wipe tests to assess the degree of loose contamination may be necessary. In areas where surface contamination may arise or its presence is suspected, the entire area and contents should be regarded as being contaminated until monitoring indicates otherwise (ICRP 57).

The main objectives of monitoring airborne activity are:

— to help to assess the likely internal exposure of workers through inhalation, and

— to provide information for setting up individual monitoring programmes for workers.

I-131 airborne activity should be measured in the hot laboratory, radioiodine treatment rooms and adjacent areas, facility radioactive waste, and effluent storage areas.

The assessment of the likely effective dose based on air monitoring data can be performed as stated in 5.2.

11.3 Individual monitoring

Individual monitoring as part of confirmatory monitoring serves to confirm the adequacy of protective measures and of assumptions made regarding the level of exposures. Individual monitoring can be performed via periodic *in vivo* measurements or urine analysis. However, due to the short half-lives of radionuclides in use for diagnostic or therapeutic administration in nuclear medicine, *in vivo* measurements are more adequate to detect contamination, particularly by common radionuclides such as Tc-99m or F-18.

The *in vivo* measurements can be performed in whole body counting facilities located near the nuclear medicine department. For departments located far from such facilities, mobile laboratories can be developed in order to perform on-site measurements [16][17][18].

12 Measurement techniques and performance criteria

12.1 General

For routine monitoring, special monitoring, or confirmatory monitoring, *in vitro* and/or *in vivo* measurement techniques, workplace monitoring techniques, or a combination of these techniques, may

be used, depending on factors such as the chemical composition of contaminant involved, the likely level of contamination, and the availability of these measurement techniques.

As stated above, I-131 presents a high risk of intake and is the largest cause of internal dose to nuclear medicine workers. Due to the cost associated with transporting workers or bioassay samples to laboratory, nuclear medicine centres may use their own devices to perform the monitoring of the workers involved in a radioiodine handling procedure. Measurements can be performed using gamma camera[9] or thyroid probe[10][11].

As detailed description of the measurement methods and techniques is beyond the scope of this International Standard, the following subclauses give a brief introduction to the measurement techniques available for *in vitro* and *in vivo* measurement.

Radiobioassay services laboratories which perform *in vivo* or *in vitro* measurements for nuclear medicine staff should apply criteria developed in ISO 28218. These criteria should be applied by stationary, as well as by mobile laboratories.

For thyroid measurements performed in the nuclear medicine services, the present International Standard specifies the requirements to apply (see 12.3).

12.2 Measurements performed in a laboratory specialised for radiobioassay

12.2.1 *In vitro*

In vitro measurement is applicable for the monitoring of the internal contamination by radionuclides used in the nuclear medicine department except for those with very short half-lives (C-11 and O-15). Urine analysis is the only bioassay method usually employed. Collection of a 24-h urine sample from the affected individual is recommended.

The usual method, for the quantification of γ emitting radionuclides, is the measurement of the γ radiations by γ spectrometry of a test specimen. The detection limit at the date of measurement is approximately 1 Bq/l, for a test specimen of 500 ml and a counting time of 60 min.

The quantification of β emitter radionuclides by liquid scintillation makes it possible to reach a limit of detection of approximately 50 Bq/l, for a test specimen of 2 ml and a counting time of 60 min.

These measurements cannot be performed in the nuclear medicine department, but in a radiobioassay laboratory, as they require complex technical equipment.

12.2.2 *In vivo*

In vivo measurements for the monitoring of nuclear services workers include the following:

— thyroid measurements;

— whole body measurements.

Absence of external contamination, particularly of the hands, should be verified before performing a whole body measurement. An *in vitro* bioassay measurement on a urine sample may be performed to confirm the internal contamination.

12.2.3 Quality assurance and quality control for bioassay laboratories

Performance checks shall be conducted to ensure the conformance of analytical processes, measurement equipment, and the facilities to predetermine operational requirements. The laboratory shall have written quality control procedures to verify that the quality of measurements or radioactivity determinations complies with the accuracy requirements as developed in ISO 28218.

In addition, laboratories performing *in vivo* or *in vitro* analyses and/or assessments for internal dosimetry should participate in national or international intercomparison exercises.

12.3 Measurements performed in nuclear medicine service

I-131 measurements can be performed in nuclear medicine department using pre-calibrated gamma camera or thyroid probe.[19] A quality assurance programme shall be adapted and the methodology of measurements shall be written, including the following:

— description of equipment (detector, analyzer, software) used to analyse the spectra;

— description of the phantom used for calibration;

— counting configuration.

Adequacy of equipment and procedures shall be assessed against established quality assurance requirements. These requirements may be determined by national regulations.

The measurements should be performed in a location with as low a background count rate as possible. The DL (detection limit) of the unit shall be determined. For routine monitoring, it shall be lower than 300 Bq as stated in 8.3.

13 Procedure for the assessment of exposures

13.1 Interpretation of individual monitoring data for dose assessment

13.1.1 General

The general procedure for dose assessment is described in ISO 27048. Internal dose assessment can be performed based on individual monitoring data after routine or special monitoring. Dose assessment is performed using the results of *in vivo* measurement or urine analysis. When possible, the biokinetic model corresponding to the physico-chemical form of the contaminant shall be used. The pulmonary absorption types used to calculate thyroid or whole body activities and daily urinary excretion presented in Tables 4 to 15 are taken from ICRP 68[2].

In case of special monitoring, time of intake is usually known. In routine monitoring, the time of any acute intake is generally unknown. Typically, it is assumed that the intakes take place at the midpoint of the monitoring interval[13]. However, a uniform chronic intake can also be considered.

13.1.2 Dose assessment based on routine monitoring

For I-131, the activity measured in the thyroid corresponding to a committed effective dose of 1 mSv (for a unique intake at the midpoint of one monitoring interval) is 7 000 Bq The activity measured in urine corresponding to the same dose is 9,5 $Bq \cdot d^{-1}$. These values are given for a time interval of 15 d as specified in 8.3 and for iodine vapour.

13.1.3 Dose assessment based on special monitoring

In the case of radioactive iodine contamination, dose assessment can be performed using thyroid measurements and/or urine analysis. Tables 4 to 6 give the activities of I-131 measured in the thyroid and the daily urine excretion ($Bq \cdot d^{-1}$) that correspond to a committed effective dose of 1 mSv from inhalation of I-131 as elemental vapour (Table 4) or as aerosol (pulmonary absorption type F and AMAD 5 µm, Table 5) or from injection of I-131 (Table 6). Tables 7 to 9 give the activities of I-123 measured in the thyroid and the daily urine excretion ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of I-123 as elemental vapour (Table 7) or as aerosol (pulmonary absorption type F and AMAD 5 µm, Table 8) or from injection of I-123 (Table 9).

Table 4 — Activity in the thyroid and daily urinary excretion after inhalation of I-131 as elemental vapour corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	1,1 E + 04	2,6 E + 04
2	1,1 E + 04	2,2 E + 03
3	1,0 E + 04	1,3 E + 02
4	9,3 E + 03	1,4 E + 01
5	8,4 E + 03	8,4 E + 00
6	7,7 E + 03	9,0 E + 00
7	6,0 E + 03	9,7 E + 00
8	6,4 E + 03	1,0 E + 01
9	5,8 E + 03	1,0 E + 01
10	5,3 E + 03	1,1 E + 01

Table 5 — Activity in the thyroid and daily urinary excretion after inhalation of I-131 as an aerosol (absorption type F, AMAD 5 µm) corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	1,1 E + 04	2,5 E + 04
2	1,1 E + 04	2,0 E + 03
3	9,9 E + 03	1,3 E + 02
4	9,0 E + 03	1,3 E + 01
5	8,2 E + 03	8,2 E + 00
6	7,5 E + 03	8,7 E + 00
7	6,8 E + 03	9,4 E + 00
8	6,2 E + 03	9,8 E + 00
9	5,6 E + 03	1,0 E + 01
10	5,1 E + 03	1,0 E + 01

Table 6 — Activity in the thyroid and daily urinary excretion after injection of I-131 corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	1,2 E + 04	2,7 E + 04
2	1,1 E + 04	2,0 E + 03
3	1,0 E + 04	1,2 E + 02
4	9,4 E + 03	1,3 E + 01
5	8,5 E + 03	8,5 E + 00
6	7,7 E + 03	9,2 E + 00
7	7,1 E + 03	9,9 E + 00
8	6,4 E + 03	1,0 E + 01
9	5,8 E + 03	1,1 E + 01
10	5,3 E + 03	1,1 E + 01

Table 7 — Activity in the thyroid and daily urinary excretion after inhalation of I-123 as elemental vapour corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	3,4 E + 05	7,9 E + 05
2	1,0 E + 05	2,4 E + 04
3	3,0 E + 04	4,4 E + 02
4	8,3 E + 03	1,3 E + 01
5	2,3 E + 03	2,3 E + 00
6	6,6 E + 02	7,7 E - 01
7	1,9 E + 02	2,6 E - 01
8	5,2 E + 01	8,3 E - 02
9	1,5 E + 01	2,6 E - 02
10	4,1 E + 00	8,2 E - 03

Table 8 — Activity in the thyroid and daily urinary excretion after inhalation of I-123 as an aerosol (absorption type F, AMAD 5 µm) corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	3,7 E + 05	8,4 E + 05
2	1,1 E + 05	2,0 E + 04
3	3,2 E + 04	5,6 E + 02
4	9,1 E + 03	1,6 E + 01
5	2,6 E + 03	2,5 E + 00
6	7,2 E + 02	8,3 E - 01
7	2,0 E + 02	2,8 E - 01
8	5,7 E + 01	9,0 E - 02
9	1,6 E + 01	2,9 E - 02
10	4,5 E + 00	8,9 E - 03

Table 9 — Activity in the thyroid and daily urinary excretion after injection of I-123 corresponding to a committed effective dose of 1 mSv

Time after intake in days	Thyroid activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	3,6 E + 05	8,4 E + 05
2	1,1 E + 05	2,1 E + 04
3	3,0 E + 04	3,6 E + 02
4	8,5 E + 03	1,2 E + 01
5	2,4 E + 03	2,4 E + 00
6	6,8 E + 02	8,0 E - 01
7	1,9 E + 02	2,7 E - 01
8	5,4 E + 01	8,6 E - 02
9	1,5 E + 01	2,7 E - 02
10	4,2 E + 00	8,4 E - 03

In the case of Tc-99m contamination in the form of pertechnetate, dose assessment can be performed using whole body measurements and/or urine analysis. Table 10 gives the activities of Tc-99m measured in the whole body and the daily urine excretion ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of Tc-99m as pertechnetate aerosol (pulmonary absorption type F and AMAD 5 µm).

Table 10 — Activity in the whole body and daily urinary excretion after inhalation of Tc-99m as pertechnetate corresponding to a committed effective dose of 1 mSv

Time after intake in days	Whole body activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	1,6 E + 06	1,9 E + 05
2	6,7 E + 04	9,2 E + 03
3	2,9 E + 03	3,8 E + 02
4	1,3 E + 02	1,6 E + 01
5	6,0 E + 00	7,1 E - 01

In the case of Ga-67 contamination in the form of citrate, dose assessment can be performed using whole body measurements and/or urine analysis. Table 11 gives the activities of Ga-67 measured in the whole body and the daily urine excretion ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of Ga-67 as aerosol (pulmonary absorption type F and AMAD 5 µm).

Table 11 — Activity in the whole body and daily urinary excretion after inhalation of Ga-67 as citrate corresponding to a committed effective dose of 1 mSv

Time after intake in days	Whole body activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	3,9 E + 06	1,0 E + 05
2	2,1 E + 06	9,0 E + 04
3	1,3 E + 06	4,2 E + 04
4	8,5 E + 05	2,0 E + 04
5	6,3 E + 05	9,9 E + 03
6	4,8 E + 05	5,6 E + 03
7	38 E + 05	3,5 E + 03
8	3,0 E + 05	2,4 E + 03
9	2,4 E + 05	1,8 E + 03
10	1,9 E + 05	1,4 E + 03

In the case of Sr-89 contamination in the form of chloride, dose assessment can be performed using urine analysis. Table 12 gives the daily urine excretion of Sr-89 ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of Sr-89 as aerosol (pulmonary absorption type F and AMAD 5 µm).

Table 12 — Daily urinary excretion after inhalation of Sr-89 as chloride corresponding to a committed effective dose of 1 mSv

Time after intake in days	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	4,8 E + 04
2	1,6 E + 04
3	1,1 E + 04
4	7,9 E + 03
5	6,2 E + 03
6	5,0 E + 03
7	4,1 E + 03
8	3,5 E + 03
9	3,0 E + 03
10	2,6 E + 03

In the case of In-111 contamination in the form of chloride, dose assessment can be performed using whole body measurements. Table 13 gives the activities of In-111 measured in the whole body that

corresponds to a committed effective dose of 1 mSv from inhalation of In-111 as aerosol (pulmonary absorption type F and AMAD 5 µm).

Table 13 — Activity in the whole body after inhalation of In-111 as chloride corresponding to a committed effective dose of 1 mSv

Time after intake in days	Whole body activity (Bq)
1	2,0 E + 06
2	1,1 E + 06
3	7,2 E + 05
4	5,2 E + 05
5	3,9 E + 05
6	3,0 E + 05
7	2,4 E + 05
8	1,9 E + 05
9	1,4 E + 05
10	1,1 E + 05

In the case of Tl-201 contamination in the form of chloride, dose assessment can be performed using whole body measurements and/or urine analysis. Tables 14 gives the activities of Tl-201 measured in the whole body and the daily urine excretion ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of Tl-201 as aerosol (pulmonary absorption type F and AMAD 5 µm).

Table 14 — Activity in the whole body and daily urinary excretion after inhalation of Tl-201 as chloride corresponding to a committed effective dose of 1 mSv

Time after intake in days	Whole body activity (Bq)	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	6,2 E + 06	1,4 E + 05
2	4,1 E + 06	1,2 E + 05
3	2,9 E + 06	9,4 E + 04
4	2,1 E + 06	7,0 E + 04
5	1,5 E + 06	5,2 E + 04
6	1,1 E + 06	3,9 E + 04
7	8,4 E + 05	2,9 E + 04
8	6,3 E + 05	2,1 E + 04
9	4,7 E + 05	1,6 E + 04
10	3,5 E + 05	1,2 E + 04

In the case of Ra-223 contamination in the form of chloride, dose assessment can be performed using urine analysis. Table 15 gives the daily urine excretion of Ra-223 ($Bq \cdot d^{-1}$) that corresponds to a committed effective dose of 1 mSv from inhalation of Ra-223 as aerosol (pulmonary absorption type M and AMAD 5 µm).

Table 15 — Daily urinary excretion after inhalation of Ra-223 as chloride corresponding to a committed effective dose of 1 mSv

Time after intake in days	Daily urinary excretion ($Bq \cdot d^{-1}$)
1	2,6 E - 01
2	4,9 E - 02
3	3,0 E - 02
4	2,0 E - 02
5	1,4 E - 02

Table 15 *(continued)*

Time after intake in days	Daily urinary excretion ($Bq \cdot d^{-1}$)
6	9,4 E - 03
7	6,6 E - 03
8	4,7 E - 03
9	3,4 E - 03
10	2,6 E - 03

Alternatively, smaller values in activity median aerodynamic diameter of aerosols or other pulmonary absorption types may be used, provided they are documented, validated, and appropriate for the process in which the individual was engaged.

13.2 Software tools

The criteria for selecting one software or computer code for bioassay data interpretation are based in the requirement of the following capabilities of the software:

a) type of intake (inhalation, ingestion, injection), pattern of intake (acute, chronic, or mixed), and date of intake;

b) type of information on the element or compound, such as number of radionuclides available, physicochemical characteristics of the compound (AMAD and absorption parameters), and choice between default and/or specific values;

c) type of measurement (urine, whole body, thyroid), the possibility of simultaneously treating several data, the flexibility of entering, handling and treating data (type of uncertainties, implemented algorithms for automatic and/or interactive data processing, problems of values below the limit of detection);

d) models available for calculation: biokinetic models of ICRP 78 or other models;

e) methods of data fitting and interpretation and the possibility of treating several data values and data from more than one monitoring method.

13.3 Uncertainties

The distributions of a measured bioassay quantity arising from the various components of uncertainty can be described using lognormal distributions, with the uncertainty quantified using the geometric standard deviation. The geometric standard deviation is often known as the scattering factor (K_{SF}) and values are provided in ISO 27048:2011, Annex B.

The general procedure for the assessment of uncertainties is described in ISO 27048.

13.4 Quality assurance of the assessment process

The continued effectiveness of any radiation programme relies on those in charge of implementing its various components, including the adoption of an effective quality assurance (QA) programme based on ISO 28218, ISO 20553, and ISO 27048. Quality assurance includes quality control, which involves all those actions by which the adequacy of tools and procedures is assessed against established requirements. QA requirements may be determined by national regulations.

14 Reporting and documentation

14.1 Reporting results for *in vitro* measurements

The results obtained by the service laboratory shall be reported to the customer and shall include the following items as a minimum:

a) sample identification:

   1) assigned number;

   2) total volume or mass of sample submitted;

   3) reference date(s) and start and stop times of sample collection and analysis;

   4) identification of the required radionuclides and other detected radionuclides;

   5) sample type;

   6) sample preservation;

   7) date of sample receipt by service laboratory;

   8) condition of package;

b) quantification of sample activity at the time of measurement, taking account of appropriate blanks and correction factors (e.g. analysis of creatinine);

c) estimates of counting uncertainty and the total propagated uncertainty (depending on the client's prescription);

d) identification of equipment and specific measurement procedures;

e) values of the decision threshold and detection limit;

f) identification of the individual responsible for the report.

The service laboratory shall retain, in a retrievable form, records required by ISO 28218.

These records shall include for a period of time specified by national legal requirements or as long as they remain current.

14.2 Reporting results for *in vivo* measurements

The results obtained by the service laboratory shall be reported and shall include the following items as a minimum:

a) subject identification;

b) date and (as appropriate) time of measurement;

c) identification of detected radionuclides;

d) identification of specific measurement procedures and equipment;

e) quantification of the amount of each radionuclides measured in each part of the body counted at the time of measurement;

f) estimates of counting uncertainty and the total propagated uncertainty (depending on the client's prescription);

g) values of the decision threshold and detection limit;

h) the value of the customer-specified or service laboratory action level for prompt notification;

i) identification of the individual responsible for the report.

The service laboratory shall retain, in a retrievable form, records required by ISO 28218.

14.3 Documentation of the dose assessment

Arrangements shall be made to ensure that the results of all assessments are reported to the client's dose record-keeping service accurately and in reasonable time.

Sufficient records shall be kept of the details of all assessments so that the exact conditions of assessment may be reproduced in the future. All reports and records shall be authenticated by the Radiation Protection Expert. Account shall be taken of the national requirements in respect of record-keeping.

Each assessment shall have the following:

a) a unique identification of dose assessment for one person and for one event;

b) the physical and chemical properties of compounds manipulated (compound, AMAD, etc.);

c) identification of the required radionuclides and other detected radionuclides;

d) the date and time of the measurements and quantities measured;

e) the potential route of intake(s);

f) the procedure for calculating doses: assumptions made in respect of temporal pattern of intake, default or specific value of AMAD, chemical and physical nature of the radioactive aerosol, together with assumptions on the absorption type;

g) the dose calculation method; if the calculations were performed manually, the reference to the biokinetic models and dose coefficients shall be documented; if software was used, the software shall be identified as well as the version number;

h) the results expressed in terms of committed effective dose from intakes of each radionuclide arising during the monitoring interval. All doses shall be given in units of millisieverts correct to one decimal place;

i) uncertainties associated with it, if calculated, but these shall only be reported if explicitly requested by the customer;

j) Identification of the Radiation Protection Expert responsible for calculating the dose.

Arrangements for reporting to national authorities have to be made where required by national legislation.

Annex A
(informative)

IAEA Safety Guide RS-G-1.2 "decision factor"

IAEA Safety Guide RS-G-1.2[4] provides a methodology to estimate the "decision factor", d_j, corresponding to the order of magnitude of the annual dose likely to be received by a worker, defined for a specific radionuclide j and a specific practice as

$$d_j = \frac{A_j \times e_j(50) \times f_{fS} \times f_{hS} \times f_{pS}}{0,001} \quad \text{(A.1)}$$

where

d_j is the decision factor (mSv);

A_j is the cumulative activity (Bq) of the radionuclide j present in the workplace over the course of the year;

$e_j(50)$ is the dose coefficient (Sv/Bq) for inhalation of radionuclide j, with the AMAD normally taken to be 5 µm for worker as considered by ICRP 78. This default parameter may not fit the actual particle size distribution present at the workplace. If there is documented evidence of smaller aerosol dimensions (by example, data issued from air monitoring), another value of AMAD can be considered;

f_{fS} is the physical form safety factor based on the physical and chemical properties of the material being handled;

f_{hS} is the handling safety factor based on the experience of the operation being performed and the form of the material;

f_{pS} is the protection safety factor based on the use of permanent laboratory protective equipment (e.g. glove box, fume hood);

0,001 is a conversion factor from Sv to mSv.

The decision factor D (mSv) for all radionuclides in the workplace (for the same worker) is the sum of all radionuclide specific decision factors (each one related to all procedures, for the same radionuclide, performed by the worker), given by

$$D = \sum_j d_j \quad \text{(A.2)}$$

Values for $e(50)$ shall be taken from ICRP 68 or from ICRP 53 and following addenda for radiopharmaceuticals used as aerosols.

In the majority of cases, f_{fS} should be 0,01, therefore Formula A.2 may be simplified to

$$d_j = 10A_j \times e_j(50) \times f_{hS} \times f_{pS} \quad \text{(A.3)}$$

Tables A.1 and A.2 present values of f_{hS} and f_{pS} suggested in IAEA Safety Guide RS-G-1.2.

Table A.1 — Handling safety factors

Process	Handling safety factors, f_{hS}
Storage (stock solution)	0,01
Very simple wet operations	0,1
Normal chemical operations	1
Complex wet operations with risk of spills	10
Simple dry operations	10
Handling of volatile compounds	100
Dry and dusty operations	100

Table A.2 — Protection safety factors

Protection measure	Protection safety factors, f_{ps}
Open bench operations	1
Fume hood	0,1
Glove box	0,01

The IAEA methodology may be excessively restrictive when applied to nuclear medicine practices. Therefore, additional correction factors have been suggested[5]. These additional factors include the following:

— $f_{workload}$, the fraction of time involved in a particular task by the worker in the scenario. It is defined by the Radiation Safety Officer according to the time assigned to the task. Its value is ≤1;

— $f_{handled\_activity}$, the fraction of the total activity that is handled by the worker in a scenario considering that in real practice, each worker, according to his responsibilities, could manipulate only a fraction of the total activity in the specific area. Its value is ≤1;

— f_{intake}, the fraction of the handled activity that could be incorporated by the worker through aerolization or volatization. The value 1×10^{-4} is assigned assuming a conservative approach to represent the potential intake from the handled activity.

When these three additional factors are included for the calculation of the "decision factor", Formula (A.1) is modified as follows:

$$d_j = \frac{A_j \times e_j(50) \times f_{fS} \times f_{hS} \times f_{pS} \times f_{workload} \times f_{handled\ activity} \times f_{intake}}{10^{-3}} \quad (A.4)$$

And the simplified Formula (A.3) as

$$d_j = 10A_j \times e_j(50) \times f_{hS} \times f_{pS} \times f_{workload} \times f_{handled\ activity} \times f_{intake} \quad (A.5)$$

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