BRITISH STANDARD

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Radiation protection instrumentation — In vivo counters — Classification, general requirements and test procedures for portable, transportable and installed equipment

The European Standard EN 61582:2006 has the status of a British Standard

ICS 13.280

BSI
British Standards

National foreword

This British Standard is the official English language version of EN 61582:2006. It was derived by CENELEC from IEC 61582:2004.

The CENELEC common modifications have been implemented at the appropriate places in the text and are indicated by tags ⟦C⟩ ⟨C⟧.

The UK participation in its preparation was entrusted to Technical Committee NCE/2, Radiation protection and measurement, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

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English version

Radiation protection instrumentation - In vivo counters - Classification, general requirements and test procedures for portable, transportable and installed equipment

(IEC 61582:2004, modified)

Instrumentation pour la radioprotection - Systèmes de mesure in vivo - Classification, exigences générales et procédures d'essai pour les appareils portables, mobiles ou à poste fixe (CEI 61582:2004, modifiée)

Strahlenschutz-Messgeräte - Einrichtungen für die in-vivo-Überwachung - Ganz- und Teilkörperzähler - Klassifizierung, allgemeine Anforderungen und Prüfverfahren für tragbare, transportable und festinstallierte Einrichtungen (IEC 61582:2004, modifiziert)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of the International Standard IEC 61582:2004, prepared by SC 45B, Radiation protection instrumentation, of IEC TC 45, Nuclear instrumentation, together with common modifications prepared by the CENELEC BTTF 111-3, Nuclear instrumentation and radiation protection instrumentation, was submitted to the formal vote and was approved by CENELEC as EN 61582 on 2006-02-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-02-01

Annex ZA has been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 61582:2004 was approved by CENELEC as a European Standard with agreed common modifications.

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CONTENTS

RADIATION PROTECTION INSTRUMENTATION – IN VIVO COUNTERS – CLASSIFICATION, GENERAL REQUIREMENTS AND TEST PROCEDURES FOR PORTABLE, TRANSPORTABLE AND INSTALLED EQUIPMENT

1 Scope and object

This International Standard specifies the classification, general design requirements, performance characteristics and test procedures for in vivo counting systems for detecting trace amounts of radionuclides in the bodies of persons working in nuclear power plants, laboratories and facilities handling radionuclides, and inhabitants living on territory which may be contaminated by either naturally occurring or artificial radionuclides. The purpose is to determine the dose equivalent to organs and the effective dose of internal radiation for the whole body.

This standard is applicable both to equipment with spectroscopic capabilities and instruments for rapid screening for gross internal contamination only.

This standard is applicable to instruments for the monitoring of certain critical organs (for example, lungs, thyroid gland, etc.) as well as instruments for monitoring the whole body.

The standard applies to equipment for the measurement of the activity of gamma-emitting radionuclides in humans in order to determine the committed dose equivalent due to internal contamination in accordance with the recommendations of the ICRP 60 and ICRP 61.

The requirements of the standard are applicable to the installed apparatus, to vehicle-mounted equipment and to portable instruments. However, Annex B defines the additional mechanical and environmental performance requirements and the additional testing required for transportable and portable assemblies. The general and radiological requirements of all types of in vivo counters are included in this standard.

Depending on the type of instrument and the organ to be checked, measurement geometry may require the subject of the monitoring procedure to stand, sit, or lie.

The detection assembly includes one or more radiation detector. Normally, these are shielded-scintillation or semi-conductor detectors. Where identification of the location of contamination is required, the detectors may be collimated.

The measurement assembly includes functional units for the processing of signals from the detection assembly as well as units for the display of the measured activity.

For the measurement of body mass a built-in weighing machine may be used.

The standard specifies general types, specific measuring characteristics, main test procedures, electrical and mechanical characteristics [C〉 *Text deleted* 〈C], as well as the requirements related to background radiation of the environment.

This equipment is not intended for the determination of external contamination of the human body or the clothing of personnel.

This standard is not applicable to equipment such as radiation detectors intended for introduction into the human body.

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.

2.1 International standards

IEC 60050-393, *International Electrotechnical Vocabulary (IEV) – Chapter 393: Nuclear instrumentation – Physical phenomena and basic concepts*

IEC 60050-394, *International Electrotechnical Vocabulary (IEV) – Chapter 394: Nuclear instrumentation – Instruments*

IEC 60068-2-1, *Environmental testing – Part 2: Tests. Tests A: Cold*

IEC 60068-2-2, *Environmental testing – Part 2: Tests. Tests B: Dry heat*

IEC 60068-2-6: *Environmental testing – Part 2: Tests – Test Fc: Vibration (sinusoidal)*

IEC 60068-2-14, *Environmental testing – Part 2: Tests. Test N: Change of temperature*.

IEC 60068-2-27: *Environmental testing. Part 2: Tests. Test Ea and guidance: Shock.*

IEC 60068-2-78, *Environmental testing – Part 2-78: Tests – Test Cab: Damp heat, steady state*

IEC 60721-3-5: *Classification of environmental conditions – Part 3-5: Classification of groups of environmental parameters and their severities – Ground vehicle installation*.

IEC 60721-3-7: *Classification of environmental conditions – Part 3-7: Classification of groups of environmental parameters and their severities – Portable and non-stationary use.*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-5:1995, *Electromagnetic compatibility (EMC – Part 4-5: Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-12:1995, *Electromagnetic compatibility (EMC) – Part 4-12: Testing and measurement techniques – Oscillatory waves immunity test*

IEC 61187:1993, *Electrical and electronic measuring equipment – Documentation*

IEC 61276:1994, *Nuclear instrumentation – Guidelines for selection of metrologically supported nuclear radiation spectrometry systems*

ISO 11929-1:2000, *Determination of the detection limit and decision threshold for ionizing radiation measurements – Part 1: Fundamentals and application to counting measurements without the influence of sample treatment*

ISO 11929-4:2001, *Determination of the detection limit and decision threshold for ionizing radiation measurements – Part 4: Fundamentals and application to measurements by use of linear-scale analogue ratemeters, without the influence of sample treatment*

2.2 Other International references

ICRP 38:1983, *Radionuclide Transformations: Energy and Intensity of Emissions*. Annals of the ICRP 11-13

ICRP 60:1990, R*ecommendations of the International Commission on Radiological Protection*. *Annals of the ICRP 21 No. 1-3, 1991*

ICRP 61:1991, *Annual Limits on Intake of Radionuclides by Workers Based on the 1990 – Recommendations*. *Annals of the ICRP 21 No. 4.*

ICRP 68:1994, *Dose Coefficients for Intakes of Radionuclides by Workers*: *A Replacement of ICRP 61. Annals of the ICRP 24 (4).*

ICRP 75, *General Principles for the Radiation Protection of Workers*

3 Terms and definitions

General terminology concerning detection and measurement of ionizing radiation is given in IEC 60050(393), IEC 60050(394), and in IEC 61276. For the purposes of this document, the definitions from the recommendations of ICRP 68 and ICRP 75 are applicable, as well as the following definitions.

3.1
conventionally true value of activity
best estimate of activity

value and its uncertainty determined from a primary or secondary standard or by means of a reference instrument which has been calibrated against primary or secondary radioactive sources

3.2
indicated (measured) activity
activity indicated by the measuring assembly under test

3.3
coefficient of variation
ratio V of the standard deviation s to the arithmetic mean of set of n measurements x_i given by the following formula

$$V = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \sqrt{\frac{1}{(n-1)} \sum_{i=1}^{n} \left(x_i - \bar{x} \right)^2}$$

3.4
calibration
process of determination of the numerical relationship between the observed indication and the value of the quantity being measured

3.5
reference radiation response (sensitivity)
R_{ref}
response of the assembly under standard test conditions (Table 1) to the reference activity expressed as

$$R_{\mathrm{ref}} = \frac{I_{\mathrm{rp}} - I_{\mathrm{b}}}{A_{\mathrm{t}}}$$

where

I_{rp} is the indication due to the conventionally true activity of the reference source and to the background;

I_{b} is the indication due to the background alone;

A_{t} is the conventionally true activity of the reference source.

3.6
minimum detectable activity
activity determined in accordance with ISO 11929-1

3.7
dynamic range
quotient of the signal from the maximum measurable indication of a quantity to the signal from the minimum detectable value of that quantity

3.8
error of indication
difference between the indicated activity A_{i} and the conventionally true activity at the point of measurement A_{c}

$$\Delta A = A_{\mathrm{i}} - A_{\mathrm{c}}$$

3.9
relative error of indication
quotient, expressed as a percentage, of the error of indication by the conventionally true value

3.10
relative intrinsic error
relative error of indication of a piece of equipment or an assembly with respect to a quantity when subjected to a specified reference quantity under specified reference conditions expressed as

$$F = \frac{A_i - A_t}{A_t}$$

where

A_i is the indicated value of a quantity;

A_t is the conventionally true value of the quantity at the point of measurement 〚C〉 *Text deleted* 〈C〛.

3.11
effective range of measurement
range of values of the quantity to be measured over which the performance of a piece of equipment or assembly meets the requirements of its specifications 〚C〉

3.12
measurement time
time delay between the initiation of the measurement and the attainment of the final reading

3.13
〚C〉 **relative** 〈C〛 **energy resolution**
〚C〉 *Text deleted* 〈C〛

The relative energy resolution 〚C〉 ε_R 〈C〛 is given by

〚C〉 $$\varepsilon_R = \frac{\text{full width in terms of energy (or channel number)}}{\text{the energy (or channel number) of the centroid of the energy of interest}}$$ 〈C〛

〚C〉 Where the full width is measured between the two points on the spectrum situated on either side of the centroid due to the energy of interest where the count rate in the energy channel is half that of the peak maximum. 〈C〛

NOTE The full width may not be symmetric in relation to the centroid.

3.14
qualification test
test performed in order to verify that the requirements of a specification are fulfilled

NOTE Qualification tests are subdivided into type tests and routine tests.

3.15
type testing
conformity testing on the basis of one or more specimens of a product representative of the production

[IEV 394-20-28]

3.16
routine test
test to which an individual device is subjected during or after manufacture to ascertain whether it complies with certain criteria

[IEV 394-20-08]

3.17
acceptance test
contractual test to prove to the customer that the device meets certain conditions of its specification

[IEV 394-20-09]

3.18
units
units of the International System (SI)[1] are used. The definition of radiation quantities and dosimetric terms are given in IEC 60050(393) and IEC 60050(394). The corresponding non-SI units are indicated in brackets

3.19
activity
the SI unit of radioactivity of any material is the Becquerel (symbol Bq)

1 Bq = 1 nuclear transition (decay) in a second

= 1 decay s^{-1}

The quantity has the unit s^{-1}

3.20
Non-SI units
The following units are also used for convenience:

For energy: electron volt (eV)

1 eV = $1{,}602 \times 10^{-19}$ J

For time: year (y), day (d), hour, (h), minute (min)

4 Classification

4.1 General classification

Dependent on the 〚C〛 radionuclides 〚C〛 and on the range of energy to be detected in vivo, monitors can be conveniently classified taking account of two considerations:

– the range of energy;
– the specificity of the measurement.

Besides, whole body counters or other types of in vivo monitoring systems can be classified into four types depending on the following:

– problem and task to be solved;
– the number of operational staff;
– the number of people to be monitored;
– the type of nuclear accident (for post-accident monitoring);
– the local environment;
– the method used to transport the system.

NOTE Since in vivo counters may include gamma-spectrometers, their characteristics may correspond to one of the groups of Tables 4 and 5 of IEC 61276.

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1 Bureau international des poids et mesures: Le Système international d'unités (SI), 7e edition, 1998.

4.2 Energy range classification

4.2.1 Low energy in vivo monitoring (range from 10 keV to 200 keV)

These in vivo counters are used for the detection of low-energy emitters (essentially actinides such as Pu, Am, U and electron capture nuclides). Because of their minimal translocation, these radionuclides are normally located in the lung, and measurements are made preferentially in this organ. However, measurements in other organs can also be considered.

4.2.2 High energy in vivo monitoring (range from 100 keV to 3 MeV)

These in vivo counters are used for the detection of high-energy emitters including activation products and fission product measurements. Because of their rapid translocation, the measurements are generally made on the whole body. However, measurements in other organs can also be considered.

4.3 Specificity of the measurement

This is dependent on the number of operational staff, the number of people to be monitored, the type of nuclear accident (for post-accident monitoring), the local environment and the method of transporting the monitoring equipment to any site.

4.3.1 Type 1 – Nuclide specific, spatially specific with very low background

These in vivo counters are precise low-level radiological monitoring equipment for the measurement of radioactivity as accurately and precisely as possible and are generally installed in atomic energy research institutions, atomic power plants, emergency treatment centres laboratories, universities and hospitals for research purposes.

The detector assemblies and driving mechanisms to move the detectors are mounted in a shielded room where special attention is paid to the materials lining the walls and to the air entering the room (radon).

Data processing and analysis and display and data storage equipment complete the whole monitoring equipment.

4.3.2 Type 2 – Nuclide specific, spatially specific with low background

These in vivo counters are used for the estimation of internal dose of individuals and are normally intended for atomic energy research institutions, atomic power plants, emergency treatment centres, etc.

The structure of this type of in vivo counter is suited to the more rapid monitoring of many subjects; a shadow shield structure (open structure covering only the detectors and their accessories), simpler than the type 1 construction, would meet this requirement.

4.3.3 Type 3 – Nuclide specific

These in vivo counters are general screening counters for radiation workers and for the mass screening of the general public after nuclear accidents. This latter screening may be an initial measurement or a subsequent measurement to determine any changes in condition.

These units are relatively easy to transfer from one place to another.

4.3.4 Type 4 – Non-nuclide and non-spatial specific

These in vivo counters perform a similar function to the type 3 and are very similar in design except that the detectors may be quite large.

NOTE Because of the difficulty of measurement and the high background dependency, measurements in the low-energy range need low background equipment. Consequently, the type 3 and type 4 equipment is not used for this range of energy.

5 General

5.1 General description of the instrument

5.1.1 General

Measurements shall be easy to make and shall be made as quickly as possible relevant to the sensitivity required so that a large number of workers or a general population can be dealt with efficiency. Facilities shall be available to introduce the results into a database.

The instruments shall be calibrated with the help of phantoms simulating the human body or where applicable separate human organs.

The instrument for measurement of the content of radionuclides in the human body may consist of the following main components:

– monitoring equipment for the detection of radioactivity including detection assembly and measurement assembly;
– auxiliary equipment.

The monitoring equipment for the detection of radionuclides contains the following parts which may or may not form a single mechanical assembly:

– detection assembly;
– measurement assembly.

5.1.2 Detection assembly

The detection assembly may consist of the following units:

– detector (scintillation counters or semi-conductor detectors, in the latter case including cryostat);
– preamplifier(s);
– additional detector(s) for the determination of ambient background radiation and compensation of the measurement against ambient background radiation;
– stable power supply for the detectors;
– collimator(s);
– shielding (iron, lead, etc.);
– chamber, armchair, chair, couch, cell, etc. (depending on the measurement geometry).

5.1.3 Measurement assembly

The measurement assembly may consist of some or all of the following units:

– measuring assembly for primary detector(s);

– measuring assembly for ambient background monitoring compensation circuit;
– sytems for the entry and treatment of anatomical information (weight, height, etc.);
– measurement unit, or spectrometer;
– data processing unit;
– stable power supply.

5.1.4 Auxiliary equipment

The auxiliary equipment may consist of the following units:

– drives for auxiliary recording and information storage;
– mass (weight) determination equipment;
– phantoms;
– source(s) for producing a high-quality check spectrum.

5.1.5 Ease of operation

The design of the instrument and equipment shall be such that the placing of the subject into the correct measuring position and movement from this position is easy.

5.1.6 Ease of decontamination

The detector(s) and other parts of the instrument and equipment shall be designed so as to minimize the possibility of contamination and be both easy to de-contaminate and dismantle.

This is not applicable to situations where the risks of contamination are excluded.

5.1.7 Size of subject

The equipment shall be designed to monitor all persons between 145 cm and 200 cm in height and having a maximum anterior-posterior dimension of 40 cm.

Where the equipment is designed to monitor children, the dimensional limits of the children for whom the particular equipment is designed shall be stated by the manufacturer.

5.2 Measurement method

To obtain the maximum performance, low background shielding or collimation of the detectors shall be used in combination with the optimum position of the subject dependent on whether the equipment is designed for the subject to be standing, sitting, or lying.

5.3 Energy range

The energy range should be as defined in 4.2.

Where the equipment is to measure specific radionuclides, instruments shall be set to measure the primary photon emission of the radionuclides of interest. It should be possible, either manually or automatically, to change the discriminator levels and channel widths so that other radionuclides with emissions within the specified energy range can be measured.

Indication of the threshold levels set in terms of energy, the primary photon energy being detected or the nuclides being measured shall be given.

5.4 Background

Indicated background radiation is due to

– ambient background radiation;
– intrusive radioactivity in the components of the instrument or equipment;
– contamination of the detector and/or chair, etc.;
– detector assembly noise;
– naturally occurring internal activity (potassium-40).

Since some instruments may be in continuous use, periodic checks should be made for any change in background conditions. Background checks may be carried out automatically. Where changes in the settings are made (for alternative nuclides), indication shall be made of the necessity of changing the background compensation where this is not automatic or of the necessity of accumulating background information where background compensation is not automatic. It shall not be possible to alter such settings during the measurement of contamination in a person.

5.5 Measurement range

The range of measurement shall not be less than three decades. The instrument shall operate within the requirements of this standard over the whole indicated measuring range.

5.6 Minimum detectable activity

Reference should be made to ISO 11929-1 for the determination of the minimum detectable count-rate.

For any particular measurement the minimum detectable activity can be determined from the relationship

$$\frac{LLD}{\varepsilon}$$

where ε is the efficiency of detection for the measurement of a particular radionuclide in a specified organ, normally expressed in count-rate per unit of activity (Bq);

LLD is the lower limit of decision threshold in terms of count rate and equal to

$$\frac{1}{2t_0} k_{1-\alpha}^2 \left[1 + \sqrt{1 + \frac{4 R_b t_0}{k_{1-\alpha}^2} \left(1 + \frac{t_0}{t_b} \right)} \right]$$

where

R_b is the background count rate;

t_0 is the measuring time;

t_b is the background measuring time;

$k_{1-\alpha}$ are the quantiles of the standard normal distribution.

For the purposes of meeting the requirements of this standard, $k_{1-\alpha}$ shall take the value 2,326 i.e. there will be 1 % risk of activity indicated when in fact there is no activity present.

6 Characteristics of equipment for low-energy emitter measurement

6.1 Energy range (10 keV to 200 keV)

The equipment shall have the capability of resolving specific gamma or X-rays of energy between at least 10 keV and 200 keV.

6.2 Minimum detectable activity

The minimum detectable activity shall be determined for each type of instrument for specified background conditions and monitoring time for each of the radionuclides of interest (see 5.6).

6.3 Ranges of measurement of activity

As a minimum, the equipment shall be capable of measuring in the body or organ of interest the following activities for either Am-241 or U-235 where the background in the vicinity of the equipment is as given under the reference condition given in Table 1. These activities are specified in becquerels and relate to a 1 % confidence interval ($k_{1-\alpha}$ = 2,326 as given in ISO 11929-1 for the limit of detection).

		Am-241	U-235
Type 1	In vivo counters	25	25
Type 2	In vivo counters	45	40

6.4 Energy resolution

The energy resolution of scintillation detector-based instruments shall not exceed an FWHM (full width half maximum) of 25 keV for the 59,54 keV gamma line of Americium-241 decay and shall be stated by the manufacturer.

The energy resolution of Germanium semi-conductor detector-based instrument should not exceed an FWHM of 1,5 keV for the 59,54 keV gamma line of Americium-241 and shall not exceed 2 keV for the 122,1 keV gamma line of Cobalt-57 and shall be stated by the manufacturer.

NOTE These resolutions are obtained with spectrometric sources (see 5.1.4) in free space, but spectra obtained in normal operation will be distorted because of self-absorption and scattering of quanta in tissue. The degree of distortion depends on the location of the radionuclide in the body.

6.5 Integral non-linearity

The permissible limit of the integral non-linearity under reference conditions for instruments with scintillation detectors shall not exceed

– ±0,5 % for type 1 and type 2 in vivo counters.

The permissible limit of integral non-linearity under reference conditions for instruments with Germanium semi-conductor detectors shall not exceed

– ±0,1 % for type 1 in vivo counters;
– ±0,2 % for type 2 in vivo counters.

6.6 Natural background level

The measured background count-rate for the stated energy regions shall be defined for a natural external background. The level of the natural background shall be specified.

The manufacturer shall state the background count-rate obtained from the naturally occurring background under normal operating conditions (with a non-radioactive phantom present). For nuclide specific counters, this shall relate to a number of specific energy regions. The manufacturer shall state the background dose equivalent rate at which the measurements were made. In the case of fixed installations, this information shall relate to the background at the installation.

6.7 Reference radiation response

The response of the equipment

– shall be determined for a particular nuclide dependent on the organ of interest

or

– shall be as defined by ISO for the purposes of lung counting[2]

or

– shall be agreed between the purchaser and the manufacturer, and the manufacturer shall specify the phantom used.

Where the counting is specific to particular organs or parts of the body the phantoms used shall be by agreement between the purchaser and manufacturer.

The manufacturer shall specify the method used to determine the reference radiation response.

For the lungs, the response to the 59,54 keV gamma line of Americium-241 shall be determined by the use of a uniformly contaminated lung phantom within an inactive whole body phantom.

7 Characteristics of equipment for high-energy emitter measurements 100 keV to 3 MeV

7.1 Minimum detection activity

The minimum detection capability shall be determined for each type of instrument for specified background conditions and monitoring time for each of the radionuclides of interest (see 5.6).

2 At the time of publication of this document, no ISO document exists.

7.2 Ranges of measurement

As a minimum, the equipment should be capable of measuring the following activities in the body or organ of interest for Cobalt-60 and Caesium-137 where the background in the vicinity of the equipment is as given under the reference condition given in Table 1. These activities are specified in becquerels and relate to a 1 % confidence interval ($k_{1-\alpha}$ = 2,326 as given in ISO 11929-1 for the decision threshold).

		Cobalt-60	Caesium-137
Type 1	In vivo counters	20	40
Type 2	In vivo counters	40	80
Type 3	In vivo counters	200	400
Type 4	In vivo counters	200	400

7.3 Energy resolution

This requirement relates solely to equipment designed to produce energy spectra and be able to identify the contribution to the total activity of individual radionuclides. It is not a requirement for gross activity counting systems which fall into the Type 4 category.

The relative energy resolution in relation to the FWHM of scintillation detector-based instruments shall not exceed 〚C〉 10 % 〈C〛 for the 661,7 keV gamma line of Caesium-137 decay and shall be stated by the manufacturer.

The energy resolution of Germanium semi-conductor detector-based instrument should not exceed an FWHM of 2 keV for the 661,7 keV gamma line of Caesium-137 and shall not exceed 4,0 keV for the 1,3325 MeV gamma line of Cobalt-60 and shall be stated by the manufacturer.

The relative energy resolution of instruments with Germanium detectors of active volume 50 cm^3 to 100 cm^3 for the 1,3325 MeV gamma line of Cobalt-60 shall not exceed an FWHM of 3 %.

NOTE These resolutions are obtained with spectrometric sources in free space but spectra obtained in normal operation will be distorted because of self-absorption and scattering of quanta in tissue. The degree of distortion depends on the location of the radionuclide in the body.

7.4 Integral non-linearity

The permissible limit of the 〚C〉 integral non-linearity (conversion response) 〈C〛 under reference conditions for instruments with scintillation detectors shall not exceed

– ±0,5 % for type 1 and type 2 in vivo counter;

– ±1,0 % for type 3 in vivo counter.

The permissible limit of 〚C〉 integral non-linearity (conversion response) 〈C〛 under reference conditions for instruments with Germanium semi-conductor detectors shall not exceed

– ±0,1 % for type 1 in vivo counter;

– ±0,2 % for type 2 in vivo counter;

– ±0,3 % for type 3 in vivo counter.

7.5 Natural background level

The measured background count-rate for the stated energy regions shall be defined for a natural external background. The level of the natural background shall be specified.

The manufacturer shall state the background count rate obtained from naturally occurring background under normal operating conditions (with a non-radioactive phantom present). For nuclide specific counters, this shall relate to a number of specific energy regions. In the case of fixed installations, this information shall relate to the background at the installation.

7.6 Reference radiation response

The response of the equipment shall be determined for particular nuclide dependent on the organ of interest.

Example:

For the whole body, the response to the 661,7 keV gamma line of Caesium-137

– shall be determined by the use of a whole-body phantom uniformly loaded with Caesium-137;

or

– shall be as defined by ISO for the purposes of lung counting[3];

or

– shall be as agreed between the purchaser and manufacturer; the manufacturer shall specify the phantom used.

Where the counting is specific to particular organs or parts of the body, the phantoms used shall be by agreement between the purchaser and the manufacturer.

For the lungs, the response to the 1,3325 MeV gamma line of Cobalt-60 shall be determined by the use of a lung phantom uniformly loaded with Cobalt-60 within a non-loaded whole-body phantom.

For the thyroid the response to the 364,5 keV gamma line of Iodine-131 shall be determined by the use of a thyroid phantom uniformly loaded with Iodine-131 within a non-loaded neck phantom.

7.7 Maximum measurable activity

For the reference nuclide, the maximum measurable activity specified by the manufacturer shall be such that any error due to dead time in the counting system would not introduce an error in the measurement of greater than 10 %.

7.8 Warm-up time

The warm-up time shall be defined by the manufacturer.

7.9 Measurement time

To achieve the range of measurement specified in 7.2 above, the measurement shall not exceed 30 min for types 1 and 2 and 5 min for types 3 and 4. This does not exclude the ability to measure for longer periods.

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3 At the time of publication of this document, no ISO document exists.

8 Performance requirements and test procedures for low-energy emitter measurements

8.1 General test procedures

8.1.1 Nature of tests

All tests in this document are regarded as type tests except those routine tests described in 8.4.2.2b), although any or all of the tests may be considered as acceptance tests by agreement between the manufacturer and the purchaser. The stated requirements are minimum requirements and may be extended for any particular instrument or function.

Many of the test procedures are similar to those of gamma spectrometers (see IEC 61276).

Reference and standard test conditions are defined in Table 1.

8.1.2 Tests performed under standard test conditions

Tests which are performed under standard test conditions are listed in 〚C〉 Tables 2 and 3 〈C〛 which indicate for each characteristic, the limits of variation and the subclause where the corresponding test method is described.

8.1.3 Tests performed with variation of influence quantities

These tests are intended to determine the effects of variation in influence quantities and are given in Tables 2 and 3 with the range of variation of each influence quantity, and the limits of corresponding test method described.

The range of variation of influence quantities indicated in Tables 2 and 3 defines a nominal operating range within which the variation in measurement shall remain within the limits stated by the manufacturer; these limits shall in no case exceed those laid down in Tables 2 and 3.

In order to test the effect of variation in any one of the influence quantities tested in Tables 2 and 3, all other quantities shall be maintained within the limits for the standard test conditions given in Table 1, unless otherwise specified in the test procedure concerned.

In order to simplify these tests for each individual influence quantity, only the routine test concerning the intrinsic error need be performed, using not less than three readings at approximately half full scale on a range.

Other aspects of the performance of the instrument need to be tested with variation of influence quantities only if it is considered that the routine test specified will not give a representative measurement.

8.2 Statistical fluctuations

For any test involving the use of radiation, if the magnitude of the statistical fluctuations arising from the random nature of the radiation being detected is a significant fraction of the variation of the measurement permitted in the tests, then sufficient readings shall be taken to ensure that the mean value of such readings may be estimated with sufficient precision to demonstrate compliance with the test in question (see Annex A).

8.3 Reference phantom and sources

8.3.1 General

Radioactive reference phantoms and sources, which are necessary for performance determination and testing of the instruments, may be the following:

– primary phantoms required for basic calibration (see 8.3.2);

– secondary phantoms or sources which can be used additionally for routine or other specific tests. The secondary phantom may not be identical in physical form to the primary phantom.

The value of the conventionally true activity of phantoms or sources shall be known with an uncertainty of not more than 10 % (k = 2) and the relative value of phantom or source activities used in the same tests should be known with an uncertainty of not more than 5 % (k = 2). If necessary, correction for radioactive decay of the source shall be made.

8.3.2 Primary phantoms

The primary phantoms consist of an organ phantom loaded with the radioactive nuclide within a non-loaded whole body phantom. The organ phantom shall be uniformly filled with the radioactive nuclide Americium-241 unless otherwise agreed between the manufacturer and purchaser. Primary phantoms shall simulate the organs. Alternatively, more applicable radionuclides may be used, for example, to determine the levels of Plutonium-239 or uranium nuclides in the lungs.

8.3.3 Secondary phantoms (radioactive sources)

The radionuclide used in a secondary phantom shall be agreed between the purchaser and manufacturer.

Secondary phantoms shall be calibrated in relation to primary phantoms under similar conditions.

8.3.4 Background phantoms

During measurements “background” phantoms (without radioactive materials) shall be used to check background response of the in vivo counter. These phantoms shall be identical to the phantoms used for performance measurements but without radioactive materials.

8.4 Radiation characteristics

8.4.1 Relative intrinsic error

8.4.1.1 Requirements

The relative intrinsic error of the sensitivity as defined in 3.10 shall be within $\pm(25 + F_{SA})$ % for type 1 monitors and $\pm(30 + F_{SA})$ % for type 2 monitors of the response given by the manufacturer; where F_{SA} is the uncertainty in per cent of the conventionally true activity of the test phantom.

8.4.1.2 Method of test

The primary phantom as defined in 8.3.2 with the reference radionuclide and the equivalent background phantom shall in turn be located at their defined position relative to the detectors, as defined by the manufacturer, and readings taken.

The nominal activity of the primary phantom shall be between ±20 % of the activity specified by the manufacturer.

8.4.2 Linearity (in relation to activity)

8.4.2.1 Requirements

Under standard test conditions with the calibration controls adjusted according to the manufacturer's instructions, the following tests shall be carried out.

8.4.2.1.1 Type tests

A test using phantoms , secondary phantoms, sources or equivalent electronic tests shall be carried out at 20 % and 80 % of the highest and lowest decade of the energy range of the equipment and at 40 % of the intermediate ranges or decades. (The method of comparison of the effective activities of the secondary phantoms and the sources is given in 8.4.2.2 below.)

8.4.2.1.2 Routine tests

Phantom tests or source tests shall be performed at least at one point. Phantom, source or equivalent electronic tests shall be performed at one point at about 50 % of each decade of the range of the equipment.

8.4.2.2 Method of test

a) Primary phantom tests

The primary phantoms simulating gamma-radiation of the radionuclide from the body and the "background" phantom should be located at their defined position relative to the detector(s) as defined by the manufacturer.

In addition, during type testing, where secondary phantoms or sources are to be used for subsequent tests, locate the appropriate secondary phantom or source at its defined position relative to the detector and establish the relative responses due to the secondary phantoms or sources due to the primary phantoms. The appropriate phantom or source used for the determination of relative response shall be of an activity such that it gives an indication within ±20 % of the indication given by a primary phantom.

b) Electronic tests

The measuring assembly alone may be tested by injection of an appropriate electronic signal at the normal detector input.

8.4.2.3 Expression of results

The requirements of 8.4.1.1 may be considered to be met if

a) the difference between any of the observed values of F, the relative intrinsic error does not exceed ($2F_1 + F_{SR}$);

b) no single observed value of F exceeds ($F_1 + F_{SA}$)

where

F_1 is the required limit of permissible error of measurement in per cent given in Table 2, or in Table 3;

F_{SA} 〖C〉 is the relative uncertainty of the conventionally true activity of the test phantom in per cent (95 % confidence); 〈C〗

F_{SR} is the relative uncertainty of the activity of the test phantom 〖C〉 relative to the 〈C〗 other sources or phantoms in the test set in per cent (95 % confidence).

8.4.3 Energy range determination

8.4.3.1 Requirements

Determination of the gamma-radiation energy range registered by an instrument is based on the experimental finding of the full energy peak centroid of mono-energetic gamma-lines of Americium-241, Cobalt-57, and Uranium-235 gamma-emitting radionuclides. Adjusting the gain of the amplifier, an energy range is chosen so that 80 % to 90 % of the available channels of the multi-channel analyser are used. Each source is left in place so that at least 2×10^3 counts are accumulated. The mean count rate during the measurement shall not be more than10^3 s^{-1}.

8.4.3.2 Measurement results

The energy range of registered gamma radiation is determined from the straight-line approximation of the conversion characteristic of the instrument (see 8.4.4).

The energy range of gamma-radiation which is able to be registered shall be as required by 6.1.

8.4.4 Determination of the integral non-linearity (INL) error

8.4.4.1 Method of test

The INL (conversion characteristic) error is also determined on the basis of experimental determination of the full-energy peak centroid position of the gamma-lines. The measurement shall be performed with the gamma-emitting radionuclides in accordance with 8.4.3.1. As a result, a number of peak centroid positions n_{io} corresponding to photon energy $E_{\gamma i}$ are obtained.

8.4.4.2 INL determination

The INL is determined for each detector assembly in the following way. The conversion characteristic 〚C〛 (channel number N versus energy E_γ) 〚C〛 is approximated with the straight line

$$N = \tilde{a} + \tilde{B} \times E_\gamma$$

where

$\tilde{a}$ 〚C〛 is the channel number for energy ZERO 〚C〛;

$\tilde{B} = 1/k$ where 〚C〛 K 〚C〛 is the energy channel width of the multi-channel analyser on the chosen energy scale of the instrument.

For each of the centroid peak positions n_{io} corresponding to the energy $E_{\gamma i}$ the deviation $\Delta E_{\gamma i}$ from the straight-line approximation of the conversion characteristic is calculated.

The INL is calculated from the formula

$$\eta(\%) = \frac{\Delta E_{\gamma i max}}{E_{\gamma max}} 100$$

where

$\Delta E_{\gamma i max}$ is the maximum of the absolute values of $\Delta E_{\gamma i}$;

$E_{\gamma max}$ is the maximum measured signal pulse height.

8.4.4.3 Requirements

The value obtained for the INL above shall not exceed the values stated in 6.5.

8.4.5 Determination of the efficiency to Americium-241 59,54 keV gamma

8.4.5.1 Method of test

A phantom containing Americium-241 in a known geometry is placed in the position relative to the detectors as defined by the manufacturer. The activity of the source shall be such as to give a count-rate of at least twice that given by the background. Then the gamma ray spectrum is registered. The measurement shall be repeated for the same measurement time T_{m} with an inactive (background) phantom.

The count rate C in the full-energy absorption peak is determined from the formula:

$$C = \frac{\sum_{i=n}^{m} C_i}{T_{\mathrm{m}}}$$

where

i is the channel number;

C_i is the counts in channel i;

n is the channel number at the lowest point of the full-energy absorption peak;

m is the channel number at the highest point of the full-energy absorption peak;

T_{m} is the measurement time.

The background count rate B in the equivalent of the full-energy absorption peak is determined from

$$B = \frac{\sum_{i=n}^{m} B_i}{T_{\mathrm{m}}}$$

where

B_i is the counts in channel i;

and all other terms have the same definition as given above.

8.4.5.2 Determination of efficiency

The effeciency ε is determined by the formula

$$\varepsilon = \frac{\overline{C} - B}{A_0 \, \Im \exp\left(-\frac{0{,}693 \quad t}{T_{0,5}}\right)}$$

where

$\overline{C}$ is the mean of the values of C obtained above;

$\Im$ is the abundance of 59,54 keV resulting from the decay of Americium-241;

$T_{0,5}$ is the half-life of Americium-241 (432,2 years);

t is the time passed from the calibration of the source in years;

A_0 is the activity of the source in becquerels at the time of its calibration.

8.4.5.3 Measurement results

The manufacturer shall state the calibration factor (reciprocal of the efficiency) for the 59,54 keV line of Americium-241 in terms of count-rate per unit activity.

8.4.6 Background

8.4.6.1 Measurement method

The method is as described in 8.4.5 above except that three measurements over a period of more than 10 min shall be taken. This should be determined in a known environment of less than 0,25 $\mu Gy \cdot h^{-1}$.

8.4.6.2 Background measurement method

The mean of the count rates in the energy ranges specified are calculated by reference to the formula given in 8.4.5.1.

8.4.6.3 Measurement results

The value of background count rates found in 8.4.6.2 above shall not exceed the equivalent value specified by the manufacturer.

8.4.7 Determination of minimum detectable activity

8.4.7.1 Determination method

The minimum detection limit values of incorporated radionuclides are determined by means of calculation based on the results achieved in the previous tests (8.4.5 to 8.4.6) and the formula given in 5.6.

In order to conform with the requirements of this standard, the minimum detectable activity should be determined using the lower limit of decision as given in 5.6 and not the lower limit of detection as given in ISO 11929-4.

The quantile $k_{1-\alpha}$ shall be given the value of 2,326 for the purposes of intercomparison of equipment; this gives a risk of false indication of 1 % and a risk of non-detection of 50 %.

The user may use other values for the quantiles $k_{1-\alpha}$ and $k_{1-\beta}$ for different probabilities of detection and false indication.

8.4.7.2 Measurement results

The minimum detectable activities shall be specified by the manufacturer under specified background conditions.

8.4.8 Determination of the maximum count rate

8.4.8.1 Requirements

The requirements are that the maximum count rate is such that any dead time should cause less than 10 % reduction in measured count rate from true count rate.

For this to be true maximum count

$$C_{max} = \frac{0,1}{1,1\mu}$$

or $0{,}0909 \times \frac{1}{\mu}$

where μ is the overall dead time.

8.4.8.2 Method of test

The maximum input count rate from the detectors is determined from the overall dead time of the equipment.

For this, two sources of the radionuclide of interest, each of activity equivalent to about but no more than 10 %, of the maximum range of the equipment are required.

First, measure the background counts in the relevant energy band as given in 8.4.6. Let the count rate be B.

Next, place one of the sources in the measuring position and take a count. This count rate is C_1.

Next, place the other source in the measuring position in such a position as not to affect the detection of radiation from the first source in any way and in no way disturbing that source. This total count rate is C_{12}.

Remove the first source and take a further count of rate C_2.

The time of counting shall be such as to give at least 10^5 counts from the sources and 10^4 from background (unless this exceeds 3 000 s).

When not in use, the sources shall be stored so that they have no influence on the equipment.

Calculate 〚C〉 $\frac{C_1 + C_2 - C_{12} - B}{C_{12}^2 + B^2 - (C_1^2 + C_2^2)}$ 〈C〛 the overall dead time μ in seconds

where C_1, C_2, C_{12} and B are expressed in s^{-1}.

8.4.9 Determination of stability

8.4.9.1 Requirement

The instrument is considered to have passed the test if, during the 24 h continuous operation, the maximum instability of the centroid position from the mean does not exceed ±2 % for instruments with scintillation detectors or ±1 % for instruments with semi-conductor detectors under standard test conditions.

8.4.9.2 Method of test

The stability is determined from the spectra data obtained from the mono-energetic gamma lines of Americium-241 (59,54 keV) and Cobalt-57 (122,1 keV). Several sequential measurements are performed during uninterrupted operation of the instrument.

Switch the device on and allow it to warm up for the manufacturer's specified warm-up period.

Affix the sources adjacent to the entrance window of the detector and acquire a spectrum, counting long enough to accumulate at least 10^4 counts in each peak. For both peaks, record

the counts in each of the channels that display the full-energy absorption peak. Compute the centroid of the peak using the following formula:

$$X = \frac{\sum_{i=n}^{m} i \times C_i}{\sum_{i=n}^{m} C_i}$$

where

n is the lowest channel number for the full energy absorption peak;

m is the highest channel number for the full energy absorption peak;

C_i is the number of counts collected in the i^{th} channel.

$$\overline{X} = \frac{\sum_{i=1}^{j} X_i}{j}$$

where j is the number of data points for X.

Compute the standard deviation for the two centroids, $S1$ and $S2$, using the formula:

$$S = \sqrt{\frac{\sum_{i=1}^{j} (X_i - \overline{X})^2}{j-1}}$$

The larger of $S1$ and $S2$ is used to compute the instability of the instrument, 〚C〛 F_{inst} 〚C〛, expressed as a percentage.

〚C〛 $$F_{\text{inst}} = \frac{\sigma K}{E_2} \times 100$$ 〚C〛

where

σ is the standard deviation;

K is the width of a single channel in energy units, keV;

E_2 is the peak energy of the upper peak (122,1 keV for Co-57).

8.4.10 Energy resolution measurement

8.4.10.1 Determination method

The method of determination of the energy resolution is as follows.

The source is removed and the background spectrum obtained is subtracted from the spectrum taken with the source. The peak centroid position corresponding to gamma-line $E_{\gamma 1}$ = 122,1 keV and $E_{\gamma 2}$ = 136 keV of Cobalt-57 are determined according to the method described in 〚C〛 8.4.9. 〚C〛

For an instrument with either a germanium or scintillation detector, Americium-241 and Cobalt-57 radionuclide sources are used and placed in sequence in the holder in front of the detector entrance window or collimator.

Adjusting the gain of the analyser amplifier, a spectrum is accumulated so that the full width at half maximum of the full-energy absorption peak for the gamma-energy line $E_{\gamma 1}$ = 59,54 keV will be at least 10 channels. There shall be at least 10^4 counts accumulated in the peak.

The source is removed and the background spectrum obtained is subtracted from the source spectrum.

Afterwards a Cobalt-57 source is placed in the holder and the spectrum is obtained for the gamma-energy line $E_{\gamma 2}$ = 122,1 keV. The peak centroid positions corresponding to the Americium-241 and Cobalt-57 source gamma lines are determined in accordance with 〚C〛 8.4.9. 〚C〛

8.4.10.2 Requirement

The energy resolution shall not exceed the values specified in 6.4.

8.4.10.3 Energy resolution determination

Knowing the position of the gamma peak centroids for both sources, the analyser channel width in energy units is determined as

$$K = \frac{E_{\gamma 1} - E_{\gamma 2}}{n_1 - n_2}$$

where

$E_{\gamma 1}$ = 59,54 keV, for Am-241 radionuclide;

$E_{\gamma 2}$ = 122,1 keV for Co-57 radionuclide;

n_1 and n_2 are channel numbers corresponding to peak centroids.

The full width half maximum of the full-absorption energy peaks $\Delta\eta$ of Americium-241 and Cobalt-57 gamma-lines is determined graphically or by software means.

The absolute energy resolution (keV) is calculated by the formula:

$$\varepsilon_{\mathrm{R}} = \Delta\eta \times K$$

The relative energy resolution (%) is calculated by the formula:

$$\varepsilon_{\mathrm{R}'} = \frac{\Delta\eta K}{E_1} \times 100$$

8.5 Environmental performance characteristics

8.5.1 General

Performing tests to establish and/or verify an in vivo counter operational range based on ambient environmental meteorological conditions is not necessary when the instrument is used in a controlled environment.

8.5.2 Electromagnetic compatibility

8.5.2.1 Immunity to electrostatic discharge (ESD)

Immunity to electrostatic discharge is defined in IEC 61000-4-2.

8.5.2.1.1 Requirements

The tests to evaluate the immunity to ESD shall use the “contact discharge” technique for conductive surfaces and coupling planes and the “air discharge” technique for insulating surfaces. Discharge points shall be based on user accessibility

8.5.2.1.2 Method of test

The following tests shall be performed, guidance can be obtain from the reference document.

a) Ten discharges per discharge point with a minimum of 1 s recovery time between each discharge.

b) The maximum intensity of each discharge is based on the technique used: 6 kV for contact and 8 kV for air discharge. These levels are based on Tables 1 and A.1 of IEC 61000-4-2, level 3.

c) Measured activity shall not differ by more than ±10 % from the measured activity without the discharge. No alarms or other outputs shall be activated when the equipment is exposed to the discharge.

8.5.2.2 Radiofrequency immunity (RF)

Radiofrequency immunity is defined in IEC 61000-4-3.

The requirements and tests for radiofrequency immunity shall be by agreement between the manufacturer and purchaser

8.5.2.3 Surge immunity

Surge immunity is defined in IEC 61000-4-5 and IEC 61000-4-12.

8.5.2.3.1 Requirements

The tests shall be based on the Class 3 requirements stated in Annex B of IEC 61000-4-5 and level 3, Table 1, requirements of IEC 61000-4-12. Pulses should be applied to the main supply terminals via a coupling/decoupling network or equivalent equipment. The repetition rate shall not exceed one per minute.

8.5.2.3.2 Method of test

The following tests shall be performed. (Guidance can be found in IEC 61000-4-5 and IEC 61000-4-12).

a) Ten pulses shall be applied to the equipment with a minimum time between surges of 1 min.

b) Each pulse should consist of a combination wave (1,2/50 μs-8/20 μs) at an intensity of 2 kV.

c) Ring wave pulses should be not more than 2 kV.

d) Measured activity shall not differ by more than ±10 % from the measured activity without the pulse. No alarms or other outputs should be activated when the equipment is exposed to the pulse.

8.5.2.4 Immunity to conducted disturbances

Immunity to conducted disturbances is defined in IEC 61000-4-6.

8.5.2.4.1 Requirements

The test applies to equipment used in the presence of RF transmitters in the frequency range of 150 kHz to 80 MHz. Equipment which does not have at least one conducting cable (mains supply, signal line, or earth connection) is excluded. The protocol us based on the Class 3 requirements stated in Annex C of IEC 61000-4-6.

8.5.2.4.2 Method of test

The following tests shall be performed. (Guidance can be obtained from IEC 61000-4-6).

a) Frequency range of 150 kHz to 〖C〉 80 MHz 〈C〗 at an intensity of 140 dB(mV).

b) The signal shall be 80 % amplitude modulated with a 1 kHz sinewave.

c) The test should be performed using an automated sweep at a rate not greater than $1{,}5 \times 10^{-3}$ decades per second or 1 % of the fundamental.

d) The response effects shall not differ by more than ±10 % from the response without the field present. No alarms or other outputs shall be activated when the equipment is exposed to the field.

NOTE Some level of susceptibility may be acceptable to the purchaser.

8.5.3 Ambient temperature

8.5.3.1 Requirements

If the ambient temperature differs by more than 5 °C from the standard temperature stated in Table 1, a performance check should be made prior to use to ensure operability. If testing is required it shall be performed in accordance with 8.5.3.2.

It is considered that the equipment passes the test if, at the extreme operating temperatures, the error of the response does not exceed

– ±5 % in the case of an instrument with a scintillation detector;

– ±0,3 % for instruments with germanium semi-conductor detectors.

8.5.3.2 Method of test

Place the monitoring equipment in an environmental chamber and set to work under reference conditions.

A Uranium-235 source is placed in front of the detector. The amplifier gain is set for the required energy range. The spectrum is accumulated until at least 2×10^3 counts are accumulated from the source in the 185,7 keV absorption peak. In accordance with 〖C〉 8.4.9 〈C〗, the peak centroids corresponding to energies 143,7 keV and 185,7 keV are determined. The straight-line parameters approximating to the response curve and the INL in the reference conditions are determined (8.4.4).

The temperature in the chamber is increased up to the highest limit specified (+35 °C) at a rate of not more than 10 °C per hour and is controlled to within ±2 °C. After 4 h at this temperature the spectrum is accumulated once more. The peak centroid positions with energies 143,7 and 185,7 keV are determined and the deviation of their positions $\Delta E_{\gamma i}$ from the straight-line response curve in the reference conditions is calculated. Then the maximum deviation value $\Delta E_{\gamma max}$ is taken from the deviations $\Delta E_{\gamma i}$ obtained and, in accordance with 8.4.10, the INL value for the maximum operating temperature is calculated.

The temperature in the chamber is then decreased to the lower limit specified (10 °C) and is kept at that temperature with an accuracy of ±2 °C.

After 4 h the spectrum from a Uranium-235 radionuclide source is again accumulated. The centroïde positions are determined and the deviation $\Delta E_{\gamma i}$ from the straight-line approximation of the response curve in the reference conditions is determined. Then the maximum deviation value $\Delta E_{\gamma max}$ is taken from the number of deviations $\Delta E_{\gamma i}$ obtained and the INL value for minimum operating temperature is calculated.

8.5.4 Relative humidity

8.5.4.1 Requirements

If the ambient relative humidity levels are greater than the limits stated in Table 1 a performance check should be made prior to use, to ensure operability.

If testing is required it shall be performed according to 8.5.4.2.

8.5.4.2 Method of test

Tests are performed using an environmental chamber. The chamber shall be stabilized at 35 °C (±0,7 °C) and 40 % relative humidity. Sufficient readings shall be obtained using guidelines previously stated to establish a pre-test baseline.

The relative humidity level shall then be increased at a controlled rate over a period of time not exceeding 3 h to between 80 % and 90 %. After 48 h have elapsed, a sufficient number of readings shall again be obtained.

The relative humidity level shall then be reduced at a controlled rate to between 35 % and 45 % and readings shall be taken after the chamber has stabilized.

8.5.4.3 Results

It is considered that the instrument passes the test if the additional error over that due to temperature alone does not exceed ±5 % for all instruments except those using germanium detectors where the additional error shall not exceed ±0,3 %.

8.5.5 Magnetic fields

8.5.5.1 Requirements

The influence of magnetic fields of external origin of 40 A/m shall not cause a variation of the INL of greater than ±10 % for instruments with scintillation counters and ±0,1 % for instruments with germanium semi-conductor detectors.

In the case of equipment without spectrometry the change in response shall be less than ±2 %.

8.5.5.2 Method of test

If magnetic fields are present, a test shall be performed to ensure the counter's operability. Actual test parameters should be agreed upon by the manufacturer and the purchaser.

8.5.6 Atmospheric pressure

The variation of atmospheric pressure in general does not affect detector(s) and electronic assemblies.

Representative tests at other values of atmospheric pressure should be performed if required.

9 Performance requirements and test procedures for high-energy emitter measurements

9.1 General test procedures

9.1.1 Nature of tests

All tests in this document are regarded as type tests except those routine tests described in 9.4.2.2b), although any or all of the tests may be considered as acceptance tests by agreement between the manufacturer and the purchaser. The stated requirements are minimum requirements and may be extended for any particular instrument or function.

Many of the test procedures are similar to those of gamma spectrometers (see IEC 61276).

Reference and standard test conditions are defined in Table 1.

9.1.2 Tests performed under standard test conditions

Tests which are performed under standard test conditions are listed in Tables 4, 5 and 6 which indicate, for each characteristic, the limits of variation and the subclause where the corresponding test method is described.

9.1.3 Tests performed with variation of influence quantities

These tests are intended to determine the effects of variation in influence quantities, and are given in Tables 4, 5 and 6 with the range of variation of each influence quantity and the limits of the corresponding test method are described.

The range of variation of influence quantities indicated in Tables 4, 5 and 6 defines a nominal operating range within which the variation in measurement shall remain within the limits stated by the manufacturer; these limits shall in no case exceed those laid down in Tables 4, 5 and 6.

In order to test the effect of variation in any one of the influence quantities tested in Tables 4, 5 and 6, all other quantities shall be maintained within the limits for the standard test conditions given in Table 1, unless otherwise specified in the test procedure concerned.

In order to simplify these tests for each individual influence quantity, only the routine test concerning the intrinsic error need be performed, using not less than three readings at approximately half full scale on a range.

Other aspects of the performance of the instrument need to be tested with the variation of influence quantities only if it is considered that the routine test specified will not give a representative measurement.

9.2 Statistical fluctuations

For any test involving the use of radiation, if the magnitude of the statistical fluctuations arising from the random nature of the radiation being detected is a significant fraction of the variation of the measurement permitted in the tests, then sufficient readings shall be taken to ensure that the mean value of such readings may be estimated with sufficient precision to demonstrate compliance with the test in question (see Annex A).

9.3 Reference phantom and sources

9.3.1 General

Radioactive reference phantoms and sources, which are necessary for performance determination and testing of the instruments, may be the following:

– primary phantoms required for basic calibration (see 8.3.2);

– secondary phantoms or sources which can be used additionally for routine or other specific tests. The secondary phantom may not be identical in physical form to the primary phantom.

The value of the conventionally true activity of phantoms or sources shall be known with an error of not more than 10 % (95 % confidence) and the relative value of phantom or source activities used in the same tests should be known with an error of not more than 5 % (95 % confidence). If necessary, correction for radioactive decay of the source shall be made.

9.3.2 Primary phantoms

The primary phantoms shall be uniformly filled with the radionuclide Caesium-137 unless otherwise agreed between the manufacturer and the purchaser. Primary phantoms shall simulate the organs. For example, to determine the levels of Iodine-131 or Cobalt-60 nuclides, a neck phantom with Iodine-131 radionuclide in the thyroid phantom or a phantom with Cobalt-60 in the lung position may be used respectively.

9.3.3 Secondary phantoms (radioactive sources)

The radionuclide used in a secondary phantom shall be agreed between the purchaser and the manufacturer.

Secondary phantoms shall be calibrated in relation to primary phantoms under similar conditions.

9.3.4 Background phantoms

During measurements “background” phantoms (without radioactive materials) shall be used to check in vivo counter background response. These phantoms shall be identical to the phantoms used for performance measurements but without radioactive materials.

9.4 Radiation characteristics

9.4.1 Relative intrinsic error

9.4.1.1 Requirements

The relative intrinsic error as defined in 3.10 shall be within ± (10 + F_{SA}) % for type 1 equipment, ± (20 + F_{SA}) % for type 2 equipment, ± (30 + F_{SA}) % for type 3 equipment and ±(40 + F_{SA}) % for type 4 equipment of the response given by the manufacturer; where F_{SA} is the uncertainty in per cent of the conventionally true activity of the test phantom.

9.4.1.2 Method of test

The primary phantom, as defined in 9.3.2, with the reference radionuclide and the equivalent background phantom shall in turn be located at their defined position relative to the detectors as defined by the manufacturer and readings taken. The nominal activity of the primary phantom shall be between ±20 % of the activity specified by the manufacturer.

9.4.2 Linearity

9.4.2.1 Requirements

Under standard test conditions with the calibration controls adjusted according to the manufacturer's instructions, the following tests shall be carried out.

a) Type tests

A test using phantoms or sources shall be performed at approximately 40 % of the highest and lowest of the measurement decades. Tests with phantoms, secondary phantoms, sources or equivalent electronic tests shall also be carried out at 20 % and 80 % of each decade of the energy range of the equipment and at 40 % of the intermediate ranges or decades. (The method of comparison of the effective activities of the secondary phantoms and sources is given in 9.4.2.2.)

b) Routine tests

Phantom, secondary phantom or source tests shall be performed at least at one point. Phantom, source or equivalent electronic tests shall be performed at one point at about 50 % of each decade of the range of the equipment.

9.4.2.2 Method of test

a) Primary phantom tests

The primary phantoms simulating gamma-radiation of the radionuclide from the body and the "background" phantom should be located at their defined position relative to the detector(s) as defined by the manufacturer.

In addition during type testing, where secondary phantoms or sources are to be used for subsequent tests, locate the appropriate secondary phantom or source at its defined position relative to the detector and establish the relative responses of the secondary phantoms or sources to the primary phantoms. The appropriate phantom or source used for the determination of relative response shall be of an activity such that it gives a response within ±20 % of the response of a primary phantom.

b) Electronic tests

The measuring assembly alone may be tested by injection of an appropriate electronic signal at the normal detector input.

9.4.2.3 Expression of results

The requirements of 9.4.2.1 may be considered to be met if

a) the difference between any of the observed values of F, the relative intrinsic error does not exceed ($2F_1 + F_{SR}$);

b) no single observed value of F exceeds ($F_1 + F_{SA}$)

where

F_1 is the required accuracy of measurement in % given in Tables 4, 5 or 6;

F_{SA} [C〉 is the relative uncertainty of the conventionally true activity of the test phantom in per cent (95 % confidence); 〈C]

F_{SR} is the relative uncertainty of the activity of the test phantom [C〉 relative to the 〈C] other sources or phantoms in the test set % (95 % confidence).

9.4.3 Response to other radio nuclides

(For type 4 in vivo counters and specific radionuclides for type 3 in vivo counters.)

9.4.3.1 Requirements

If the type 3 or type 4 in vivo counters determines a limited number of radio nuclides, the response of the instrument to radio nuclides other than that of the reference nuclides shall be specified by the manufacturer. The radionuclides of interest shall be agreed upon between the manufacturer and the purchaser.

9.4.3.2 Method of test

The method of test is identical to that described in 9.4.1.2 but uses the appropriate radionuclides of interest

9.4.4 Energy range determination

This is not required for type 4 in vivo counters.

9.4.4.1 Requirements

Determination of the gamma-radiation energy range registered by an instrument is based on the experimental finding of the full-energy peak centroids of mono-energetic gamma-lines of Am-241, Co-57, Ba-133, Cs-137, Mn-54, Co-60, Y-88 and Th-228 gamma-emitting radio nuclides.

Adjusting the gain of the amplifier, an energy range is chosen so that 80 % to 90 % of the available channels of the multi-channel analyser are used. Each source is left in place so that at least 2×10^3 counts are accumulated. The mean count rate during the measurement shall not be more than $10^3\ s^{-1}$.

9.4.4.2 Measurement results

The energy range of registered gamma radiation is determined from the straight-line approximation of the conversion characteristic of the instrument (see 9.4.5).

The energy range of the gamma-radiation which can be registered shall be as required by 4.2.2.

9.4.5 Determination of the integral non-linearity (INL) error

This is not necessarily a requirement for types 3 and 4 in vivo counters.

9.4.5.1 Measurement procedure

The INL (conversion characteristic) error is also determined on the basis of experimental determination of the full-energy peak centroid position of mono-energetic gamma-lines. The measurement shall be performed with the gamma-emitting radionuclides in accordance with 9.4.4.1 and 9.4.4.2. As a result, a number of peak centroid positions n_{io} corresponding to photon energy $E_{\gamma i}$ are obtained.

9.4.5.2 INL determination

The INL is determined in the following way. The conversion characteristic 〚C〛 (channel number N versus energy E_γ) 〚C〛 is approximated with the straight line:

$$N = \tilde{a} + \tilde{B} \times E_\gamma$$

where

$\tilde{a}$ 〚C〛 is the channel number for energy ZERO; 〚C〛

$\tilde{B} = 1/k$ where 〚C〛 K 〚C〛 is the energy channel width of the multi-channel analyser on the chosen energy scale of the instrument.

For each of the centroid peak positions n_{io} corresponding to the energy $E_{\gamma i}$ the deviation $\Delta E_{\gamma i}$ from the straight-line approximation of the conversion characteristic is calculated.

The INL is calculated from the formula

$$\eta(\%) = \frac{\Delta E_{\gamma i\max}}{E_{\gamma\max}} \times 100$$

where

$\Delta E_{\gamma i\max}$ is the maximum of the absolute values of $\Delta E_{\gamma i}$;

$E_{\gamma\max}$ is the maximum measure signal pulse height.

9.4.5.3 Measurement results

The value obtained for the INL above shall not exceed the values stated in 7.4.

9.4.6 Determination of the efficiency to Caesium-137 661,7 keV gamma

9.4.6.1 Measurement procedure

A phantom containing Caesium-137 in a known geometry is placed in the position relative to the detectors as defined by the manufacturer. The activity of the source shall be such as to give a count-rate of at least twice that given by background. Then the gamma ray spectrum is registered or, in the case of type 〚C〛 4 〚C〛 in vivo counters with no spectral analysis, a measurement is made. The measurement time is chosen to give a total count of at least 10^4 counts in the full-energy absorption peak or a total count of 10^4 in the case of type 4 in vivo counters. The measurement including placing the phantom in position shall be repeated five times.

The measurement shall then be repeated for the same measurement time T_m with an inactive (background) phantom.

The count rate C in the full-energy absorption peak is determined from the formula:

$$C = \frac{\sum_{i=n}^{m} C_i}{T_{\mathrm{m}}}$$

where

i is the channel number;

C_i is the counts in channel i;

n is the channel number at the lowest point of the full energy absorption peak;

m is the channel number at the highest point of the full energy absorption peak;

T_{m} is the measurement time.

The background count rate B in the equivalent of the full-energy absorption peak is determined from

$$B = \frac{\sum_{i=n}^{m} B_i}{T_{\mathrm{m}}}$$

where

B_i is the counts in channel i;

and all other terms having the exact numerical values given above.

In the case of types 3 and 4 in vivo counters without spectral analysis:

C is the count rate from the active phantom and background over time T;

B is the count rate from the background phantom only over time T.

9.4.6.2 Determination of efficiency

Efficiency ε is determined from the formula

$$\varepsilon = \frac{\overline{C} - B}{A_0 \Im \exp\left(-\frac{0{,}693 \quad t}{T_{0,5}}\right)}$$

where

$\overline{C}$ is the mean value of the values of C obtained above;

$\Im$ is the abundance of 661,7 keV resulting from the decay of Caesium-137 = 0,85;

t is the time passed from the calibration of the source in years;

$T_{0,5}$ is the half-life Caesium-137 (30 years);

A_0 is the activity of the source in becquerels at the time of its calibration.

9.4.6.3 Measurement results

The manufacturer shall state the calibration factor (the reciprocal of the efficiency) for the 661,7 keV line of Caesium-137 in terms of count-rate per unit activity.

9.4.7 Determination of the efficiency to Iodine-131

9.4.7.1 Measurement method

The determination of the efficiency to the gamma energy of 364,5 keV from Iodine-131 is made using a thyroid phantom loaded with iodine inside a whole body phantom or neck phantom. The phantom is placed in position relative to the detectors as defined by the manufacturer. The gamma ray spectrum is registered or, in the case of the in vivo counters with no spectral analysis, a direct measurement is made.

Measurements and calculations are made according to 9.4.6.1.

9.4.7.2 Determination of efficiency

The same formula as used in 9.4.6.2 is used.

However, for Iodine-131,

$T_{0,5}$ = 8,04 days;

$\Im$ = 0,812 for units with spectral analysis.

For type 4 in vivo counters without spectral analysis, the equipment will be sensitive to the other gamma emissions so for Iodine-131 $\Im$ should be taken as 0,972 (values taken from ICRP 38).

9.4.8 Cobalt-60 efficiency determination

This information is provided by agreement between the purchaser and the manufacturer using lung phantoms uniformly loaded with Cobalt-60 within a body phantom. The measurement method and calculation are as given in 9.4.6 . In the case of Sodium Iodide detector systems, to avoid problems with overlap between the 1,173 MeV and 1,332 MeV peaks, the energy range of the equipment shall be such as to incorporate both these peaks so

$T_{0,5}$ = 5,271 years

$\Im$ = 1,00 (2,00 for NaI, where the two energies are taken together) (values taken from ICRP 38).

9.4.9 Background

9.4.9.1 Measurement method

The method is as described in 8.4.6 except that three measurements over a period of more than 10 min shall be taken. This shall be determined in a known environment of less than 0,25 $\mu Gy \cdot h^{-1}$.

9.4.9.2 Background measurement method

The mean of the count rates in the energy ranges specified are calculated with reference to the formula given in 8.4.5.1.

9.4.9.3 Measurement results

The value of background count rates found in 9.4.9.2 shall not exceed the equivalent value specified by the manufacturer.

9.4.10 Determination of minimum detection limit

9.4.10.1 Determination method

The minimum detection limit values of incorporated radionuclides are determined by means of calculation based on the results achieved in the previous tests (9.4.6 to 9.4.9) and the formula given in 5.6.

For the purposes of conforming with the requirements of this standard the minimum detection limit should be determined using the lower limit of decision as give in 5.6 and not the lower limit of detection as given in ISO 11929-4.

The quantile $k_{1-\alpha}$ shall be given the value of 2,326 for the purposes of intercomparison of equipments; this gives a risk of false indication of 1 % and a risk of non-detection of 50 %.

The user may use other values for the Quantiles $k_{1-\alpha}$ and $k_{1-\beta}$ for different probabilities of detection and false indication

9.4.10.2 Measurement results

The minimum detectable activities shall be specified by the manufacturer under specified background conditions.

9.4.11 Determination of the maximum count rate

9.4.11.1 Requirements

The requirements are that the maximum count rate (given in Tables 4, 5 and 6) is such that any dead time should cause less than 10 % reduction in measured count rate from true count rate.

For this to be true, maximum count

$$C_{\max} = \frac{0{,}1}{1{,}1\mu}$$

or

$$0{,}0909 \times \frac{1}{\mu}$$

where μ is the overall dead time.

9.4.11.2 Method of test

The maximum input count rate from the detectors is determined from the overall dead time of the equipment.

For this, two sources of the radionuclide of interest, the activity of each being about 10 %, but no more, of the maximum range of the equipment, are required.

First, measure the background counts in the relevant energy band as given in 9.4.9. Let the count rate be B.

Next, place one of the sources in the measuring position and take a count. This count rate is C_1.

Next, place the other source in the measuring position in a position not to effect the detection of radiation from the first source in any way and in no way disturbing that source. This total count rate is C_{12}.

Remove the first source and take a further count of rate C_2.

The time of counting shall be such as to give at least 10^5 counts from the sources and 10^4 from background (unless this exceeds 3 000 s).

When not in use, the sources shall be stored so that they have no influence on the equipment.

Calculate 〚C〉 $\frac{C_1 + C_2 - C_{12} - B}{C_{12}^2 + B^2 - (C_1^2 + C_2^2)}$ 〈C〛 the overall dead time μ in seconds

where C_1, C_2, C_{12} and B are in s^{-1}.

9.4.12 Determination of stability

9.4.12.1 Requirements

a) For Type 1, 2 and 3 equipment

The instrument is considered to have passed the test if, during 24 h continuous operation, the maximum instability of the centroid position from the mean does not exceed ±2 % for instruments with scintillation detectors or ±0,2 % for instruments with semi-conductor detectors.

b) For type 4 equipment

The ratio of the standard deviation to the mean of the readings obtained over a 24 h period shall not exceed 4 %.

9.4.12.2 Method of test

a) For equipment with multi-channel analysers

The stability is determined from the spectra data obtained from the mono-energetic gamma lines of Co-57 (E_1 = 122,1 keV) and Y-88 (E_2 = 1836 keV). Several sequential measurements are performed during uninterrupted operation of the instrument.

Switch the device on and allow it to warm up for the manufacturer's specified warm-up period.

Affix the sources adjacent to the entrance window of the detector and acquire a spectrum, counting long enough to obtain at least 10^4 counts in each peak. For both peaks, record the counts in each of the channels that display the full-energy absorption peak. Compute the centroid of the peak using the following formula.

$$X = \frac{\sum_{i=n}^{m} i \times C_i}{\sum_{i=n}^{m} C_i}$$

where

n is the lowest channel number for the full-energy absorption peak;

m is the highest channel number for the full-energy absorption peak;

C_i is the number of counts collected in the i^{th} channel.

Record the centroid positions, $X1$ and $X2$, for the two peaks. Repeat the process, acquiring new spectra at 1 h intervals, for a period of at least 24 h. Do not move the sources before all data are taken.

Compute the mean centroid positions for the two peaks using the equation which follows in general form (substitute $X1$ or $X2$, as appropriate, for X).

$$\overline{X} = \frac{\sum_{i=1}^{j} X_i}{j}$$

where j is the number of data points for X.

Compute the standard deviation for the two centroids, $S1$ and $S2$, using the formula:

$$S = \sqrt{\frac{\sum_{i=1}^{j} (X_i - \overline{X})^2}{j-1}}$$

The larger of $S1$ and $S2$ is used to compute the instability of the instrument, 〖C〗 F_{inst} 〖C〗, expressed as a percentage.

〖C〗 $F_{\text{inst}} = \frac{\sigma K}{E_2} \times 100$ 〖C〗

where

σ is the standard deviation;

K is the width of a single channel in energy units, keV;

E_2 is the peak energy of the upper peak (1836 keV for Yttrium-88).

b) For equipment without spectrometry

Affix an appropriate source to the entrance window of the detector(s). Switch the instrument on and allow the warm-up interval specified by the manufacturer to elapse.

Determine the measurement time, T_{m}, such that at least 10^4 counts will be collected from the source plus background in a single measurement interval. The same measurement time must be used for each datum point acquired during this test.

Perform a count cycle at 1 h intervals over a period of 24 h, recording the resultant count for each interval. Compute the mean and the standard deviation for the data collected.

9.4.13 Energy resolution measurement

9.4.13.1 Determination method

The method of determination of the energy resolution is as follows.

The source is removed and the background spectrum is accumulated which is to subtracted from the previous spectrum. The peak centroid position corresponding to gamma-line $E_{\gamma 1}$ = 1332,5 keV and $E_{\gamma 2}$ = 1173,2 keV of Cobalt-60 are determined according to the method described in 〖C〗 9.4.12.2. 〖C〗

For an instrument with a either a germanium scintillation detector, Caesium-137 and Cobalt-57 radionuclide sources are used that are in sequence placed in the holder in front of the detector entrance window or collimator.

Adjusting the gain of the analyser amplifier a spectrum is accumulated so that the full width at half maximum of the full-energy absorption peak for the gamma-energy line $E_{\gamma 1}$ = 661,7 keV will be at least 10 channels. There shall be at least 10^4 counts accumulated in the peak.

The source is removed and the background spectrum is accumulated that is subtracted from the source spectrum.

Afterwards, a Cobalt-57 source is placed in the holder and the spectrum is accumulated for the gamma-energy line $E_{\gamma 2}$ = 122,1 keV. The peak centroid positions corresponding to Caesium-137 and Cobalt-57 source gamma lines are determined in accordance with [C] 9.4.12.2. [C]

9.4.13.2 Requirement

The energy resolution shall not exceed the values specified in 7.3.

9.4.13.3 Energy resolution determination

Knowing the position of the gamma peak centroids for both sources the analyser channel width in energy units is determined as

$$K = \frac{E_{\gamma 1} - E_{\gamma 2}}{n_1 - n_2}$$

where

$E_{\gamma 1}$= 1332,5 keV, for Co-60 radionuclide;

$E_{\gamma 2}$ = 661,7 keV for Cs-137 radionuclide;

n_1 and n_2 are channel numbers corresponding to peak centroids.

The full width half maximum of the full-absorption energy peaks $\Delta\eta$ of Co-60 and Cs-137 gamma-line are determined graphically or by software means.

The absolute energy resolution (keV) is calculated by the formula:

$$\varepsilon_{\mathrm{R}} = \Delta\eta \times K$$

The relative energy resolution (%) is calculated by the formula:

$$\varepsilon_{\mathrm{R'}} = \frac{\Delta\eta K}{E_1} \times 100$$

9.5 Environmental performance characteristics

9.5.1 General

Performing tests to establish and/or verify an in vivo counter's operational range based on ambient environmental meteorological conditions is not necessary when the instrument is used in a controlled environment.

9.5.2 Electromagnetic compatibility

9.5.2.1 Immunity to electrostatic discharge (ESD)

Immunity to electrostatic discharge is defined in IEC 61000-4-2.

9.5.2.1.1 Requirements

The tests to evaluate the immunity to ESD shall use the "contact discharge" technique for conductive surfaces and coupling planes and the "air discharge" technique for insulating surfaces. Discharge points shall be based on user.

9.5.2.1.2 Method of test

The following tests shall be performed according to IEC 61000-4-2.

a) Ten discharges per discharge point with a minimum of 1 s recovery time between each discharge.

b) The maximum intensity of each discharge is based on the technique used: 6 kV for contact, and 8 kV for air discharge. These levels are based on Tables 1 and A.1 of IEC 61000-4-2, level 3.

c) Response effects shall not exceed ±10 % of the response without discharge. No alarms or other outputs shall be activated when the equipment is exposed to the discharge.

9.5.2.2 Radiofrequency immunity (RF)

Radiofrequency immunity is defined in IEC 61000-4-3.

The requirements and tests for radiated radiofrequency immunity shall be by agreement between the manufacturer and purchaser.

9.5.2.3 Surge immunity

Surge immunity is defined in IEC 61000-4-5 and IEC 61000-4-12, 5.4.15.3.

9.5.2.3.1 Requirements

The tests shall be based on the Class 3 requirements stated in Annex B of IEC 61000-4-5 and level 3, Table 1, requirements of IEC 61000-4-12. Pulses should be applied to the main supply terminals via a coupling/decoupling network, or equivalent equipment. The repetition rate shall not exceed one per minute.

9.5.2.3.2 Method of test

The following tests shall be performed according to IEC 61000-4-5 and IEC 61000-4-12.

a) Ten pulses shall be applied to the equipment with a minimum time between surges of 1 min.

b) Each pulse should consist of a combination wave (1,2/50 μs to 8/20 μs) at an intensity of 2 kV.

c) Ring-wave pulses should be not more than 2 kV.

d) Response effects shall not differ by more than ±10 % from the response without the pulse. No alarms or other outputs should be activated when the equipment is exposed to the pulse.

9.5.2.4 Immunity to conducted disturbances

Immunity to conducted disturbances is defined in IEC 61000-4-6.

9.5.2.4.1 Requirements

The test applies to equipment used in the presence of RF transmitters in the frequency range of 150 kHz to 80 MHz. Equipment which does not have a least one conducting cable (mains supply, signal line, or earth connection) is excluded. The protocol is based on the class 3 requirements stated in Annex C of IEC 61000-4-6.

9.5.2.4.2 Method of test

The following tests shall be performed according to IEC 61000-4-6.

a) Frequency range of 150 kHz to 80 MHz at an intensity of 〖C〉 140 dB(mV) 〈C〗.

b) The signal shall be 80 % amplitude modulated with a 1 kHz sine wave.

c) The test should be performed using an automated sweep at a rate not greater than $1{,}5 \times 10^{-3}$ decades per second, or 1 % of the fundamental.

d) Response effects shall not differ by more than ±10 % from the response without the field present. No alarms or other outputs shall be activated when the equipment is exposed to the field. Note some level of susceptibility may be acceptable (this shall be specified by the purchaser).

9.5.3 Ambient temperature

9.5.3.1 Requirements

If the ambient temperature differs by more than 5 °C from the standard temperature stated in Table 1, a performance check should be made prior to use to ensure operability. If testing is required the test shall be performed according to 9.5.3.2.

9.5.3.2 Method of test

Place the equipment in an environmental chamber and set to work under reference conditions.

a) Equipment fitted with multi-channel analysers

A Thorium-228 source is placed in front of the detector. The amplifier gain is set for the required energy range. The spectrum is accumulated until at least 2×10^3 counts are accumulated from the source in the 2,614 MeV absorption peak. In accordance with 9.4.5, the peak centroids corresponding to energies 0,240 MeV, 0,583 MeV and 2,614 MeV are determined. The straight-line parameters approximating to the response curve and the INL in the reference conditions are determined (see 9.4.5).

The temperature in the chamber is increased up to the highest limit specified (+35 °C) at a rate of not more than 10 °C per hour and is controlled to within ±2 °C. After 4 h at this temperature, the spectrum is accumulated once more. The peak centroid positions with energies 0,240 MeV, 0,583 MeV and 2,614 MeV are determined and the deviation of their positions $\Delta E_{\gamma i}$ from the straight-line response curve in the reference conditions is calculated. Then the maximum deviation value $\Delta E_{\gamma max}$ is taken from the deviations $\Delta E_{\gamma i}$ obtained and, in accordance with 6.4, the INL value for the maximum operating temperature is calculated.

The temperature in the chamber is then decreased to the lower limit specified (10 °C) and is kept at that temperature with an accuracy of ±2 °C.

After 4 h the spectrum from a Thorium-228 radionuclides source is again accumulated. The centroid positions are determined and the deviation $\Delta E_{\gamma i}$ from the straight-line approximation of the response curve in the reference conditions is determined. Then the maximum deviation value $\Delta E_{\gamma max}$ is taken from the number of deviations obtained and the INL value for minimum operating temperature is calculated.

b) Equipment without spectroscopy

With a source suitably placed near the detectors and under standard test conditions take a reading and note this reading. Increase the temperature to 35 °C at a rate not exceeding 10 °C per hour and hold it at that value ±2 °C. After 4 h take a further reading and note this reading. Reduce the temperature to +10 °C at a rate not exceeding 10 °C per hour and hold it at this value ±3 °C. After 4 h take a further reading and note the reading.

NOTE Due to the relative size of in vivo counters, testing the entire instrument is difficult. Tests, therefore, should be performed on components that could be susceptible as agreed upon between the manufacturer and the purchaser.

9.5.3.3 Results

a) Equipment fitted with multi-channel analysers

It is considered that the equipment passes the test if at the extreme operating temperatures the error of the response curve does not exceed

– ±5 % in the case of instrument with a scintillation detector;

– ±0,2 % in the case of type 3 instruments with germanium semi-conductor detectors.

b) Equipment without spectroscopy

The readings shall be within ±5 % of the reading under test conditions at the temperature extremes.

9.5.4 Relative humidity

9.5.4.1 Requirements

If the ambient relative humidity levels are greater than the limits stated in Table 1, a performance check should be made prior to use, to ensure operability.

If testing is required the test shall be performed according to 9.5.4.2.

9.5.4.2 Methods of test

Tests are performed using an environmental chamber. The chamber shall be stabilized at 35 °C ± 2 °C and 35 % to 45 % relative humidity. Sufficient readings shall be obtained using guidelines previously stated to establish a pre-test baseline.

The relative humidity level shall then be increased at a controlled rate over a period of time not exceeding 3 h to between 80 % and 90 %. After 48 h have elapsed, a sufficient number of readings shall again be obtained.

The relative humidity level shall then be reduced at a controlled rate to 40 % ± 5 % and readings shall be taken after the chamber has stabilized.

9.5.4.3 Results

It is considered that the instrument passes the test if the additional error over that due to temperature alone to the response characteristic does not exceed ±5 % for all instruments except those using germanium detectors where the additional error shall be ± 0,3 %.

9.5.5 Magnetic fields

9.5.5.1 Requirements

The influence of magnetic fields of external origin of 40 A/m shall not cause a variation of the INL of greater than ±10 % for instruments with scintillation counters and ±0,1 % for instruments with germanium semi-conductor detectors.

In the case of equipment without spectrometry the change in response shall be less than ±2 %.

9.5.5.2 Method of test

If magnetic fields may be present, a test shall be performed to ensure the in vivo counters' operability. Actual test parameters should be agreed upon by the manufacturer and the purchaser.

9.5.6 Atmospheric pressure

The variation of atmospheric pressure, in general, does not affect detector(s) and electronic assemblies.

Representative tests at other values of atmospheric pressure shall be performed if required.

10 Documentation

10.1 Type test report

The manufacturer shall make available, at the request of the purchaser a report on the type tests carried out according to the requirements of this standard.

10.2 Certificate

A certificate shall be provided with each instrument, giving at least the following general information.

Manufacturer's name and/or trademark

Type of detector(s)

Effective range of activity measurement of the whole body and/or separate organs

Minimum detectable capability for stated background and radionuclides

Effective range of photon energy

Permissible gamma background

Radionuclides for which the instrument is designed to measure

Measuring time

Maximum permissible cable length between any assemblies

Temperature range

Dimensions and mass of the instrument

Statement that this equipment is tested in accordance with this standard and meets the requirements specified herein.

Storage and transportation requirements

10.3 Operation and maintenance manual

Each instrument shall be supplied with an appropriate instruction manual in accordance with IEC 61187.

Table 1 – Reference and standard test conditions

Influence quantities	Reference conditions [a]	Standard test conditions[a]
Primary phantom	Phantom containing the appropriate radionuclide in the appropriate physical form	Phantom containing the appropriate radionuclide in the appropriate physical form
Reference radionuclide for low-energy measurements Reference radionuclide for high-energy measurements	^{241}Am ^{137}Cs	^{241}Am ^{137}Cs
Warm-up time (Electronic devices)	30 min	≥30 min
Ambient temperature	20°C	18°C to 22°C
Relative humidity	65 %	50 % to 75 %
Atmospheric pressure	101,3 kPa	86 kPa to 106 kPa
Power supply voltage	Nominal supply voltage U_N	Nominal power supply U_N ± 1 %
Power supply frequency	Nominal frequency	Nominal frequency ± 1 %
Power supply waveform	Sinusoidal	Sinusoidal with total harmonic distortion lower than 5 %
Gamma radiation background	Air Kerma rate of 0,2 μGy·h^{-1}	Air Kerma rate of less than 0,25 μGy·h^{-1}
Magnetic field	Negligible	Less than twice the induction due to the earth's magnetic field.
[a] Unless otherwise indicated by manufacturer.		

Table 2 – Low-energy in vivo counting with scintillation detectors

Characteristics		In vivo monitor types		Reference subclause
		1	2	
Relative Intrinsic error	%	±25	±30	8.4.1
Linearity	%	±25	±25	8.4.2
Energy range	keV	10-200	10-200	8.4.3, 6.1
Integral non-linearity, not more than	%	±0,5	±0,5	8.4.4, 6.5
Efficiency	%	a	a	8.4.5
Background level	s^{-1}	a	a	8.4.6
Minimum detectable activity	Bq	a	a	8.4.7
Maximum count rate, more than	s^{-1}	5×10^4	5×10^4	8.4.8
Time stability of pulse height response (for 24 h continuous operation), not more than	%	±2,0	±2,0	8.4.9
Energy resolution for 59,54 keV line Am-241		a	a	8.4.10,6.4
Electromagnetic compatibility		In accordance with 8.5.2		8.5.2
Temperature instability of integral non-linearity (from +10 °C to +35 °C), not more than	%/10°C	±5	±5	8.5.3
Instability of integral non-linearity at relative humidity (from 20 % to 80 % at 35°C), not more than	%	±5	±5	8.5.4
Instability of integral non-linearity due to magnetic field of external origin. 40 $A\cdot m^{-1}$, not more than	%	±10	±10	8.5.5
Atmospheric pressure [b]		–	–	8.5.6

[a] Should be stated by manufacturer for each type of in vivo counter.

[b] The range of atmospheric pressure variation and the allowable limits of characteristic variation shall be by agreement between the manufacturer and purchaser.

Table 3 – Low-energy in vivo counting with Ge semi-conductor detectors

Characteristics	In vivo monitor types	Reference subclause
Relative intrinsic error %	±25	8.4.1
Linearity %	±25	8.4.2
Energy range keV	10-200	8.4.3, 6.1
Integral non-linearity, not more than %	± 0,1	8.4.4, 6.5
Efficiency %	a	8.4.5
Background level s^{-1}	a	8.4.6
Minimum detectable activity Bq	a	8.4.7
Maximum count rate, more than s^{-1}	5×10^4	8.4.8
Time stability of pulse height response (for 24 h continuous operation), not more than %	±1	8.4.9
Energy resolution for 59,54 keV line of Am-241	1,5 keV	8.4.10, 6.4
Electromagnetic compatibility	In accordance with 8.5.2	8.5.2
Temperature instability of integral non-linearity (from +10 °C to +35 °C), not more than %/10 °C	±0,3	8.5.3
Humidity instability 40 % to 85 %	±0,3	8.5.4
Instability of integral non-linearity due to a magnetic field of external origin. 40 $A \cdot m^{-1}$, not more than %	±0,1	8.5.5
Atmospheric pressure	b	8.5.6

a Should be stated by the manufacturer for each type of counting equipment.

b The range of atmospheric pressure variation and the allowable limits of characteristic variation shall be by agreement between the manufacturer and purchaser.

Table 4 – High-energy in vivo counting with scintillation detectors

Characteristics	In vivo monitor types				Reference subclause
	1	2	3	4	
Relative intrinsic error %	±10	±20	±30	±40	9.4.1
Linearity %	±10	±20	±30	±40	9.4.2
Response to other radionuclides			a	a	9.4.3
Energy range keV	100-3000	100-3000	100-3000		9.4.4,4.2.2
Integral non-linearity, not more than %	±0,5%	±0,5%	±_1%		9.4.5 and 7.4
Efficiency	a	a	a	a	9.4.6, 9.4.7 and 9.4.8
Background level s^{-1}	a	a	a	a	9.4.9
Minimum detectable activity Bq	a	a	a	a	9.4.10
Maximum count rate	a	a	a	a	9.4.11
Time stability of pulse height response (for 24 h continuous operation) not more than %	±2,0	±2,0	±2,0	±4,0	9.4.12
Energy resolution for 661,7 keV line of Cs-137, not more than %	9,0	9,0	9,0		9.4.13
Electromagnetic compatibility	In accordance with 9.5.2				9.5.2
Temperature instability of integral non-linearity (from +10 °C to +35 °C), not more than %	±5	±5	±5	±5	9.5.3
Instability of integral non-linearity at relative humidity (from 20 % to 80 % at 35 °C), not more than %	±5	±5	±5	±5	9.5.4
Instability due to magnetic field of external origin 40 $A \cdot m^{-1}$, not more than %	±10	±10	±10	±10	9.5.5
Atmospheric pressure	b				9.5.6

[a] Should be stated by the manufacturer for each type of counting system.

[b] The range of atmospheric pressure variation and the allowable limits of characteristic variation shall be by agreement between the manufacturer and purchaser.

Table 5 – High-energy in vivo counting with Ge semi-conductor detectors

Characteristics		In vivo monitor types			Reference subclause
		1	2	3	
Relative intrinsic error	%	±10	±20	±30	9.4.1
Linearity	%	±10	±20	±30	9.4.2
Response to other radionuclides		a	a	a	9.4.3
Energy range	keV	[C] 100-3 000 [C]	100-3 000		9.4.4
Integral non-linearity, not more than	%	±0,1	±0,2	±0,3	9.4.5, 7.4
Efficiency	%	a	a	a	9.4.6 to 9.4.8
Background level	s^{-1}	a	a	a	9.4.9
Minimum detectable activity	Bq	a	a	a	9.4.10
Maximum input count rate, more than	s^{-1}	5×10^4	1×10^5	1×10^5	9.4.11
Time stability of pulse height response (for 24 h continuous operation), not more than	%	±0,2	±0,2	±0,2	9.4.12
Energy resolution for 1,332 MeV line Co-60 and for detector active volume 50-100 cm^3, not more than	keV	3	3	3	9.4.13, 7.3
For other detectors					
1,332 MeV line from Co-60	keV	4	4	4	
661,7 keV line from Cs-137	keV	2	2	2	
Electromagnetic compatibility		In accordance with 9.5.2			9.5.2
Temperature instability of integral non-linearity (from +10 °C to +35 °C), not more than	%/10 °C	±0,2	±0,2	±0,2	9.5.3
Instability of integral non-linearity at relative humidity (from 20 % to 80 % at 35°C), not more than	%	±0,3	±0,3	±0,3	9.5.4
Instability of integral non-linearity due to a magnetic field of external origin. 40 $A \cdot m^{-1}$, not more than	%	±0,1	±0,1	±0,1	9.5.5
Atmospheric pressure			b		9.5.6

a Should be stated by the manufacturer for each type of equipment.

b The range of atmospheric pressure variation and the allowable limits of characteristic variation shall be by agreement between the manufacturer and purchaser.

Table 6 – High-energy in vivo counting without spectroscopy

Characteristics		Requirements	Reference subclause
Relative intrinsic error	%	±30 for type 3 ±40 for type 4	9.4.1
Linearity	%	±30 for type 3 ±40 for type 4	9.4.2
Response to other radionuclides		a	9.4.3
Energy range	keV		9.4.4
Energy resolution		Not required	
Efficiency	%	a	9.4.6 to 9.4.8
Background level	s^{-1}	a	9.4.9
Minimum detectable activity	Bq	a	9.4.10
Maximum count rate	s^{-1}	a	9.4.11
Electromagnetic compatibility		In accordance with 9.5.2	9.5.2
Temperature instability of integral non-linearity (from +10 °C to +35°C), not more than	%	±5	9.5.3
Instability due to humidity	%	±5	9.5.4
Instability due to magnetic field of external origin. 40 $A \cdot m^{-1}$, not more than	%	±2	9.5.5
Atmospheric pressure		b	9.5.6

a Should be stated by the manufacturer for each type of equipment.

b The range of atmospheric pressure variation and the allowable limits of characteristic variation shall be by agreement between the manufacturer and purchaser.

Annex A
(informative)

A guide to the number of independent instrument readings required to establish a true difference in indication (relevant for normal distribution)

The following tabulation (taken from ANSI N42. 17A-D8) gives the number of instrument readings required to detect true differences (95 % confidence level) between two sets of instrument readings on the same instrument.

The table is derived under the assumption that the probability of saying that there is a difference when there is no true difference and probability of saying that there is no difference when there is a true difference are both equal to 0,05.

Table A.1 — Number of instrument readings required to detect true differences (95 % confidence level) between two sets of instrument readings on the same instrument

Percentage difference	Coefficient of variation	Number of readings
5	0,5	1
5	1,0	1
5	2,0	4
5	3,0	9
5	4,0	16
5	5,0	25
5	7,5	56
5	10,0	99
5	12,5	154
5	15,0	223
5	20,0	396
10	0,5	1
10	1,0	1
10	2,0	1
10	3,0	3
10	4,0	4
10	5,0	6
10	7,5	14
10	10	24
10	12,5	37
10	15,0	53
10	20,0	94
15	0,5	1
15	1,0	1
15	2,0	1
15	3,0	1
15	4,0	2
15	5,0	3
15	7,5	6
15	10,0	10
15	12,5	13
15	15,0	23
15	20,0	40
20	0,5	1
20	1,0	1
20	2,0	1
20	3,0	1
20	4,0	1
20	5,0	2
20	7,5	3
20	10,0	6
20	12,5	9
20	15,0	12
20	20,0	21

Annex B
(normative)

Additional requirements and test procedures for transportable and portable assemblies

B.1 Field of application

This annex defines the additional mechanical and environmental performance requirements and testing for transportable and portable assemblies.

Engineering controls should be used to limit an assembly's susceptibilities during normal movement. Efforts shall be made to test complete assemblies, but if this is not possible, an evaluation shall be performed to identify those components that may be the most susceptible to the expected transportation conditions. Tests shall be performed on those components.

The requirements given below are general requirements, more stringent requirements may be by agreement between the manufacturer and purchaser, in which case the requirements shall be chosen from IEC 60721-3-5 and IEC 60721-3-7 and the testing should be undertaken taking account of the requirements of the other relevant parts of IEC 60068 given in Clause 2.

The general and radiological requirements of all types of in vivo counters are in the main part of this standard.

B.2 Environmental performance characteristics

Transportable and portable assemblies may be stored and possibly operated in uncontrolled or inadequately controlled environments. This may cause an assembly to be exposed to temperature and humidity extremes for substantial periods of time prior to, or during, use. The assembly may be exposed to shock and vibration during movement that stationary assemblies may not be exposed to.

The following requirements and tests are in addition to the performance requirements stated in the main part of this standard, and the temperature and humidity tests in this annex supplement those given in the main part of this standard.

B.2.1 Operational requirements

B.2.1.1 Ambient temperature

B.2.1.1.1 Requirements

Depending on the operating environment (i.e., temperature stability of the enclosure), a wider temperature range may be needed to ensure functionality. If the ambient temperature in operation is unknown, functionality shall be checked over the temperature range of +5 °C to +40 °C.

The equipment passes the test if, at extreme operating temperatures, the error of the response curve (see 8.5.3.2 or 9.5.3.2, as applicable) does not exceed ±10 % in the case of instruments with a scintillation detector or ±0,4 % for instruments with germanium semiconductor detectors

B.2.1.1.2 Method of test

Place the equipment (or appropriate components) in an environmental chamber. Stabilize the temperature at the reference value (20 °C ± 2 °C), switch the assembly on, and verify functionality using guidance found in 8.5.3.2 or 9.5.3.2. Reduce the relative humidity to ensure that the dew point is not exceeded then reduce the temperature to +5 °C at a rate not greater than 10 °C per hour.

Maintain this temperature until equilibrium is attained.

NOTE This can be accomplished using additional temperature sensors placed on the assembly being tested.

Switch the assembly on and ensure functionality.

Functionality shall be ensured using a technique that can be performed remotely without opening the environmental chamber to the extent practical.

Soak the equipment at +5 °C for 16 h, ensuring functionality every hour. After the soak period is complete, ramp the temperature at a rate not greater than 10 °C per hour to +40 °C verifying functionality every hour.

Soak the equipment at the maximum temperature set point for 16 h, ensuring functionality every hour. After the soak period is complete, reduce the temperature to the reference value at a rate of 10 °C per hour.

Allow the equipment to operate at the reference temperature until equilibrium is attained and verify functionality.

B.2.1.2 Relative humidity

B.2.1.2.1 Requirements

Depending on the operating environment (i.e., temperature stability of the enclosure), the assembly may be operated over a broad relative humidity range. Possible breakdowns can occur after exposures to high levels of humidity. If the relative humidity is uncontrolled, functionality shall be checked during and after exposure to 93 % relative humidity at +40 °C.

The equipment passes the test if the additional error, over that due to temperature alone, does not exceed ±10 % for all instruments except those using germanium detectors where the additional error shall be less than ±0,6 %.

B.2.1.2.2 Method of test

Tests are performed using an environmental chamber. The chamber shall be stabilized at +40 °C and 40 % relative humidity. Sufficient readings shall be obtained using guidelines previously stated to establish a pre-test baseline.

The relative humidity level shall then be increased at a controlled rate over a period of time not exceeding 4 h to 93 % ($^{+5}_{-0}$ %). Readings shall be obtained at 8 h intervals for 96 h.

The relative humidity level shall then be reduced at a controlled rate to 40 % (±5 %) and readings shall be taken after the chamber has stabilized.

B.2.1.3 Temperature shock

B.2.1.3.1 Requirements

Portable and transportable equipment may be operated in areas where the assembly can be exposed to rapid temperature changes such as that caused by opening and closing of entrance doors.

The equipment shall be designed such that those components that need to operate in a stable environment are protected through insulation or other techniques to prevent exposure. Specific tests should be performed as necessary based on agreement between the manufacturer and user. The following is provided as guidance only.

The equipment passes the test if, after 15 min at extreme operating temperatures, the error of the response curve (see 8.5.3.2 or 9.5.3.2 as applicable) does not exceed ±10 % in the case of equipment with a scintillation detector or ±0,4 % for equipment with germanium semi-conductor detectors.

The stated temperature extremes shall be used unless others are selected by agreement between the manufacturer and the purchaser.

B.2.1.3.2 Method of test

Place the equipment (or appropriate components) in an environmental chamber. Stabilize the temperature at 20 °C ± 2 °C, switch the assembly on, and verify functionality using guidance found in 8.5.3.2 or 9.5.3.2 as applicable. Reduce the relative humidity to ensure that the dew point is not exceeded. Switch the assembly off and quickly (in less than 5 min) reduce the temperature to –25 °C.

Switch the assembly on and take readings as required in this standard. Continue to take readings at 15 min intervals for 3 h.

Increase the ambient temperature to +5 °C, allow equilibrium to be reached, and switch the assembly off. Quickly (in less than 5 min) return the ambient temperature to +30 °C. Switch the assembly on and take readings as required in this standard. Continue to take readings at 15 min intervals for 3 h. This completes the first cycle. Repeat the cycle four additional times for a total of five cycles.

Return the temperature to 20 °C ± 2 °C, switch the assembly on, and verify functionality using guidance found in 8.5.3.2 or 9.5.3.2 as applicable.

B.2.2 Temperature storage requirements

B.2.2.1 Requirements

Portable and transportable equipment may be exposed to uncontrolled environments for long periods of time. Depending on the areas of use and storage, specific temperature test points are difficult to determine. It is therefore recommended that assemblies be designed for storage temperatures from –25 °C to +70 °C.

Where detectors are susceptible to high temperatures, the detectors shall be easily removable from the assembly prior to testing. If they cannot be removed, actions shall be taken to prevent exposure to high temperature.

The equipment passes the test if, at extreme operating temperatures, the error of the response curve does not exceed ±5 % in the case of equipment with a scintillation detector or ±0,2 % for equipment with germanium semi-conductor detectors.

B.2.2.2 Method of test

Place the equipment (or appropriate components) in an environmental chamber. Stabilize the temperature at +20 °C ± 2 °C, switch the assembly on, and verify functionality using guidance found in 8.5.3.2 or 9.5.3.2 as applicable. Switch the equipment off and reduce the relative humidity to ensure that the dew point is not exceeded. Reduce the temperature to –25 °C at a rate not to exceed 10 °C per hour. Soak the equipment for 16 h, and then increase the temperature to +70 °C at a rate not greater than 10 °C per hour. Soak the assembly for 16 h then decrease the temperature to –25 °C using the same change rate. Repeat this process for a total of 3 cycles.

Upon completion of the third cycle, return the temperature to the reference value and switch the assembly on. Verify functionality using guidance found in 8.5.3.2 or 9.5.3.2 as applicable.

B.2.3 Transportation requirements

B.2.3.1 General

The requirements stated below are based on the expected mechanical exposures for equipment installed in enclosed or partly opened, heated or unheated unventilated compartments. Vibration and shock parameters are based on travel over well-developed roads using all types of vehicles except tracked vehicles.

B.2.3.2 Vibration

B.2.3.2.1 Requirements

Portable and transportable equipment shall be designed to operate after exposure to vibration environments that are expected during normal movement after installation. Measures shall be taken to isolate the equipment from the effects of vibration.

The equipment shall be exposed to sinusoidal vibration using the following parameters shown in Table B.1

Table B.1 – Sinusoidal vibration parameters

Displacement	3,5 mm	3,5 mm
Acceleration	10 $m \cdot s^{-2}$	15 $m \cdot s^{-2}$
Frequency range	5-200 Hz	200-500 Hz
Number of axes	1	1
Sweep cycles	10	10

The equipment passes the test if the error of the response curve does not exceed ±5 % in the case of equipment with a scintillation detector, and ±0,2 % for equipment with germanium semi-conductor detectors after vibration.

B.2.3.2.2 Method of test

Position and mount the equipment as it would be mounted when in use. Switch the equipment on, and verify functionality in accordance with 8.4.1 or 9.4.1. Switch the equipment off and start the vibration exposure. Upon completion of 10 sweep cycles, switch the equipment on and verify functionality according to 8.4.1 or 9.4.1 as applicable.

B.2.3.3 Shock

B.2.3.3.1 Requirements

Portable and transportable equipment shall be designed to operate after exposure to transportation shocks that can occur during normal movement after installation. Measures shall be taken to isolate the equipment from the effects of shock.

Efforts shall be made to test complete equipment, but, if this is not possible, an engineering evaluation shall be performed to determine those components that may be the most susceptible to shock, and tests shall be performed on those components.

The equipment shall be exposed to half-sine shocks using the parameters shown in Table B.2.

Table B.2 – Half-sine shock parameters

Peak acceleration	150 $m \cdot s^{-2}$	300 $m \cdot s^{-2}$
Duration	11 ms	6 ms
Number of shocks per direction	3	3
Direction of shocks	3	1

The equipment passes the test if the error of the response curve does not exceed ±5 % in the case of equipment with a scintillation detector and ±0,2 % for equipment with germanium semi-conductor detectors after the shock test.

B.2.3.3.2 Method of test

Position and mount the equipment as it would be mounted when in use. Switch the equipment on, and verify functionality according to 8.4.1 or 9.4.1 as applicable. Switch the equipment off and perform the test. Upon completion of three shocks, switch the equipment on and verify functionality in accordance with 8.4.1 or 9.4.1 as applicable.

B.3 Documentation

The manufacturer shall make available, at the request of the purchaser a report on the type tests carried out according to the requirements of this annex. The report should be based on the requirements stated in Clause 10.

Bibliography

IEC 60050(151), *International Electrotechnical Vocabulary – Part 151: Electrical and magnetic devices*

IEC 61000-4-8:2001, *Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test*

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050-393	-[1)]	International Electrotechnology Vocabulary - Part 393: Nuclear instrumentation - Physical phenomena and basic concepts	-	-
IEC 60050-394	-[1)]	International Electrotechnical Vocabulary - Chapter 394: Nuclear instrumentation: Instruments	-	-
IEC 60068-2-1	-[1)]	Environmental testing - Part 2: Tests - Tests A: Cold	EN 60068-2-1	1993[2)]
IEC 60068-2-2	-[1)]	Basic environmental testing procedures - Part 2: Tests - Tests B: Dry heat	EN 60068-2-2[3)]	1993[2)]
IEC 60068-2-6	-[1)]	Environmental testing - Part 2: Tests - Test Fc: Vibration (sinusoidal)	EN 60068-2-6	1995[2)]
IEC 60068-2-14	-[1)]	Environmental testing - Part 2: Tests - Test N: Change of temperature	EN 60068-2-14[4)]	1999[2)]
IEC 60068-2-27	-[1)]	Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock	EN 60068-2-27	1993[2)]
IEC 60068-2-78	-[1)]	Environmental testing - Part 2-78: Tests - Test Cab: Damp heat, steady state	EN 60068-2-78	2001[2)]
IEC 60721-3-5	-[1)]	Classification of environmental conditions - Part 3: Classification of groups of environmental parameters and their severities - Section 5: Ground vehicle installations	EN 60721-3-5	1997[2)]

1) Undated reference.

2) Valid edition at date of issue.

3) EN 60068-2-2 includes supplement A to IEC 60068-2-2.

4) EN 60068-2-14 includes A1 to IEC 60068-2-14.

Publication	Year	Title	EN/HD	Year
IEC 60721-3-7	-[1)]	Classification of environmental conditions - Part 3: Classification of groups of environmental parameters and their severities - Section 7: Portable and non-stationary use	EN 60721-3-7	1995[2)]
IEC 61000-4-2	-[1)]	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995[2)]
IEC 61000-4-3	-[1)]	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2006[2)]
IEC 61000-4-5	1995	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995
IEC 61000-4-6	-[1)]	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	-	-
IEC 61000-4-12	1995	Electromagnetic compatibility (EMC) - Part 4-12: Testing and measurement techniques - Oscillatory waves immunity test	EN 61000-4-12	1995
IEC 61187 (mod)	1993	Electrical and electronic measuring equipment - Documentation	EN 61187 + corr. March	1994 1995
IEC 61276	1994	Nuclear instrumentation - Guidelines for selection of metrologically supported nuclear radiation spectrometry systems	-	-
ISO 11929-1	2000	Determination of the detection limit and decision threshold for ionizing radiation measurements - Part 1: Fundamentals and application to counting measurements without the influence of sample treatment	-	-
ISO 11929-4	2001	Determination of the detection limit and decision threshold for ionizing radiation measurements - Part 4: Fundamentals and application to measurements by use of linear-scale analogue ratemeters, without the influence of sample treatment	-	-

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