INTERNATIONAL STANDARD

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# Radiation protection — Performance criteria for radiobioassay

*Radioprotection — Critères de performance pour l'analyse radiotoxicologique*



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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 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 28218 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This first edition of ISO 28218 cancels and replaces ISO 12790-1:2001, which has been technically revised.

# Introduction

In the course of employment, individuals might work with radioactive materials that, under certain circumstances, could be taken into the body. Radiation protection programmes for these individuals can include means for *in vivo* or *in vitro* measurements of radioactive material that has entered the body. The performance criteria required for such measurements usually depend upon the purpose for the radiobioassay measurement, which can include determining the internal human burden of radioactive material, estimating doses and dose commitments, radiation protection management, medical management when appropriate, and providing the necessary data for legal and record-keeping requirements.

Analytical methods for radiobioassay are not currently standardized, but are available in the literature. Guidance on the evaluation of data from the monitoring of workers occupationally exposed to the risk of internal contamination by radioactive substances is provided in ISO 27048 as well as other publications of national and international regulations and guides, the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurement (NCRP), the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Units and Measurements (ICRU). Recommendations of the ICRP, NCRP, IAEA and ICRU, as well as experience with the practical application of these recommendations to the conduct of radiobioassay services and the interpretation and use of radiobioassay results in radiation protection programmes, have been considered in the development of this International Standard.

In addition to superseding ISO 12790-1:2001, this International Standard complements the requirements of ISO 20553. This International Standard develops, expands and applies the principles defined in the aforementioned standards for radiobioassay laboratories. It also provides a consensus on the statistical definitions and formulations of the quantitative performance criteria of decision threshold, detection limit, relative bias and repeatability. These concepts follow the requirements of ISO 11929. In particular, the concept of minimum detectable amount (MDA) used in ISO 12790-1:2001 has been abandoned in favour of detection limit ($y^{\#}$).

Clauses 5 to 8 primarily provide guidance for radiobioassay service laboratories, whereas Clause 9 relates to testing laboratories and provides criteria for performance testing. The information in these clauses provides beneficial insight for service laboratories, for users of the laboratory's services, and for testing laboratories, and it provides a possible basis for an inter-laboratory quality assurance plan.

In this International Standard, the following verbal forms apply:

— “shall” is used to denote a requirement;

— “should” is used to denote a recommendation;

— “may” is used to denote permission (neither a requirement nor a recommendation).

To conform with this International Standard, all radiobioassay needs to be performed in accordance with its requirements, but not necessarily with its recommendations; however, justification needs to be documented for deviations from recommendations.

# Radiation protection — Performance criteria for radiobioassay

## 1 Scope

This International Standard provides criteria for quality assurance and control, and evaluation of performance of radiobioassay service laboratories.

Criteria and guidance for *in vivo* radiobioassay and *in vitro* radiobioassay are given in separate clauses.

The following are within the scope of this International Standard:

— the accuracy of

  — *in vivo* measurements of activity and quantities of selected important radionuclides in test phantoms, and

  — *in vitro* measurements of activity and quantities of selected important radionuclides in test samples;

— minimal requirements for detection limit;

— minimum testing levels and testing ranges;

— requirements for reporting radiobioassay results by service laboratories;

— quality assurance in service laboratories;

— quality control in service laboratories;

— protocol for reporting test evaluations by service laboratories to the testing laboratory;

— default procedures when the service laboratory customer does not specify the performance criteria;

— applications of $f_p$ for different methods (see Annexes A and B).

The following are not within the scope of this International Standard:

— detailed radiochemical methods for separating radionuclides from biological samples;

— detailed procedures for *in vivo* and *in vitro* radioactivity measurements;

— biokinetic data and mathematical models for converting radiobioassay results into dose (dose assessment);

— procedures for the preparation and distribution of test samples and phantoms by the testing laboratories.

## 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 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*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99, ISO 5725-1, ISO 5725-2, ISO 5725-3 and the following apply.

**3.1**
**accuracy**
characteristic of an analysis or determination that ensures that both the bias and repeatability of the resulting quantity remain within specified limits

**3.2**
**activity**
number of spontaneous nuclear disintegrations per unit time

**3.3**
**aliquot**
〈*in vitro* radiobioassay〉 representative portion of a whole

**3.4**
**appropriate blank**
uncontaminated sample, unexposed person or phantom that is ideally identical in physiochemically and radiologically significant ways with the sample, person or phantom to be analysed

**3.5**
**background**
ambient signal response recorded by measurement instruments that is independent of radioactivity contributed by the radionuclides concerned

**3.6**
**bias**
systematic error of the indication of a measuring instrument

**3.7**
**freedom from bias**
ability of a measuring instrument to give indications free from systematic error

**3.8**
**blind testing**
testing of capabilities when the service laboratory is not aware that they are being tested for conformance

**3.9**
**certified reference material**
**CRM**
reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of the metrological traceability

**3.10**
**concentration**
activity or mass per unit volume or per unit mass

**3.11**
**confidence interval**
interval about an estimate of a stated quantity, within which the expected value of the quantity is expected to lie (with a specified probability)

**3.12**
**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 the critical value is exceeded by the result of an actual measurement, this is taken to indicate that the hypothesis should be rejected. The statistical test is designed in such a way that the probability of wrongly rejecting the hypothesis (error of the first kind) is at most equal to a given value, $\alpha$.

**3.13**
**detection limit**
smallest true value of the measurand that is detectable by the measuring method

NOTE The detection limit is the smallest true value of the measurand that is associated with the statistical test and hypothesis in accordance with the **decision threshold** (3.12) by the following characteristics: if in reality the true value is equal or exceeds the detection limit, the probability of wrongly not rejecting the hypothesis (error of the second kind) is at most equal to a given value, $\beta$.

**3.14**
***in vitro* radiobioassay**
measurements to determine the presence of, or to estimate the amount of, radioactive material in the excreta or in other biological materials removed from the body

**3.15**
***in vivo* radiobioassay**
measurements of radioactive material in the human body utilizing instrumentation that detects radiation emitted from the radioactive material in the body

**3.16**
**measurand**
particular quantity subject to measurement

**3.17**
**monitoring**
measurements made for the purpose of assessment or control of exposure to radioactive material and the interpretation of the results

**3.18**
**minimum testing level**
**MTL**
amount of radioactive material that the service laboratory is intended to be able to measure for participation in the performance testing programme, assuming the samples are free of interference from other radionuclides, unless specifically addressed

NOTE The MTLs are not intended to be interpreted as the appropriate detection limit required for a specific internal dosimetry programme, but rather as an acceptable minimum testing level for radiobioassay service laboratories based on good measurement practice.

**3.19**
**phantom**
surrogate person, or part of a person, used for calibration of *in vivo* measurement systems

NOTE A phantom is constructed to allow placement of radionuclides in a geometry approximating internal depositions. A phantom could be used as an **appropriate blank** (3.4).

**3.20**
**quality assurance**
planned and systematic actions necessary to provide adequate confidence that an analysis, measurement or monitoring programme will perform satisfactorily in service

**3.21**
**quality control**
actions that control the attributes of the analytical process, standards, reagents, measurement equipment, components, system or facility in accordance with predetermined quality requirements

**3.22**
**radiobioassay**
measurement of amount or concentration of radionuclide material in the body, or in biological material excreted or removed from the body (measurand), and analysed for purposes of estimating the quantity of radioactive material in the body

**3.23**
**reagent blank**
contribution of the reagents to the measurement process determined by carrying the reagents through all the operations that are used for the sample

**3.24**
**relative bias**
quotient of the bias divided by the expected value

**3.25**
**relative standard deviation**
$\sigma_r$
quotient of the estimated standard deviation of a series of determinations, $y_1, y_2, \ldots yx_i, y_n$, of a quantity divided by the arithmetic mean value, $\bar{y}$, of $y_i$, i.e.

$$\sigma_r = \frac{\sqrt{\sum_{i=1}^{n}(y_i - \bar{y})^2}}{\bar{y}}$$

or, for a single measurement, the quotient of the estimate of the standard deviation divided by the value of the single measurement (synonymous with the relative standard deviation, multiplied by 100 when expressed as percent)

**3.26**
**repeatability**
closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

**3.27**
**reproducibility**
closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement

**3.28**
**service laboratory**
laboratory performing *in vivo* or *in vitro* radiobioassay measurements

**3.29**
**standard deviation**
***s***
quantity characterizing the dispersion of the results for a series of $n$ measurements of the same measurand, given by the equation

$$s = \sqrt{\frac{\sum_{i=1}^{n}(y_i - \bar{y})^2}{(n-1)}}$$

where

$y_i$ is the result of the $i$th measurement;

$\bar{y}$ is the arithmetic mean of the $n$ results considered

**3.30**
**systematic error**
mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand

**3.31**
**testing laboratory**
laboratory responsible for evaluating the performance of service laboratories in meeting the performance specifications of ISO 28218

**3.32**
**traceability**
property of the result of a measurement or the value of a standard, whereby it can be related to stated references through an unbroken chain of comparisons all having stated uncertainties

NOTE 1 Stated references are usually national or International Standards.

NOTE 2 The unbroken chain of comparisons is called a traceability chain.

**3.33**
**transfer reference standard**
**TRS**
material that contains radionuclide components of interest in chemical and physical forms similar to radiobioassay specimens and that is used to quantify the amount of activity present in a person or sample measured

NOTE The radionuclides used for the preparation of the TRS are, when possible, related to CRMs. The preparation procedures are verified and documented.

**3.34**
**unbiased**
in a state wherein a measurement of a random variable has zero bias

NOTE In other words, the measured value of the quantity is equal to the expected value of the quantity being determined.

**3.35**
**uncertainty of measurement**
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurement

**3.36**
**validation**
act of defining the method capability and determining whether it can be properly applied as intended, or a test to determine whether the overall implemented analysis fulfils specified requirements

**3.37**
**verification**
act of confirming, substantiating or assuring that an action, condition or goal has been implemented, completed or accomplished in accordance with the specified requirements or a test, in order to prove that a particular step of the analysis fulfils specified requirements

## 4 Symbols

| | |
|---|---|
| $A_{ai}$ | actual quantity in the test phantom or *in vitro* sample for the $i$th measurement |
| $A_i$ | value of the $i$th measurement in a category being tested |
| $B_r$ | relative bias |
| $B_{ri}$ | relative bias statistic for the $i$th measurement |
| $n$ | number of measurements of the same measurand |
| $s$ | standard deviation |
| $s_B$ | standard deviation of a total blank count |
| $s_{Br}$ | standard deviation of the relative bias applied for performance testing |
| $t$ | counting time interval used in the procedure (seconds) |
| $m$ | number of the input quantities |
| $X_i$ | input quantity ($i = 1,..., m$) |
| $x_i$ | estimate of the input quantity $X_i$ |
| $u(x_i)$ | standard uncertainty of the input quantity $X_i$ associated with the estimate $x_i$ |
| $h_1(x_1)$ | standard uncertainty $u(x_1)$ as a function of the estimate $x_1$ |
| $u_{rel}(w)$ | relative standard uncertainty of a quantity $W$ associated with the estimate $w$ |
| $G$ | model function |

| | |
|---|---|
| $Y$ | random variable as an estimator of the measurand; also used as the symbol for the non-negative measurand itself, which quantifies the physical effect of interest |
| $\tilde{y}$ | true value of the measurand; if the physical effect of interest is not present, then $\tilde{y} = 0$, otherwise, $\tilde{y} > 0$ |
| $y$ | determined value of the estimator $Y$, estimate of the measurand, primary measurement result of the measurand |
| $y_j$ | values $y$ from different measurements ($j = 0,1, 2,...$) |
| $u(y)$ | standard uncertainty of the measurand associated with the primary measurement result $y$ |
| $\tilde{u}(\tilde{y})$ | standard uncertainty of the estimator $Y$ as a function of the true value $\tilde{y}$ of the measurand |
| $\hat{y}$ | best estimate of the measurand |
| $u(\hat{y})$ | standard uncertainty of the measurand associated with the best estimate $\hat{y}$ |
| $y^*$ | decision threshold of the measurand |
| $y^\#$ | detection limit of the measurand |
| $\tilde{y}_i$ | approximations of the detection limit $y^\#$ |
| $y^\triangleleft$ | lower confidence limit of the measurand |
| $y^\triangleright$ | upper confidence limit of the measurand |
| $\alpha$ | probability of the error of the first kind |
| $\beta$ | probability of the error of the second kind |
| $1-\gamma$ | probability for the confidence interval of the measurand |
| $k_p$ | quantile of the standardized normal distribution for the probability $p$ (e.g. $p = 1-\alpha$, $1-\beta$, or $1-\gamma/2$) |
| $k_q$ | quantile of the standardized normal distribution for the probability $q$ |
| $\Phi(t)$ | distribution function of the standardized normal distribution; $\Phi(k_p) = p$ applies. |



# 5 Performance measures

## 5.1 Decision threshold ($y^*$) and detection limit ($y^\#$)

### 5.1.1 Preamble

The value of the detection limit indicates the ability of the service laboratory to detect a radionuclide in a sample or person. The decision threshold provides a way of distinguishing the difference between the count rate from the measurand under analysis and the count rate from the appropriate blank. For *in vivo* measurements, the sample matrix (i.e. the person) of the measurand is a variable, therefore the detection limit is person dependent. For consistency, the detection limit calculated for a given sample represented by a uniform source distribution, either in a person or in a phantom, shall therefore be used to characterize the detection capability of the service laboratory. The service laboratory shall determine and document typical values of the detection limit for documented measurement conditions for each measurand for which a service is provided.

### 5.1.2 General procedure for the determination of the characteristic limits

#### 5.1.2.1 Introduction

##### 5.1.2.1.1 Preamble

The general procedures for the calculation of the characteristic limits are given in ISO 11929. The main features are summarized here to facilitate the presentation of the examples given in Annexes A and B. Further details are provided in ISO 11929. A short presentation of the meaning of the symbols taken from ISO 11929, and the logical connection between them, is given below.

A non-negative measurand shall be assigned to the physical effect to be investigated in any given measurement task. This measurand quantifies the effect and assumes the true value $\tilde{y} = 0$ if the effect is not present in a particular case. A random variable $Y$, an estimator, shall be assigned to the measurand. In the following discussion, the symbol $Y$ is used for the measurand itself. A value $y$ of the estimator $Y$, determined from measurements, is an estimate of the measurand. This value shall be calculated as the primary measurement result, together with the primary standard uncertainty $u(y)$ associated with $y$. These two values form the primary complete measurement result for the measurand and are obtained in accordance with ISO/IEC Guide 98-1 by evaluation of the measurement data and other information by means of a model (of the evaluation), which mathematically connects all the quantities involved. In general, the fact that the measurand is non-negative is not explicitly taken into account in the evaluation. Therefore, $y$ may be negative, especially when the measurand approaches a true value $\tilde{y} = 0$. The best estimate $\tilde{y}$ of the measurand is calculated in 5.1.2.5 from the primary measurement result $y$ and its standard uncertainty $u(y)$. In deriving the value of $\tilde{y}$, the knowledge that the measurand is non-negative is taken into account. The standard uncertainty $u(\tilde{y})$ associated with $\tilde{y}$ is smaller than $u(y)$.

##### 5.1.2.1.2 General model

In general, the non-negative measurand $Y$ is a function of several input quantities $X_i$ in the following form:

$$Y = G\left(X_1, \ldots\ldots, X_m\right) \tag{1}$$

##### 5.1.2.1.3 Calculation of the primary measurement result $y$ and the associated standard uncertainty

Equation (1) is the model of the evaluation. Substituting given estimates $x_i$ of the input quantities $x$ in the model function $G$ of Equation (1) yields the primary measurement result $y$ of the measurand as

$$y = G\left(x_1, \ldots\ldots, x_m\right) \tag{2}$$

The standard uncertainty $u(y)$ of the measurand associated with the primary measurement result $y$ follows, if the input quantities $X_i$ are independently measured and standard uncertainties $u(x_i)$ associated with the estimates $x_i$ are given, from the following relation:

$$u^2\left(y\right) = \sum_{i=1}^{m}\left(\frac{\partial G}{\partial X_i}\right)^2 u^2\left(x_i\right) \tag{3}$$

##### 5.1.2.1.4 Calculation of the standard uncertainty $\tilde{u}^2(\tilde{y})$

If $u(x_1)$ is known as a function $h_1(x_1)$, $y$ is replaced by $\tilde{y}$ and Equation (2) is solved for $x_1$. This results in $x_1$ as a function of $\tilde{y}$ and $x_2, \ldots x_m$. The function replaces $x_1$ in Equation (3) and in $h_1(x_1)$ yielding $\tilde{u}^2(\tilde{y})$.

If $u(x_1)$ is known as a function $h_1(x_1)$, it is often sufficient to use the following approximation, especially if the primary measurement result of the measurand is not much larger than the associated uncertainty $u(y)$:

$$\tilde{u}^2\left(\tilde{y}\right) = u^2\left(y_1\right) \tag{4}$$

If only $\tilde{u}(0) = u(y_0)$ (measurement of background or blank) and $y_1 > 0$ (measurement currently carried out) are known, then the following linear interpolation often suffices:

$$\tilde{u}^2(\tilde{y}) = \tilde{u}^2(0) \cdot \left(1 - \frac{\tilde{y}}{y_1}\right) + u^2(y_1) \cdot \frac{\tilde{y}}{y_1} \tag{5}$$

#### 5.1.2.2 Calculation of the decision threshold $y^*$

The decision threshold is calculated as

$$y^* = k_{1-\alpha}\tilde{u}(0) \tag{6}$$

An effect of the measurand $Y$ is recognized as present if $y > y^*$. If not, the calculation of the confidence limits and of the best estimate $\hat{y}$ of the measurand with the associated standard uncertainty $u(\hat{y})$ are omitted.

With the approximation $\tilde{u}(\tilde{y}) = u(y)$, the relation $y^* = k_{1-\alpha}u(y)$ applies.

#### 5.1.2.3 Calculation of the detection limit $y^\#$

The detection limit $y^\#$ is the smallest solution of Equation (7):

$$y^\# = y^* + k_{1-\beta}\tilde{u}\left(y^\#\right) \tag{7}$$

Equation (7) is an implicit equation. The detection limit can be calculated by solving it or, more simply, by iteration. The approximation $\tilde{y}_i$ for $y^\#$ is repeatedly substituted in the right-hand side of Equation (7) to produce with the starting approximation $\tilde{y}_{i+1}$. As starting approximation, $\tilde{y}_0 = 2y^\#$ can be chosen.

The detection limit does not exist if $y^\# < y^*$.

If the approximation in Equation (4) is used, Equation (7) simplifies to Equation (8):

$$y^\# = \left(k_{1-\alpha} + k_{1-\beta}\right) \cdot u(y) \tag{8}$$

If the linear interpolation in accordance with Equation (5) is used, Equation (7) becomes Equation (9):

$$y^\# = a + \sqrt{a^2 + \left(k_{1-\beta}^2 - k_{1-\alpha}^2\right) \cdot \tilde{u}^2(0)}\,; \quad a = \left[k_{1-\alpha} \cdot \tilde{u}(0)\right] + \frac{1}{2} \cdot \frac{k_{1-\beta}^2}{y_1}\left[u^2\left(y_1\right) - \tilde{u}^2(0)\right] \tag{9}$$

If $\alpha = \beta$, then

$$y^\# = 2 \cdot a \tag{10}$$

#### 5.1.2.4 Calculation of the confidence limits

The limits of a confidence interval are provided for a physical effect, recognized as present in accordance with 5.1.2.2, in such a way that the confidence interval contains the true value of the measurand with the specified probability $1-\gamma$. The confidence limits take into account that the measurand is non-negative.

The confidence limits are calculated as follows:

$$y^\triangleleft = y - k_p u(y) \text{ with } p = \omega \cdot (1 - \gamma/2) \tag{11}$$

and

$$y^{\triangleright} = y + k_q u(y) \text{ with } q = 1 - \omega\gamma/2$$

where $\omega$ is the integral of the standardized normal distribution

$$\omega = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{y/u(y)} \exp\left(-v^2/2\right) dv = \Phi\left[y/u(y)\right] \tag{12}$$

and $\Phi(k_p) = p$.

$\omega = 1$ may be set if $y/u(y) \geqslant 4$ and the value of the approximations symmetrical to $y$ apply:

$$y^{\triangleleft,\triangleright} = y \pm k_{1-\gamma/2} u(y) \tag{13}$$

#### 5.1.2.5 Calculation of the best estimate of the measurand with the associated standard uncertainty

The determined primary measurement result $y$ of the measurand shall be compared with the decision threshold $y^*$. If $y > y^*$, then the physical effect quantified by the measurand is recognized as present. Otherwise, the hypothesis that the effect is absent cannot be rejected.

On the basis of the measured quantity $y$ and its standard uncertainty $u(y)$, the best estimate of the measurand and its associated standard uncertainty are calculated as follows:

$$\hat{y} = y + \frac{u(y) \cdot \exp\left\{-y^2/\left[2u^2(y)\right]\right\}}{\omega\sqrt{2\pi}}; \quad u(\hat{y}) = \sqrt{u^2(y) - (\hat{y} - y)y} \tag{14}$$

For $y/u(y) \geqslant 4$, the following approximations apply:

$$\hat{y} = y; \quad u(\hat{y}) = u(y) \tag{15}$$

### 5.2 Relative bias and bias performance criteria

The relative bias is a measure of how close the assessed activity is to the actual activity. Since the actual activity is rarely known, this criterion applies to measurements on suitable mock-ups, phantoms, or test samples. These may be used with appropriate reference to standards to determine and minimize fixed (deterministic) errors, for determining the detection limit and for replications to determine repeatability. The rationale for the selection of the particular statistics is given in this subclause and in 5.3:

— a relative bias statistic is defined in this International Standard for the purposes of performance testing of a finite number of measurements in each category of analysis;

— the relative bias statistic ($B_{ri}$) for the $i$th measurement in a category with respect to the correct value of the measurand is defined as:

$$B_{ri} = \frac{(A_i - A_{ai})}{A_{ai}} \tag{16}$$

where

$A_i$ is the value of the $i$th measurement in a category being tested, not necessarily a replicate, but possibly a different quantity of measurand for each measurement;

$A_{ai}$ is the actual quantity in the measurand for the $i$th measurement.

The relative bias $B_r$ for that category is calculated as the average of the individual relative biases $B_{ri}$ and is defined as follows:

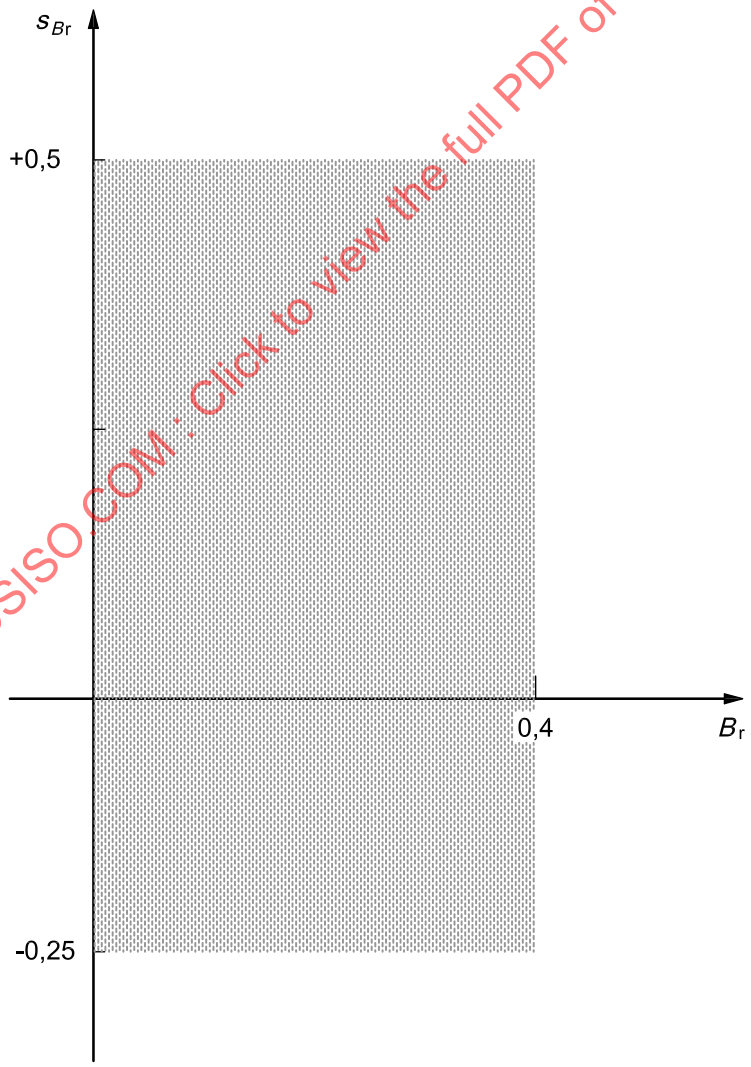
$$B_r = \sum_{i=1}^{n} \frac{B_{ri}}{n} \tag{17}$$

where $n$ is the number of test measurements in a given test category.

The sample size $n$ shall be at least five to ensure statistical reliability.

For testing purposes, as described in Clause 9 and in the service laboratory internal quality control, $B_r$ shall be between −0,25 and +0,50 (unless the customer or regulator specifies a narrower range) when $A_{ai}$ is greater than or equal to the customer's MTL (or the MTL given in Tables 1 and 2 when the customer does not specify MTLs) for any specified radionuclide. The MTL should be greater than the detection limit, since uncertainties will be large at this level: 5 to 10 times $y^{\#}$ is appropriate unless contractually specified. Test samples with quantities below the MTL should be analysed for purposes of periodically checking performance near the service laboratory's $y^{\#}$ of a given analytical procedure; however, performance on test samples below the MTL is not required to meet the performance criteria for $B_r$. When $B_r$ is outside the −0,25 to +0,50 range in internal service laboratory quality control checks, the service laboratory shall make appropriate corrections in phantom calibrations or measurement protocols to reduce or eliminate bias.






**Key**

$B_r$ relative bias

$s_{Br}$ repeatability

**Figure 1 — Acceptable limits for relative bias, $B_r$, and repeatability, $s_{Br}$**

### 5.3 Repeatability performance criteria

For testing purposes and for service laboratory quality control, the repeatability of the measurement process is selected to be the relative dispersion of the values of $B_{ri}$ from their mean $B_r$ and is defined as follows:

$$s_{Br} = \sqrt{\frac{\sum_{i=1}^{n}(B_{ri} - B_r)^2}{(n-1)}}$$

The absolute value of the repeatability statistic, $s_{Br}$, shall be less than or equal to 0,4 (unless the customer specifies a smaller value) when $A_{ai}$ is equal to or greater than the customer's MTL for any given radionuclide in a category (or the MTL given in Tables 1 and 2 when the customer does not specify MTLs). Performance on test samples below the MTL is not required to meet the acceptable value of $s_{Br}$. When $s_{Br}$ is greater than 0,4 in internal service laboratory quality control checks, appropriate corrective action shall be taken to bring the repeatability into the acceptable range.

It should be noted that the statistics $B_r$ and $s_{Br}$ were selected to be unbiased estimators of the underlying true bias and repeatability.

## 6 Performance criteria for *in vivo* radiobioassay

### 6.1 General

The provisions of this International Standard apply to any *in vivo* radiobioassay system used to measure radionuclides that are distributed throughout the whole body or localized in individual tissues or organs such as thyroid, lungs, liver, bone and so on. Procedures shall be validated, written, reviewed and approved in accordance with the service laboratory's quality assurance plan.

### 6.2 Responsibilities of the customer that could impact the service laboratory's performance

This subclause includes items that could impact the quality of the work performed by the service laboratory. The service laboratory should request that the customer take the following precautions prior to submitting workers to the service laboratory:

a) specify the radionuclide(s) to be analysed;

b) provide accurate and unambiguous identification of the workers;

c) provide information about the material to which the worker may have been exposed [e.g. physical, specially activity median aerodynamic diameter (AMAD), chemical form, isotopic composition];

d) provide information on the main suspected route of exposure and on the frequency of the monitoring;

e) specify the part of the body on which the measurement has to be made, whole body counting or organ (lungs, thyroid, etc.);

f) specify the required reporting requirements.

### 6.3 Service laboratory criteria

#### 6.3.1 General

The *in vivo* radiobioassay service laboratory shall be adequately equipped, shielded, provided with the necessary services, and be appropriately located. The minimum requirements for the facility are described in 6.3.2 and 6.3.3.

### 6.3.2 Equipment

The minimum requirement for the equipment comprising the *in vivo* measurement system, which includes the detectors, electronic support, shielding and software, shall be such that the performance of the system meets the bias and repeatability requirements of Clause 5 and the customer's requirements for the detection limit.

The laboratory should also consider installing a background radiation counter and recording or alarming systems or other appropriate devices to alert the operator when background changes occur that are sufficient in magnitude to affect the required detection capabilities.

### 6.3.3 Services

Personnel decontamination facilities shall be provided at the *in vivo* radiobioassay service laboratory, should be in proximity to the counting facility and should be kept away from contaminated areas.

Anti-claustrophobial features in the measurement area, such as a failsafe, door-opening device that can be operated by the individual being counted, a two-way intercom, music, and restful lighting, may be helpful.

Appropriate means (either procedural or instrumental) shall be used to confirm any activity detected as internal deposition rather than external contamination. Decontamination measures, such as showering, followed by recounting may be used as a means for removing and distinguishing external contamination.

Adequate ventilation and, in services where liquid nitrogen is used, oxygen analysers and alarms shall be provided in the measurement area. Contamination-free clothing shall be available to personnel for *in vivo* measurements.

### 6.3.4 Location

In order to minimize background radiation levels and the possibility of contamination, the service laboratory should be located at an appropriate distance from areas where radioactive materials are processed, stored or transported or where radiation is generated. The location shall be subsequently reviewed at intervals in order to determine whether the interference from sources such as accelerators, reactors and other radiation sources has increased. The *in vivo* radiobioassay laboratory shall be designed with sufficient ventilation, filtration and shielding in order to avoid interfering background fluctuations, such as those due to radon.

## 6.4 Identification of radionuclides

Except for circumstances where there is only one radionuclide of interest or for systems used for screening, measurement systems shall provide identification of the radionuclides they are designed to measure. The method of identification, either automated or manually performed, shall be capable of identifying the significant components in mixtures of radionuclides of interest to the customer.

## 6.5 Quantification

Quantification shall be accomplished by calibration with known sources of the radionuclide incorporated in a suitable mock-up or phantom of the body or the body part of interest (or suitably validated mathematical phantom). Whenever the phantom does not sufficiently match the subject's physical characteristics, as in chest wall thickness for low-energy photons, physical measurements of the subject may be used to establish an appropriate calibration. If not, a correction factor shall be used so that performance criteria can be met.

The *in vivo* programme (both the counter design and the operational protocol) shall be designed to minimize measurement uncertainties when used to measure actual depositions of measurand in individuals. A major source of uncertainty can occur because individuals and the distribution of radionuclides within those individuals will be different from those represented by phantoms used for counter calibration and performance testing.

An estimate shall be generated and documented to assess the magnitudes of the uncertainties associated with the procedure for the radionuclides of importance to the customer. At least an estimate of the uncertainty associated with each of the following items should be quantified:

a) subject size;

b) chest wall thickness for lung measurements;

c) counting geometries of the organ with respect to the detector;

d) distribution of the activity within the organ;

e) interference from the activity in portions of the body not being measured;

f) interference from other radionuclides;

g) counting statistics during calibration;

h) counting statistics during the *in vivo* count of the subject; and

i) calibration source uncertainties.

Steps in an *in vivo* radiobioassay programme that can be taken to reduce uncertainty include calibration for varying subject size or chest wall thickness, multiple measurements over the retention period, and use of geometries that minimize source location dependence.

For some types of *in vivo* measurements, the radionuclide measured might be only an intermediate step to determine the measurand of interest (e.g. bismuth-214 for radium-226; americium-241 for plutonium-239; thorium-234 for uranium-238; uranium-235 for uranium-234). The ratio of the radionuclide of interest to the radionuclide being counted shall be determined or estimated. Steps shall be taken to quantify the uncertainties involved.

## 6.6 Reporting results

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 radionuclide(s) for which the subject was analysed and other radionuclides detected;

d) identification of specific measurement procedures and equipment;

e) quantification of the amount of each radionuclide measured in each part of the body counted at the time of measurement (this may include negative or zero values if needed);

f) estimates of counting uncertainty and the total propagated uncertainty (which includes counting and other random and systematic uncertainties);

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.

### 6.7 Records retention

The service laboratory shall retain, in a retrievable form, records required by this International Standard. These records shall include the following:

a) with no period of time other than a period of time specified by national legal requirements:

   1) results of quality assurance audits;

   2) radiobioassay equipment calibrations;

   3) training received;

b) with a period of time specified by national legal requirements or, in the absence of legal requirements, a minimum period of 30 years for dose relevant information is recommended:

   1) results of all quality control performance checks;

   2) procedures by which the measurements were made, including generic methods and examples of calculations;

   3) all data used in the determination of the person's result, including measurement spectra;

   4) reported results specified in 6.6.

## 7 Performance criteria for *in vitro* radiobioassay

### 7.1 General

Urine and faecal samples are frequently collected and analysed to assist medical or radiation protection personnel in estimating the intake of radioactive material by the worker. On occasion, samples of breath, nasal fluid, blood, hair, finger nails or other biological specimens are analysed. The performance criteria of this International Standard for *in vitro* measurements, however, are directed primarily toward ensuring and improving the accuracy of measurements of radioactivity in excreta samples.

### 7.2 Responsibilities of the customer that could impact the service laboratory's performance

This subclause includes items that could impact the quality of the work performed by the service laboratory. The service laboratory shall request that the customer take the following precautions prior to submitting samples to the service laboratory:

a) specify the radionuclide(s) to be analysed;

b) provide information about the material to which the worker may have been exposed (e.g. physical or chemical form);

c) collect, preserve and send samples in a manner such that loss of activity is minimal and sample contamination is prevented;

d) provide a sample of adequate size for each type of analysis requested, including adequate amounts to allow verification or additional analysis if needed;

e) provide containers that are free from external and internal contamination;

f) take precautions to ensure the integrity of the container and prevent leakage from the container and/or cross-contamination of samples during the shipment and storage of samples;

g) provide accurate and unambiguous identification of samples;

h) specify the reporting requirements; and

i) alert the service laboratory of potentially “highly contaminated” samples, samples that may contain chelated material, samples that may contain additives or preservatives or both, or samples that may contain extremely insoluble material.

## 7.3 Analytical methodology

### 7.3.1 General

Analytical procedures, laboratory facilities and the equipment used for nuclear measurements may vary widely among laboratories. Method validation shall be undertaken and specific procedures documented before being used to analyse biological samples for estimating radioactivity burdens. Analytical determinations shall be made in accordance with the performance criteria given in Clause 5.

### 7.3.2 Analytical equipment and facilities

Equipment used to process biological samples shall be procured and used in conformance with the quality assurance plan established by the service laboratory. Equipment and facilities shall be suitable and appropriate for safe and proper sample preparation, chemical processing, and radionuclide quantification required to comply with the requirements of this International Standard and national regulations.

### 7.3.3 Operating procedures and instructions

#### 7.3.3.1 Preamble

The reliability of analytical procedures shall be established prior to use for radiobioassay. These procedures shall be documented, reviewed, and approved in accordance with the service laboratory's quality assurance plan.

#### 7.3.3.2 Sample preparation

Written procedures shall include all steps from receipt of the sample at the service laboratory facility to preparation for analyses. Taking an aliquot of a homogeneous sample to determine the activity present in the total sample is an acceptable procedure. However, the entire sample should be prepared for analysis and the aliquot taken after the sample preparation has been completed.

#### 7.3.3.3 Chemical procedures

The chemical procedure(s) shall be capable of identifying and measuring radionuclides present at the customer's detection limit. The procedure(s) shall remove, when necessary, elements and/or radionuclides that hinder identification and quantification of the measurand. All chemical procedures used shall be documented.

#### 7.3.3.4 Identification of radionuclides

Written procedures shall be included for tasks such as measurement, identification, data reduction and reporting of results.

The service laboratory shall use appropriate techniques to ensure proper identification of specific radionuclide(s) as requested, and shall be capable, where necessary, of separating or resolving a mixture of radionuclides that might be applicable to a known or suspected intake. Such methods may include spectroscopy, half-life determinations, and chemical separations.

#### 7.3.3.5 Quantification

The laboratory shall determine analytical results and uncertainties in units of activity (Bq) or mass as requested, and shall be capable of separating or resolving a mixture of radionuclides, where necessary and possible. The appropriate volume, recovery and decay corrections shall be made. An estimate shall be generated and documented to assess the magnitudes of the uncertainties associated with the procedure for the radionuclides of importance to the customer. As a minimum, the uncertainties shall include those associated with calibration, counting, measurement of volume or weight, losses from chemical separations, transfer operations and impurities.

### 7.4 Reporting results

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 radionuclides for which the sample was analysed and other radionuclides detected;

   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 (which includes counting other random and systematic uncertainties);

d) identification of equipment and specific measurement procedures;

e) values of the decision level and detection limit;

f) identification of the individual responsible for the report.

### 7.5 Records retention

The service laboratory shall retain, in a retrievable form, records required by this International Standard. These records shall include:

a) for a period of time specified by national legal requirements or as long as they remain current:

   1) results of quality assurance audits;

   2) radiobioassay equipment calibrations;

   3) training received by the staff of the service laboratory;

b) with a period of time specified by national legal requirements or in the absence of a legal requirement, a minimum period of 30 years for dose relevant information is recommended:

   1) results of all quality control performance checks;

   2) procedures by which the measurements were made including calculations and generic examples;

   3) all data used in the determination of the sample results, including measurement spectra;

   4) reported results specified in 6.5.

# 8 Quality assurance and quality control for radiobioassay laboratories

## 8.1 General

As a minimum, the quality assurance and quality control practices cited below for radiobioassay shall be established by both testing and service laboratories. The provisions of this clause pertain to both *in vivo* and *in vitro* radiobioassay.

## 8.2 Quality assurance

The fundamental requirements for a full measurement quality assurance plan include:

a) compliance with general operational requirements stated in accepted written criteria;

b) a documented in-house quality assurance plan;

c) periodic performance evaluations, including proficiency measurement tests and on-site expert assessments; and

d) documented procedures and quality assurance plan for services provided to customers.

To ensure the quality of a laboratory's output over extended periods of time, its production process shall be solidly based on sound scientific principles, method validation and product verification. The four fundamental requirements for a full measurement quality assurance programme as described above provide the strategy for safeguarding the quality of the laboratory's product, whether it is a measurement or service. Furthermore, these requirements ensure periodic comparison of the laboratory's measurement capabilities with those of the national standardization authority, continued stability of the laboratory process and periodic evaluation of the final product to confirm that it meets specifications.

Operating within the guidance of the documented criteria under an in-house quality assurance plan, periodic peer assessments and documented quality procedures for customer services ensure stable operation between proficiency evaluations.

The in-house quality assurance plan shall provide for programme assessments, adequate operational environment, personnel qualifications, procedure manual, instrumentation, calibration, data reduction, record system and data reporting. Control over the analytical process between proficiency evaluations provides another assurance of end products with reproducible quality. Adoption of a total quality management approach would ensure continued improvement of operations.

The objective of periodic on-site expert evaluations, i.e. assessments, is to ensure the technical and scientific soundness of the laboratory's methods and processes. The experts will review and evaluate the laboratory's analytical and service procedures (including validation of all key steps, and product and/or service verification), documentation, quality assurance plan, and proficiency tests results (pre- and post-start-up) to see that the operations are based on solid scientific grounds to meet the operational criteria. The expert evaluation ensures that the process to be used by the laboratory is capable of yielding analytical services that meet technical and quality specifications.

The proficiency tests periodically evaluate measurement consistency with the appropriate national standards and test the laboratory and its capabilities to verify their ability to produce high-quality products and/or services. Although the term “traceability” has many facets, for this discussion it is interpreted as the demonstrated lineage of measurement quality to the appropriate national standard. As discussed above, one component of traceability is verified through appropriate periodic proficiency testing by a hierarchical metrology system. An essential element of the state of being traceable is successful completion of tests within specified limits of accuracy. Finally, the traceable measurement process can be used to verify the quality of a laboratory's service/product output. For the specific area of radioactivity measurements, two measurement proficiency testing strategies are available: 1) known concentrations of radionuclides of undisclosed values are sent to the laboratory for analysis (implicit traceability), and 2) the laboratory assays its material and sends it to the testing laboratory for conformational analysis (explicit traceability). In both cases, analyses are carried out and comparisons are made between the value obtained by the laboratory and that obtained by its testing laboratory. The laboratory is then notified of the percentage difference through a report. For implicit traceability testing, only the laboratory's measurement capabilities are being tested. On the other hand, when the laboratory assays its own product then sends an aliquot to the testing laboratory for conformational and explicit traceability measurements, both the laboratory's analytical processes and measurement capabilities are being tested.

Through the combination of all these measurement quality assurance strategies, the quality and integrity of the laboratory's measurements or services can be ensured. Of these strategies, major emphasis should be placed on strong in-house quality assurance plans, active and thorough on-site expert evaluations, strict adherence to the documented operational criteria, and laboratory evaluation by “blind” testing. This combination of checks will ensure that the analytical processes remain in control within specified performance objectives. Although periodic end-product evaluation remains a necessary precaution, its frequency can be minimal when the analytical processes remain in control.

Radiobioassay laboratory quality assurance plans shall include the following elements:

— identification and preparation of samples;

— validation of procedures or methods;

— measurement of radioactivity;

— data reduction; and

— documentation.

Systematic actions shall be included in the quality assurance plan, as listed in 7.3, in order to provide adequate confidence that a measurement or analytical procedure will be performed satisfactorily.

## 8.3 Quality assurance plan

### 8.3.1 Points of the plan

The service laboratory shall have a written quality assurance plan to ensure conformance to policies, procedures, and instructions. The plan shall include the following:

a) organization structure, management and operational responsibilities (reference to an in-house quality assurance manual);

b) instructions and procedures, including procedure and software validation;

c) qualification and training of laboratory personnel;

d) document control;

e) procurement of materials;

f) identification and control of material and samples (chain of custody);

g) inspection and testing of material and equipment;

h) control and maintenance of calibration standards;

i) corrective action;

j) review of procedures, specifications and operating logs;

k) observation of operations and evaluation of quality control data;

l) quality assurance records; and

m) documentation of detection limit, relative bias, repeatability and methods of calculating results for periodic quality control determinations.

#### 8.3.2 Responsible quality assurance person or organization

The quality assurance plan shall designate an organization or person with sufficient knowledge to identify quality assurance problems, and with sufficient authority to initiate or recommend corrective actions and to provide verification of deficiency corrections.

### 8.4 Quality control

#### 8.4.1 General

Performance checks shall be conducted to ensure the conformance of analytical processes, measurement equipment and the facilities to predetermine operational requirements.

#### 8.4.2 Quality control procedures

The laboratory shall have written quality control procedures to verify that the quality of measurements or radioactivity determinations complies with the accuracy requirements specified in Clause 5. The quality control procedures shall include the following:

a) use of traceable radionuclide reference standards;

b) performance checks of measurement systems;

c) instrument calibration;

d) intra-laboratory analyses (e.g. known quantities, replicates and blanks);

e) participation in available inter-laboratory inter-comparison programmes;

f) computational checks;

g) review of procedures, specifications and operating logs;

h) observation of operations and evaluation of quality control data;

i) evaluating conformance to the performance criteria of this International Standard;

j) evaluating quality control data to ensure the long-term consistency of analytical results; and

k) verification of $y^{\#}$ determinations.

### 8.4.3 Performance checks of instrumentation for *in vivo* and *in vitro* radiobioassay

Performance of the measurement equipment shall be checked and evaluated at regular intervals while the equipment is in use. These checks shall be sufficient to demonstrate that the measurement equipment is properly calibrated and that all components are functioning properly. Measurements should include instrument background and response checks. In the case of *in vivo* radiobioassay, measurement system response stability shall be established by means of a check source and a "tolerance chart". The response should not vary by more than 5 % from the established mean. The response should be checked at the beginning of the operating period, at the conclusion of the operating period. Replicate *in vivo* measurements should also be made periodically. Techniques such as quality control or tolerance charts shall be used for the evaluation of instrument performance. A quality control measurement shall be performed prior to use of the instrument, and the number of quality control measurements should comprise at least 5 % of the measurement with no fewer than five quality control measurements.

### 8.4.4 Performance checks on *in vitro* (biological samples) radiobioassay procedures

Reagent blank and biological samples of each type known to contain only natural or baseline levels of radioactivity shall be analysed periodically to determine the values of appropriate blanks. Samples containing known quantities of each radionuclide of interest shall be analysed to determine bias and repeatability of the analytical procedures. Replicate samples shall also be processed periodically. Statistical techniques such as quality control charts shall be used to evaluate *in vitro* radiobioassay procedure performance data. The number of quality control samples shall comprise at least 5 % of the measurement with no fewer than five quality control measurements.

### 8.4.5 Performance criteria checks for *in vivo* and *in vitro* radiobioassay

The service laboratory shall periodically assess the $y^{\#}$, the relative bias and the repeatability.

Evaluation of counter background and calculation of $y^{\#}$ with comparison of these values to historical data may provide evidence that interference levels are changing. Any effect on repeatability and bias as stipulated in Clause 5 shall be evaluated.

### 8.4.6 Use of reference radioactive materials for equipment calibrations

Radionuclide standards used for equipment calibrations and to test the accuracy of analytical procedures and/or measurement equipment shall either be those designated as CRM, TRS, or standards directly compared with appropriate CRMs and where available, with the same measuring apparatus (see Reference [5]). Instrument quality control checks are not required to be traceable standards. In certain *in vitro* analyses, where standards are not available, the chemical procedure for the determination of the unknown may be tested by using a CRM of a different radioisotope of the same element. Detector efficiency calibrations should be checked in accordance with a frequency established and documented by the laboratory. In addition, corrections of detector efficiency should be made when anomalies are detected by routine performance checks and whenever measurement equipment or source preparation procedures are changed. Procedures for preparation of secondary or intra-laboratory standards for quality assurance checks shall be documented. The physical and chemical form and matrix of any standards for performing in-house quality assurance checks should be such that the test matrix will duplicate the same analytical problems or characteristics as the unknown samples to be analysed.



## 9 Performance testing programme

### 9.1 General

This clause sets forth the minimum technical standards to be followed by any testing laboratory in carrying out a programme to inter-compare or accredit one or more service laboratories with regard to their ability to conform to the requirements of this International Standard. This clause is designed for a blind testing programme to determine in a consistent manner the inherent measurement capabilities of radiobioassay laboratories. It does not include all procedures required for a complete accreditation programme; only the

technical performance requirements for testing conformance are included. Procedures for inspection, certification and programme administration shall be developed by the individual testing laboratories and the accrediting organization.

## 9.2 *In vivo* radiobioassay

### 9.2.1 General

A testing laboratory shall conduct a testing programme for *in vivo* radiobioassay measurement performance in accordance with the minimum standards established in 9.2.2 to 9.2.7 for test protocols, radionuclide categories and test phantoms.

### 9.2.2 Testing protocols

#### 9.2.2.1 Preamble

The testing laboratory shall develop a testing protocol for evaluating the performance of the *in vivo* radiobioassay service laboratory. The testing protocol shall be made available to the service laboratory prior to performance testing. The following provisions shall be included in the performance testing programme.

#### 9.2.2.2 Distribution and instructions

The testing laboratory shall maintain and provide test phantoms including appropriate blanks to the *in vivo* radiobioassay service laboratory for performance testing purposes. The phantoms shall be those specified in 9.2.5 to 9.2.7. The phantoms shall contain the appropriate test radionuclides by category as indicated in Table 1. The testing laboratory shall identify the test category for each phantom but shall not divulge the activity or the identity of the radionuclide(s). The ability of the testing laboratory to quantitatively measure the amount of radionuclide placed in each phantom shall be affirmed by establishing traceability to the national standardization authority.

#### 9.2.2.3 Test selection

Each service laboratory shall have the option of being tested and evaluated as follows, unless otherwise stipulated by applicable national legal requirements:

a) for an entire category, the service laboratory shall be evaluated for the entire category for the radionuclides listed in Table 1;

b) for a specific radionuclide, the service laboratory designates a specific radionuclide in a category of Table 1 to be used for testing; in this event, the evaluation of the test results shall be for that radionuclide only.

#### 9.2.2.4 Measurement protocol

The testing laboratory shall instruct the service laboratory to determine the amount of the radionuclide with a minimum of five measurements. The service laboratory shall be advised of any other procedures necessary to ensure that the tests allow the minimum performance criteria of this International Standard to be met. The service laboratory shall be instructed to use the analytical procedure and counting times normally employed for analysis of the radionuclide under consideration. Any deviations from the routine measurement protocol shall be documented in the report to the testing laboratory.

#### 9.2.2.5 Reporting protocol

The service laboratory shall be required by the testing laboratory to report the following information for each radionuclide detected:

a) reference date and time (date and time specified by the testing laboratory, to which the decay correction is made);

b) the measured activity of the test radionuclide(s) (and total counts and the net count rate, if available) for each of the five repetitive measurements in the category, and the mean;

c) the calibration factor for the test radionuclide(s);

d) the protocol for estimating the $y^{\#}$;

e) estimate of the standard uncertainty (reference paragraph where used total propagated uncertainty);

f) a description of the *in vivo* radiobioassay measurement system used for the test measurement;

g) identification of the procedure used for the test.

#### 9.2.2.6 Evaluation of laboratory performance

The testing laboratory shall determine, for each test category, whether the results reported by the service laboratory meet the performance criteria of this International Standard.

#### 9.2.2.7 Frequency of testing

A participating service laboratory shall be retested at least once every three years for each radionuclide, or shall be retested upon its (the service laboratory's) request. Testing is also required upon changing measurement equipment.

A participating service laboratory shall be evaluated by an on-site assessment team at least every three years, or shall be re-evaluated upon its request.

### 9.2.3 Test categories

The categories in which tests are available for the measurement of radionuclides distributed in the lungs, thyroid or total body are presented in Table 1.

**Table 1 — MTL for *in vivo* radiobioassay performance testing**

| Measurement category | Type | Radionuclide | MTL[ab] |
|---|---|---|---|
| I. Transuranium elements via X-rays | Lung | Plutonium-238 | 9 kBq |
| II. Americium-241 | Lung | Americium-241 | 0,1 kBq |
| III. Thorium-234 | Lung | Thorium-234 in equilibrium with its parent U-238 | 0,5 kBq |
| IV. Uranium-235 | Lung | Uranium-235 | 30 Bq |
| V. Fission and activation products | Lung | Any two from:<br>— Manganese-54<br>— Cobalt-57<br>— Cobalt-58<br>— Cobalt-60<br>Plus:<br>— Caesium-134[c]<br>— Caesium-137/Barium-137m[c] | <br>3 kBq<br>2,5 kBq<br>3 kBq<br>3 kBq<br><br>3 kBq<br>3 kBq |
| VI. Fission and activation products | Total body | All of the following:<br>— Caesium-134<br>— Caesium-137/Barium-137m<br>— Cobalt-60[c]<br>— Manganese-54[c] | 3 kBq |
| VII. Radionuclides in the thyroid | Thyroid | Iodine-131 or Iodine-125[d] | 3 kBq |

[a] The upper bound of the testing range shall not exceed 10 times the stated MTL.

[b] The highest and lowest activities of radionuclides (not including K-40) in any one test phantom shall be within a factor of three of each other, except for Ce-144 in Category V, whose activity shall not exceed that of any other radionuclide by more than a factor of 30.

[c] These radionuclides shall be present in the phantom for interference but shall not be tested.

[d] The MTLs for I-131 and I-125 may be used also for their respective surrogates, namely Ba-133 and I-129.



### 9.2.4 Test radionuclides and activity ranges

#### 9.2.4.1 Preamble

Although in practice the *in vivo* radiobioassay measurement of a certain radionuclide may require specialized techniques, the test radionuclides of Table 1 represent a minimum testing programme suitable for evaluating the capabilities of a service laboratory to measure radionuclides in a specified category. In general, the MTLs selected for test samples shall be at least 5 to 10 times the $y^{\#}$ levels that are attainable by competent analysts using well-developed procedures and instruments that give reliable results. They are not necessarily the best "state-of-the-art" values, in that there may be analytical methods that can provide a lower detection capability but perhaps at greater costs. The activity of any source, including aliquots, used for testing shall be traceable to the national standardizing authority.

#### 9.2.4.2 Specification for test radionuclide

The test radionuclide(s) for each of the categories shall be those specified in Table 1.

#### 9.2.4.3 Selection of activity

The amounts of activity used in a given test phantom shall be within the range specified for that category in Table 1.

#### 9.2.4.4 Certification of activity

The testing laboratory shall determine the amount(s) of activity of the radionuclide(s) in the phantoms using a measurement procedure meeting the requirements of 5.2 and 5.3 reduced by a factor of 5 (i.e. $B_r$ shall be between –0,05 and +0,10, and $s_{Br}$ should be less than or equal to 0,08). See Reference [16].

The ability of the testing laboratory to measure quantitatively shall be affirmed by establishing traceability to the national standardization authority. The testing laboratory shall demonstrate measurement traceability with this authority for each test radionuclide.

### 9.2.5 Test phantom for lung measurement

The testing laboratory shall provide a commercially available reference torso phantom or compatible test organs to the service laboratory for *in vivo* performance testing.

The torso phantom for measurement of activity in the lungs shall simulate the torso, skeleton and lungs. The phantom shall have a chest wall over the lungs that simulates muscle tissue with a known thickness. For inter-comparisons between service laboratories, the same phantom shall be used for all laboratories tested.

The simulated tissues of the phantom shall have transmission and scatter characteristics for low-energy photons that closely approximate those for normal tissue.

The torso phantom shall contain an interchangeable pair of simulated lungs. The activity of each test radionuclide in the simulated lung pair should approximate a uniform distribution.

### 9.2.6 Test phantom for total body measurements

The testing laboratory shall provide a phantom to the service laboratory for *in vivo* performance testing. The phantom used shall be commercially available to the service laboratory.

The whole-body test phantom for measurement of radionuclides uniformly distributed in the total body shall simulate at least the whole-body proportions of a reference man (see Reference [6]). In addition, whole-body test phantoms used for *in vivo* performance testing may include phantoms representing people with different stature.

### 9.2.7 Test phantoms for thyroid and for other types of *in vivo* measurement

The testing laboratory shall provide an appropriate commercially available phantom to the service laboratory for *in vivo* radiobioassay measurement performance testing.

## 9.3 *In vitro* radiobioassay

### 9.3.1 General

A testing laboratory shall conduct testing programmes for *in vitro* radiobioassay measurements performance in accordance with minimum standards established in 9.3.2 and 9.3.3.

### 9.3.2 Testing protocol

#### 9.3.2.1 Preamble

The testing laboratory shall develop a protocol for evaluating the performance of *in vitro* radiobioassay service laboratories. The protocol shall be made available to the service laboratory prior to performance testing. The following provisions shall be included in the performance testing programme.

#### 9.3.2.2 Distribution and instructions

The testing laboratory shall either obtain or prepare the test samples. The testing laboratory shall provide test samples, including appropriate blanks, to the service laboratory for performance testing purposes. The test samples shall consist of either natural or artificial urine or faecal matter or both, spiked with known quantities of one or more of the test radionuclide(s) within the ranges specified in Table 2. The testing laboratory shall submit the test samples to the service laboratories in typical sample sizes. For gamma or alpha spectroscopy of urine, such samples should be approximately 1 l in volume. For liquid scintillation counting, the sample volume may be smaller. Faecal matter may be ashed, and a sample of at least 2 g submitted to the laboratory.

The sample shall be stabilized and preserved in a manner in which the loss of activity to the walls of the container is minimal. The testing laboratory may add a quenching agent to the test samples. The testing laboratory shall indicate the test category for each sample and may indicate the radionuclide, but shall not disclose the amount of radionuclide in the sample.

**Table 2 — MTL for *in vitro* radiobioassay performance testing**

| Measurement category | Radionuclide[a] | MTL[bc] (per litre or per faecal sample) |
|---|---|---|
| I. BETA activity: average energy < 100 keV | Hydrogen-3 | 2 kBq |
| | Carbon-14 | 2 kBq |
| | Sulfur-35 | 20 Bq |
| | Radium-228 | 0,9 Bq |
| II. BETA activity: average energy ⩾ 100 keV | Phosphorus-32 | 4 Bq |
| | Strontium-89/-90 | 4 Bq |
| | or Strontium-90 | 4 Bq |
| III. ALPHA activity: isotopic analysis | Thorium-228/-230 or Thorium-232 | 0,02 Bq |
| | Uranium-234/-235 or Uranium-238 | 0,02 Bq |
| | Neptunium-237 or Plutonium-238 | 0,01 Bq |
| | Plutonium-239/240 or Americium-241 | 0,01 Bq |
| IV. Elements (mass concentration) | Thorium (ICPMS) | 100 ng/l |
| | Uranium (ICPMS) | 50 ng/l |
| | Plutonium (TIMS) | 0,02 pg/l |
| V. GAMMA (photon) activity | Caesium-137/Barium-137m | 2 Bq |
| | Cobalt-60 | 2 Bq |
| | Iodine-125 | 4 Bq |

[a] An *in vitro* radiobioassay service laboratory may elect to be tested for a specific radionuclide or elect to be tested for the category. The testing laboratory selects the test radionuclide if a category is requested.

[b] The upper bound of the testing range shall not exceed 20 times the stated MTL.

[c] Artificial sample matrix may be required when testing with natural radionuclides of uranium and thorium.

#### 9.3.2.3 Test selection

Each service laboratory shall have the option of being tested and evaluated as follows:

a) for an entire category: the service laboratory shall be evaluated for an entire category listed in Table 2;

b) for a specific radionuclide: the service laboratory designates a specific radionuclide within a category to be used for testing. In this event, the evaluation of the test results will be for that radionuclide only.

#### 9.3.2.4 Measurement protocol

The testing laboratory shall provide the service laboratory with a minimum of three samples for a specific radionuclide with activities within the testing range. The service laboratory shall be advised of any other procedures necessary to ensure that the tests will allow the minimum performance criteria of this International Standard to be met. The service laboratory shall measure each sample using the analytical procedure and counting times normally employed for analysis of the radionuclide under consideration. Any deviations from the routine measurement protocol shall be documented.

#### 9.3.2.5 Reporting protocol

The service laboratory shall be required by the testing laboratory to report the following information for each sample analysed:

a) reference date and time (date and time specified by the testing laboratory, to which the decay correction is made);

b) identification of sample;

c) measured amount, activity or concentration corrected for decay;

d) the protocol for estimating the detection limit;

e) brief description of apparatus and equipment used in analysis;

f) identification of the analytical procedures used in analysis;

g) estimates of the standard uncertainty.

#### 9.3.2.6 Evaluation of laboratory performance

The testing laboratory shall determine for each test category whether the results reported by the service laboratory meet the performance criteria of this International Standard.

#### 9.3.2.7 Frequency of testing

A participating service laboratory shall be retested at least every three years for each radionuclide or shall be retested upon its (the service laboratory's) request.

A participating service laboratory shall be evaluated by an on-site assessment team at least every three years, or shall be re-evaluated upon its (the service laboratory's) request.

### 9.3.3 Test radionuclides and activity ranges

#### 9.3.3.1 Preamble

The specified test radionuclides of Table 2 represent a minimum testing programme suitable for judging the capabilities of a service laboratory to measure radionuclides in a specified category. In general, the MTLs

selected for test samples shall be 5 to 10 times the levels of the detection limit that are attainable by competent analysts using well-developed procedures and instruments that give reliable results. They are not necessarily the best “state-of-the-art” values, in that there may be analytical methods that can provide improved detection, but perhaps at greater costs.

#### 9.3.3.2 Specification for test radionuclide

The test radionuclide(s) for each of the categories shall be those specified in Table 2.

#### 9.3.3.3 Selection of activity

The amounts of activity used in a test sample shall be within the range specified in Table 2 for that category.

#### 9.3.3.4 Certification of activity

The testing laboratory should determine the amount(s) of activity of the test radionuclide(s) in the TRS sample with a standard deviation of 3 % or less. The ability of the testing laboratory to quantitatively measure shall be affirmed by traceability to the national standardization authority. The testing laboratory shall demonstrate measurement traceability with this authority for each test radionuclide.

# Annex A
(informative)

# Detection limit — Models for applications

## A.1 Model in ionizing-radiation measurements

The model can be specified as follows:

$$Y = G\left(X_1,\ldots\ldots,X_m\right) = \left(X_1 - X_2X_3 - X_4\right)\cdot\frac{X_6X_8\cdots}{X_5X_7\cdots} = \left(X_1 - X_2X_3 - X_4\right)\cdot W \tag{A.1}$$

with the abbreviation

$$W = \frac{X_6X_8\cdots}{X_5X_7\cdots} \tag{A.2}$$

where

$X_1$ is the gross count rate, $\rho_g$;

$X_2$ is the background count rate, $\rho_0$;

and the other input quantities, $X_i$, are calibration, correction or influence quantities, or conversion factors, e.g. the emission or response probability. In particular, $X_3$ is a shielding factor and $X_4$ an additional background correction quantity.

If some of these input quantities are not involved, $x_i = 1$ and $u(x_i) = 0$ shall be set for them. For the count rates, $x_1 = r_g = n_g/t_g$ and $u^2(x_1) = n_g/t_g^2$, as well as $x_2 = r_0 = n_0/t_0$ and $u^2(x_2) = n_0/t_0^2$ apply.

By substituting the estimates $x_i$ in Equation (A.1), the primary estimate $y$ of the measurand $Y$ results in the following:

$$y = G\left(x_1,\ldots\ldots,x_m\right) = \left(x_1 - x_2x_3 - x_4\right)\cdot w \tag{A.3}$$

with the abbreviation:

$$w = \frac{x_6x_8\cdots}{x_5x_7\cdots} \tag{A.4}$$

with the following partial derivatives:

$$\frac{\partial G}{\partial X_1} = W\,;\quad \frac{\partial G}{\partial X_2} = -X_3W\,;\quad \frac{\partial G}{\partial X_3} = -X_2W\,;\quad \frac{\partial G}{\partial X_4} = -W\,;\quad \frac{\partial G}{\partial X_i} = \pm\frac{Y}{X_i}\ \left(i \geqslant 5\right) \tag{A.5}$$

and by substituting the estimates $x_i$, $w$ and $y$, Equation (3) yields the standard uncertainty $u(y)$ of the measurand associated with $y$, as follows:

$$u^2\left(y\right) = w^2\cdot\left[u^2(x_1) + x_3^2u^2(x_2) + x_2^2u^2(x_3) + u^2(x_4)\right] + y^2u_{\text{rel}}{}^2(w) \tag{A.6}$$

where

$$u_{\mathrm{rel}}{}^2(w) = \sum_{i=5}^{m} \frac{u^2(x_i)}{x_i^2} \tag{A.7}$$

is the sum of the squared relative standard uncertainties of the quantities $X_5$ to $X_m$. For $m < 5$, the values $w = 1$ and $u_{\mathrm{rel}}{}^2(w) = 0$ apply.

By replacing $y$ with $\tilde{y}$, Equation (A.3) is solved for $x_1$. This results in $x_1$ as a function of $\tilde{y}$ and $x_2$,……,$x_m$ as follows:

$$x_1 = \tilde{y} / w + x_2 x_3 + x_4 \tag{A.8}$$

The function replaces $x_1$ in Equation (A.6) and the standard uncertainty $\tilde{u}^2(\tilde{y})$ can be evaluated.

The other quantities are then calculated as stated in the body of this International Standard, in accordance with Equations (6), (7), (11), (12), (13), (14) and (15).

## A.2 Model for general chemical analytics

Equations (A.1) and (A.3) can be re-written in the simplified forms with $x_3 = 1$ and $x_4 = 0$, as follows:

$$Y = (X_1 - X_2) \cdot W \; ; \quad y = (x_1 - x_2) \cdot w \tag{A.9}$$

with the same abbreviations for $W$ and $w$ as in Equations (A.2) and (A.4).

The standard uncertainty $u(y)$ of the measurand associated with $y$ is as follows:

$$u^2(y) = w^2 \cdot \left[ u^2(x_1) + u^2(x_2) \right] + y^2 \cdot u_{\mathrm{rel}}{}^2(w) \tag{A.10}$$

The calculation of $u_{\mathrm{rel}}{}^2(w)$ is carried out on the basis of the expression in Equation (A.7).

As $u(x_1)$ is not generally known as a function $h_1(x_1)$, it is sufficient to use the approximations in Equations (4) and (5). It follows from Equation (A.10) for $y = 0$ (i.e. $x_1 = x_2$):

$$\tilde{u}^2(0) = u^2(0) = 2 \cdot w^2 \cdot u^2(x_2) \tag{A.11}$$

Equation (6) for the decision threshold, Equations (9) and (10) for the detection limit and Equations (11) to (15) for the other characteristic limits will apply.

## A.3 General expressions of practical use

In cases where $x_1$ (or $x_2$) is expressed as follows:

$$x_1 = \frac{x_{1,1}}{x_{1,2}} \tag{A.12}$$

then the uncertainty $u^2(x_1)$ is generally calculated as follows:

$$u^2(x_1) = (x_1)^2 \left( \frac{u^2(x_{1,1})}{x_{1,1}^2} + \frac{u^2(x_{1,2})}{x_{1,2}^2} \right) \tag{A.13}$$

In the case of $n$ multiple measurements, the estimates $x_1$ of the input quantity are obtained as an average with their associated standard uncertainties, $s^2(x_1)$, as follows:

$$\overline{x_1} = \frac{1}{n}\sum_{i=1}^{m} x_{1,i} \tag{A.14}$$

and

$$s^2(x_1) = \frac{1}{n-1}\sum_{i=1}^{m} (x_{1,i} - \overline{x_1})^2 \tag{A.15}$$

# Annex B
(informative)

# Detection limit — Application examples

## B.1 Example 1: Direct measurement of an internal contamination with whole body count (WBC) (linear background)

### B.1.1 General

The general model for calculating the radionuclide activity is given in the ICRU Report 69 (ICRU 2003)[17], from where the symbols and the procedure for calculating the background contribution are taken.

### B.1.2 Model

The model is as follows:

$$A_{\mathrm{B}} = \frac{n_{\mathrm{P}} - \frac{P}{2 \cdot n_{\mathrm{m}}} n_0}{t \cdot \varepsilon}$$

where

$A_{\mathrm{B}}$ is the activity;

$n_{\mathrm{P}}$ is the number of counts under the peak;

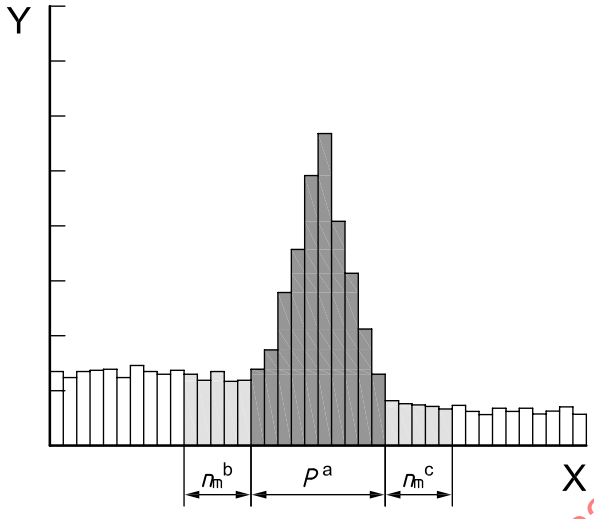
$n_0$ is the number of counts in the regions $B_1$ and $B_2$;

$P$ is the number of channels within the peak;

$n_{\mathrm{m}}$ is the number of channels in the regions $B_1$ ($B_2$);

$t$ is the time of the measurement;

$\varepsilon$ is the efficiency.




**Key**

X channel
Y counts

a Peak region.
b Region $B_1$.
c Region $B_2$.

**Figure B.1 — Regions of the spectrum and relative parameters** (from ICRU 2003)



### B.1.3 Associations

On the basis of Equations (A.3) and (A.4):

$$y = A_B\,;\quad x_1 = n_P\,;\quad x_2 = \frac{P}{2n_m}\,;\quad x_3 = n_0\,;\quad x_4 = 0\,;\quad x_5 = t\,;\quad x_7 = \varepsilon$$

$$w = \frac{1}{x_5 \cdot x_7} = \frac{1}{t \cdot \varepsilon}$$

Setting the uncertainties:

$$u^2(x_1) = n_P\,;\quad u^2(x_2) = 0\,;\quad u^2(x_3) = n_0\,;\quad u^2(x_4) = 0\,;\quad u^2(x_5) = 0\,;\quad u^2(x_7) = u^2(\varepsilon)$$

On the basis of Equation (A.7):

$$u_{rel}{}^2(w) = \frac{u^2(x_5)}{x_5{}^2} + \frac{u^2(x_7)}{x_7{}^2} = \frac{u^2(\varepsilon)}{\varepsilon^2}$$

On the basis of Equation (A.8):

$$n_P = \left(\tilde{y} \cdot t \cdot \varepsilon\right) + \frac{P}{2n_m} n_0$$

### B.1.4 Standard uncertainty

On the basis of Equation (A.6):

$$u^2(y) = \frac{1}{(t \cdot \varepsilon)^2} \cdot \left[ n_P + \left( \frac{P}{2n_m} \right)^2 n_0 \right] + y^2 \left( \frac{u^2(\varepsilon)}{\varepsilon^2} \right)$$

By replacing $n_P$ in the previous function:

$$\tilde{u}^2(\tilde{y}) = \frac{1}{(t \cdot \varepsilon)^2} \cdot \left[ (\tilde{y} \cdot t \cdot \varepsilon) + \frac{P}{2n_m} n_0 + \left( \frac{P}{2n_m} \right)^2 n_0 \right] + \tilde{y}^2 \left( \frac{u^2(\varepsilon)}{\varepsilon^2} \right)$$

### B.1.5 Decision threshold $y^*$

From Equation (6):

$$y^* = k_{1-\alpha} \tilde{u}(0) = k_{1-\alpha} \frac{1}{(t \cdot \varepsilon)} \cdot \sqrt{\left[ \frac{P}{2n_m} n_0 + \left( \frac{P}{2n_m} \right)^2 n_0 \right]}$$

### B.1.6 Detection limit $y^\#$

From Equation (7):

$$y^\# = y^* + k_{1-\beta} \tilde{u}\left(y^\#\right) = y^* + k_{1-\beta} \sqrt{\frac{1}{(t \cdot \varepsilon \cdot)^2} \cdot \left[ \left( y^\# \cdot t \cdot \varepsilon \right) + \frac{P}{2n_m} n_0 + \left( \frac{P}{2n_m} \right)^2 n_0 \right] + y^{\#2} \left( \frac{u^2(\varepsilon)}{\varepsilon^2} \right)}$$

The equation is an implicit equation. The detection limit can be calculated by iteration or by solving the above equation for $y^\#$. In case of equal probability of the errors of first and second kind ($\alpha = \beta$, i.e. $k_\alpha = k_\beta = k$), the explicit equation for calculating the detection limit is as follows:

$$y^\# = \frac{k \frac{1}{t \cdot \varepsilon} \left( k + 2 \sqrt{\left[ \frac{P}{2n_m} n_0 + \left( \frac{P}{2n_m} \right)^2 n_0 \right]} \right)}{1 - k^2 \left( \frac{u^2(\varepsilon)}{\varepsilon^2} \right)}$$

Confidence limits and best estimate are calculated from Equations (11) to (15). See Tables B.1 to B.3.



**Table B.1 — Input quantities and specifications**

| Quantity | Symbol | Value | Standard uncertainty | Unit |
|---|---|---|---|---|
| Number of counts under the peak | $n_P$ | 2 251 | 47,44 | 1 |
| Number of counts in the regions $B_1$ and $B_2$ | $n_0$ | 1 249 | 35,34 | 1 |
| Duration of the measurement | $t$ | 900 | — | s |
| Number of channels within the peak | $P$ | 15 | — | 1 |
| Number of channels in the regions $B_1$ ($B_2$) | $n_m$ | 6 | — | 1 |
| Efficiency | $\varepsilon$ | 3.20E-03 | 1.60E-04 | $s^{-1}$ $Bq^{-1}$ |

**Table B.2 — Intermediate values**

| Quantity | Symbol | Value | Unit |
|---|---|---|---|
| Probability of the error of first kind | $\alpha$ | 0,05 | 1 |
| | $k_{1-\alpha}$ | 1,645 | 1 |
| Probability of the error of second kind | $\beta$ | 0,05 | 1 |
| | $k_{1-\beta}$ | 1,645 | 1 |
| Confidence level | $1-\gamma$ | 0,95 | 1 |
| | $k_{1-\gamma/2}$ | 1,960 | 1 |
| Condition for the approximations in Equations (13) and (15) | $y/u(y)$ | 9,39 | 1 |
| Parameter in accordance with Equation (12) | $\omega$ | 1 | 1 |
| Parameter in accordance with Equation (11) | $p$ | 0,975 | 1 |
| Quantile | $k_p$ | 1,96 | 1 |
| Parameter in accordance with Equation (11) | $q$ | 0,975 | 1 |
| Quantile | $k_q$ | 1,96 | 1 |

**Table B.3 — Results**

| Quantity | Symbol | Value | Unit |
|---|---|---|---|
| Activity | $y$ | 239 | Bq |
| Standard uncertainty associated with the activity | $u(y)$ | 25 | Bq |
| Decision threshold | $y^*$ | 34 | Bq |
| Measurement effect present? | $y > y^*$ | yes | — |
| Detection limit | $y^\#$ | 69 | Bq |
| Lower confidence limit | $y^\triangleleft$ | 190 | Bq |
| Upper confidence limit | $y^\triangleright$ | 289 | Bq |
| Best estimate of the measurand | $\hat{y}$ | 239 | Bq |
| Uncertainty of the best estimate | $u(\hat{y})$ | 25 | Bq |



## B.2 Example 2: Determination of plutonium by alpha spectrometry

### B.2.1 General

All the measurements are carried out with the same counting time (time pre-selection mode). The model for calculating the activity of the radionuclide $A_i$ (left column) depends on the measurement yield $Y$, for which the uncertainty is calculated in the right column. The detector efficiency (not given here) allows the calculation of the chemical yield, important for quality control.