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Radiological protection — Sealed radioactive sources — General requirements and classification

Radioprotection — Sources radioactives scellées — Exigences générales et classification

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Foreword

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

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

ISO 2919 was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

This third edition cancels and replaces the second edition (ISO 2919:1999), which has been technically revised.

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Introduction

Safety is the prime consideration when establishing standards about the use of sealed radioactive sources. Sealed-source users have established an enviable record of safe usage as a result of careful scrutiny of the conditions of application of the sealed radioactive source by the regulating authority, the supplier and the user. However, as the application of sealed radioactive sources becomes more diversified and as regulating agencies become more numerous, an International Standard is needed to specify the characteristics of a sealed radioactive source and the essential performance and safety testing methods for a particular application and, thus, maintain the record of safe usage.

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Radiological protection — Sealed radioactive sources — General requirements and classification

1 Scope

This International Standard establishes a classification system for sealed radioactive sources that is based on test performance and specifies general requirements, performance tests, production tests, marking and certification. It provides a set of tests by which manufacturers of sealed radioactive sources can evaluate the safety of their products in use and users of such sources can select types which are suitable for the required application, especially where protection against the release of radioactive material, with consequent exposure to ionizing radiation, is concerned. This International Standard can also serve as guidance to regulating authorities.

The tests fall into several groups, including, for example, exposure to abnormally high and low temperatures and a variety of mechanical tests. Each test can be applied in several degrees of severity. The criterion of pass or fail depends on leakage of the contents of the sealed radioactive source.

NOTE Leakage test methods are given in ISO 9978.

Although this International Standard classifies sealed sources by a variety of tests, it does not imply that a sealed source will maintain its integrity if used continuously at the rated classification. For example, a sealed source tested for 1 h at 600 °C might, or might not, maintain its integrity if used continuously at 600 °C.

A list of the main typical applications of sealed radioactive sources, with a suggested test schedule for each application, is given in Table 3. The tests constitute minimum requirements corresponding to the applications in the broadest sense. Factors to be considered for applications in especially severe conditions are listed in 4.2.

This International Standard makes no attempt to classify the design of sources, their method of construction or their calibration in terms of the radiation emitted. Radioactive materials inside a nuclear reactor, including sealed sources and fuel elements, are not covered by this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 361, *Basic ionizing radiation symbol*

ISO 9978:1992, *Radiation protection — Sealed radioactive sources — Leakage test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
capsule
protective envelope used to prevent leakage of radioactive material

3.2
device
any piece of equipment designated to utilize one or several sealed sources

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3.3
dummy sealed source
facsimile of a sealed source, the capsule of which has the same construction and is made of exactly the same materials as those of the sealed source it represents, but containing, in place of the radioactive material, a substance resembling it as closely as is practical in physical and chemical properties

3.4
leachable
soluble in water, yielding quantities greater than 0,1 mg/g in 100 ml of still water maintained at 50 °C for 4 h

3.5
leakage
transfer of contained radioactive material from the sealed source to the environment

3.6
leaktight
having met the limiting values given in Table 1 of ISO 9978:1992 after leakage testing

3.7
model designation
manufacturer's unique term (number, code or a combination of these) which is used to identify a specific design of sealed source

3.8
non-leachable
insoluble in water, yielding quantities less than 0,1 mg/g in 100 ml of still water maintained at 50 °C for 4 h

3.9
prototype sealed source
original of a sealed source which serves as a pattern for the manufacture of all sealed sources identified by the same model designation

3.10
sealed source
radioactive material sealed in a capsule or associated with a material to which it is closely bonded, this capsule or bonding material being strong enough to maintain leaktightness of the sealed source under the conditions of use and wear for which it was designed

3.11
test source
sample used in the performance tests described in this International Standard, having the same material and construction as sealed sources of the model for which classification is being established

NOTE A test source may be a dummy sealed source, prototype or production source.

3.12
source assembly
sealed source contained within or attached to a source holder

3.13
source holder
mechanical device capable of retaining the sealed source

3.14
source in device
sealed source which remains within the shielded equipment during exposure, thus providing some mechanical protection during use

3.15
unprotected source
sealed source which, for use, is removed from the shielding

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4 Designation and classification

4.1 Designation

The classification of the sealed source type shall be designated by the code ISO/, followed by two digits to indicate the year of approval of the standard used to determine the classification, followed by a solidus (/), followed by a letter, followed by five digits and a set of parentheses containing one or more digits.

The letter shall be either C or E:

— C indicates that the activity of the sealed source does not exceed the level specified in Table 2;

— E indicates that the activity of the sealed source exceeds the level specified in Table 2.

The five digits shall be the class numbers which describe the performances for temperature, external pressure, impact, vibration and puncture respectively, in the order shown in Table 1.

If required, a number is inserted between the parentheses describing the type of bending test the source has passed. Bending tests required for sources that have a particular shape (long slender sources, brachytherapy needles) are listed in Table 1 and specific requirements are given in 7.7. Multiple tests may be performed and described to satisfy the test criteria.

The parentheses may be omitted if no bending test is required.

EXAMPLES

— a typical industrial radiography source design for unprotected use would be designated “ISO/11/C43515(1)” or “ISO/11/C43515”;

— a typical brachytherapy source design would be designated “ISO/11/C53211(8)”;

— a typical irradiator source design would be designated “ISO/11/E53424(4,7)”.

4.2 Classification

The classification levels are given in Table 1. Table 1 provides a list of environmental test conditions with class numbers arranged in increasing order of severity. The performance requirements given in Table 3 do not consider the effects of fire, explosion and corrosion.

In their evaluation of sealed sources, the manufacturer and user shall consider the probability of fire, explosion, corrosion, etc. and the possible results from such events. Factors which should be considered when determining the need for special testing are as follows:

a) consequences of loss of activity;

b) quantity of radioactive material contained in the sealed source;

c) radionuclide group;

d) chemical and physical form of the radioactive material;

e) environment in which the source is stored, moved and used;

f) protection afforded to the sealed source or source-device combination.

Annex C contains some general information on adverse environmental conditions. The user and manufacturer should decide jointly on the additional tests, if any, to which the sealed source shall be subjected.

Annex D contains examples of special tests.

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Table 1 — Classification of sealed-source performance

Test	Class								
	1	2	3	4	5	6	7	8	X
Temperature	No test	−40 °C (20 min) +80 °C (1 h)	−40 °C (20 min) +180 °C (1 h)	−40 °C (20 min) +400 °C (1 h) and thermal shock to 20 °C	−40 °C (20 min) +600 °C (1 h) and thermal shock to 20 °C	−40 °C (20 min) +800 °C (1 h) and thermal shock to 20 °C	Not used	Not used	Special test
External pressure	No test	25 kPa absolute to atmos-pheric	25 kPa absolute to 2 MPa absolute	25 kPa absolute to 7 MPa absolute	25 kPa absolute to 70 MPa absolute	25 kPa absolute to 170 MPa absolute	Not used	Not used	Special test
Impact	No test	50 g from 1 m or equivalent imparted energy	200 g from 1 m or equivalent imparted energy	2 kg from 1 m or equivalent imparted energy	5 kg from 1 m or equivalent imparted energy	20 kg from 1 m or equivalent imparted energy	Not used	Not used	Special test
Vibration	No test	3 times 10 min 25 Hz to 500 Hz at 49 m/s^2 (5 g) [a]	3 times 10 min 25 Hz to 50 Hz at 49 m/s^2 (5 g) [a] and 50 Hz to 90 Hz at 0,635 mm peak to peak and 90 Hz to 500 Hz at 98 m/s^2 (10 g) [a]	3 times 30 min 25 Hz to 80 Hz at 1,5 mm peak to peak and 80 Hz to 2 000 Hz at 196 m/s^2 (20 g) [a]	Not used	Not used	Not used	Not used	Special test
Puncture	No test	1 g from 1 m or equivalent imparted energy	10 g from 1 m or equivalent imparted energy	50 g from 1 m or equivalent imparted energy	300 g from 1 m or equivalent imparted energy	1 kg from 1 m or equivalent imparted energy	Not used	Not used	Special test
Bending	No test	Test 7.7.1 100 N (10,2 kg) for $L/D > 15$	Test 7.7.1 500 N (51 kg) for $L/D > 15$	Test 7.7.1 1 000 N (102 kg) for $L/D > 15$	Test 7.7.1 2 000 N (204 kg) for $L/D > 15$	Test 7.7.1 4 000 N (408 kg) for $L/D > 15$	Test 7.7.2 for $L > 100$ mm and for $L/D > 10$	Test 7.7.3 for brachy-therapy needle with $L > 30$ mm	Special test

[a] 1 g = 9,8 m/s^2.

4.3 Determination of classification

The classification of each sealed source type shall be determined by one of the following methods:

— subjecting two test sources of that model to each test in Table 1, as described in Clause 7;

— engineering analysis which demonstrates that the sealed-source model would pass the tests of Clause 7 if these tests were performed.

5 Activity level requirements

The specified activity of sealed sources, below which a separate evaluation of the specific usage and design is not required, is given in Table 2 for each of the four radionuclide groups defined in Annex A.

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Sealed sources containing more than the specified activity shall be subject to further evaluation of the specific usage and design. For classification purposes, the activity level of a sealed source according to Table 2 shall be considered at its time of manufacture.

Except if required, evaluation of the specific usage and design of the sealed source shall be considered only when the activity of the principal radionuclide exceeds the value shown in Table 2. If the activity exceeds this value, the specifications of the sealed sources shall be considered on an individual basis.

Table 2 — Specified activity according to radionuclide group

Radionuclide group (from Annex A)	Specified activity TBq (Ci)	
	Leachable	**Non-leachable**
A	0,01 (0,3)	0,1 (3)
B1	1,11 (30)	11,1 (300)
B2	11,1 (300)	111 (3 000)
C	18,5 (500)	185 (5 000)

6 Performance requirements

6.1 General requirements

All sealed sources shall be tested after manufacture to ensure freedom from surface contamination. This shall be done in accordance with one of the tests specified in 5.3 of ISO 9978:1992.

All sealed sources shall be tested after manufacture to ensure freedom from leakage. This shall be done in accordance with one or more of the methods specified in ISO 9978.

Where feasible, the radiation output shall be established after manufacture. For some sources, this may not be possible and a relative measurement against an agreed reference standard, or a statement of radioactive content, may be substituted (e.g. beta emitters may be measured by ion current output or other methods).

The content activity of all sealed sources shall be estimated. This can be done from the result of the radiation output measurement or from radioactive assay of the batch of material used in manufacture.

Test sealed sources shall be subjected, as specified herein, to the tests described in Clause 7. A classification for the sealed-source model shall be given in accordance with Clause 4.

A certificate containing the results of tests on each sealed source shall be provided in accordance with Clause 9.

Each sealed source shall be marked in accordance with Clause 8.

The sealed-source capsule shall be physically and chemically compatible with its contents. In the case of a sealed source produced by direct irradiation, the capsule shall not contain significant quantities of radioactive material unless that material is adequately bonded into the capsule material and radioactive test methods in accordance with ISO 9978 show that the sealed source is leak-free.

The tracer in a test source shall be soluble in a solvent which does not attack the capsule and shall be safe to use at maximum activity in a test environment (e.g. approximately 1 MBq ^{137}Cs).

6.2 Requirements for typical usage

A list of some typical applications in which a sealed source, source assembly or source in device is used, together with minimum performance requirements, is defined in Table 3.

One or more of the bending tests specified in 7.7 may also be required.

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For test sources where the ratio of active length (L) to minimum outer capsule diameter (D) is equal to or greater than 15 (i.e. $L/D \geq 15$), the bending tests required are those described in 7.7.1. For example, for sealed sources used in category I irradiators, class 4 is required; for those used in categories II, III and IV irradiators, class 5 is required.

For test sources where the ratio of active length (L) to minimum outer capsule diameter (D) is 10 or greater (i.e. $L/D \geq 10$) and an active length equal to or greater than 100 mm (i.e. $L \geq 100$ mm), the bending test required is that described in 7.7.2 and is class 7.

For sealed sources in the form of brachytherapy needles having an active length (L) of equal to or greater than 30 mm (i.e. $L \geq 30$ mm), the bending test required is that described in 7.7.3 and is class 8.

These requirements take into account normal usage and reasonable accidental risks, but do not include exposure to fire, explosion or corrosion. For sealed sources normally mounted in devices, consideration is given to the additional protection afforded to the sealed source by the device when the class number for a particular usage was assigned. Thus, for all usages shown in Table 3, the class numbers specify the tests to which the sealed source shall be subjected, except that for the ion generator category. For these, the complete source assembly or source in device may be tested.

The tests specified herein do not cover all sealed-source usage situations. If the conditions of a particular usage or the conditions relating to potential accidents do not match the classification specified in Table 3, the manufacturer and user shall consider making appropriate tests on an individual basis.

The numbers shown in Table 3 refer to the class numbers used in Table 1.

6.3 Procedure for establishing classification and performance requirements

6.3.1 Establish the relevant radionuclide group from Annex A.

6.3.2 Determine the specified-activity value in accordance with Table 2.

6.3.3 An evaluation of hazards due to fire, explosion, corrosion, etc. shall be made for all sealed sources.

a) If the sealed-source activity exceeds the allowable level given in Table 2, or if there is a significant probability of the source being exposed to fire, explosion and corrosion, a separate evaluation of the tests required shall be made, which shall include source design and specific usage.

b) If the sealed-source activity does not exceed the allowable level given in Table 2, and if no significant hazard is identified, the minimum classification required for the sealed source and its application may be used (see 6.2).

6.3.4 After the required minimum classification of the sealed source for the particular application or usage has been established, the performance standards required can be obtained directly from Table 1.

6.3.5 Alternatively, the sealed-source class can be determined from Table 1 and suitable applications may be selected from Table 3.

Since Table 1 is arranged in order of increasing severity from class 1 to class 8, sealed sources of an established classification may be used in any suitable application having the same or less stringent specific performance requirements.

6.4 Recommended working life (RWL)

6.4.1 The recommended working life (RWL) is the period of time within which the manufacturer expects the source to meet its stated performance requirements under design conditions of environment and usage.

6.4.2 At the end of the RWL, or if the design conditions of use are exceeded, an assessment should be made to verify its fitness for continued use or the source should be replaced.

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6.4.3 Exceeding the RWL does not necessarily mean that the source is unfit for use or transport. It means that an assessment is required to ensure continuing fitness for use.

6.4.4 The assessment should include leakage and/or contamination testing and a review of the design safety for the source and the application, and the effects of the environment during use.

6.4.5 An individual source can have its RWL extended by a qualified body, preferably the manufacturer, based on inspection and technical assessment.

6.4.6 It is the user's responsibility to carry out routine inspection and testing, and to maintain the source conditions of use in accordance with the manufacturer's instructions.

Table 3 — Sealed source classification and performance requirements for typical usage

Sealed source usage		Sealed source class, depending on test				
		Tempera-ture	Pressure	Impact	Vibration	Puncture
Radiography — Industrial	Sealed source	4	3	5	1	5
	Source to be used in device	4	3	3	1	3
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
	Brachytherapy[2] a	5	3	2	1	1
	Surface applicators b	4	3	3	1	2
Gamma gauges	Unprotected source	4	3	3	3	3
(medium and high energy)	Source in device	4	3	2	3	2
Beta gauges and sources for low-energy gamma gauges or X-ray fluorescence analysis b		3	3	2	2	2
Oil-well logging		5	6	5	2	2
Portable moisture and density gauge (including hand-held or dolly-transported)		4	3	3	3	3
General neutron source application (excluding reactor startup)		4	3	3	2	3
Calibration source activity > 1 MBq		2	2	2	1	2
Gamma irradiation sources d	Category I b	4	3	3	2	3
	Categories II, III and IV c	5	3	4	2	4
Ion generators c	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors b	3	2	2	2	2

a Manufactures and users may wish to formulate other or special test procedures which represent normal use and likely accident conditions.

b Excluding gas-filled sources.

c The "source in device" or the "source assembly" may be tested.

d For this International Standard, gamma irradiators have been divided into four distinct categories: Category I: Self-contained — Dry source storage, Category II: Panoramic — Dry source storage, Category III: Self-contained — Wet source storage, Category IV: Panoramic — Wet source storage.

7 Test methods

7.1 General

7.1.1 The test procedures given in this clause are acceptable procedures for determining performance classification numbers. All the criteria stated are minimum requirements. Procedures that can be demonstrated to be at least equivalent are also acceptable. All tests, except the temperature tests, shall be carried out at ambient temperature.

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7.1.2 For each test, at least two test sources of the model type shall be subjected to the test, and all shall pass as defined in 7.1.5.

7.1.3 The tests shall be performed in the most vulnerable orientation for the test. This should be determined by engineering analysis. Where more than one orientation is considered to be vulnerable, the tests should be performed on all vulnerable orientations using at least two test sources.

7.1.4 Different test sources may be used for each of the tests. The tests may be performed in any order and are not required to be cumulative.

7.1.5 Compliance with the tests shall be determined by the ability of the sealed source to maintain its leaktightness after each test has been performed. After each test, the source shall be examined visually for loss of integrity and it shall also pass an appropriate leakage test carried out in accordance with ISO 9978. When the leakage test is performed on a simulated source, the suitability of the chosen method shall be justified.

7.1.6 A source with more than one encapsulation shall be deemed to have passed a test if it can be demonstrated that at least one encapsulation is leaktight after the test.

7.2 Temperature test

7.2.1 Apparatus

The heating or cooling equipment shall have a test zone volume of at least five times the volume of the test specimen.

7.2.2 Procedure

Perform all the tests in air, except for the low-temperature tests where an atmosphere of carbon dioxide ("dry ice") is a permitted alternative.

NOTE Use of dry ice can result in a temperature lower than the requirement.

Sealed sources to be subjected to temperatures below ambient shall be cooled to the test temperature in less than 45 min.

Sealed sources to be subjected to temperatures above ambient shall be heated in accordance with the temperature–time relationship specified in Table 4 or another similar temperature-rise curve.

Table 4 — Temperature–time relationship for tests at temperatures above ambient

Temperature °C	**Maximum time limit** min
80	5
180	10
400	25
600	40
800	70

For classes 2 and 3, retain sealed sources at the upper test temperature for at least 1 h, then allow them to cool slowly to ambient temperature in the furnace or laboratory atmosphere.

For classes 4, 5 and 6, retain sealed sources at the upper test temperature for at least 1 h, then subject them to a thermal shock by transferring them, within 15 s, to water at ambient temperature (about 20 °C). The water shall have a flow rate of at least ten times the sealed source volume per minute, or, if the water is stationary, it shall have a volume of at least twenty times the sealed source volume.

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7.3 External pressure test

7.3.1 Apparatus

The pressure gauge shall be in calibration and should have a pressure range at least 10 % greater than the test pressure. The vacuum gauge shall be capable of reading pressures at least as low as 20 kPa absolute. Different test chambers may be used for the low- and high-pressure tests specified in Table 1.

7.3.2 Procedure

Place the sealed source in the chamber and expose it to the test pressure for two periods of 5 min each. Return the pressure to atmospheric between the periods.

Conduct the low-pressure test in air. Conduct the high-pressure test by a hydraulic method using water as the medium in contact with the sealed source.

Hydraulic oil should not be used in direct contact with the sealed source because of the possibility of temporary blockage of small leaks.

7.4 Impact test

7.4.1 Apparatus

7.4.1.1 Steel hammer, the upper part of which is equipped with a means of attachment, and the lower part of which shall have an external diameter of (25 ± 1) mm and a flat striking surface with its outer edge rounded to a radius of (3,0 ± 0,3) mm.

The centre of gravity of the hammer shall lie on the axis of the circle, which defines the striking surface; this axis itself passing through the point of attachment. The mass of the hammer for each test class is given in Table 1.

7.4.1.2 Steel anvil, the mass of which is at least ten times that of the hammer. It shall be rigidly mounted so that it does not deflect during impact and shall have a flat surface, large enough to support the entire sealed source.

7.4.2 Procedure

Choose the mass of the hammer in accordance with the class of test selected, as shown in Table 1.

For all drop heights, the distance of the drop is measured between the top of the sealed source positioned on the anvil and the face of the hammer in its position prior to release. Normally, this height is 1 m, except as allowed in Table 1 for equivalent imparted energy.

Position the sealed source so that it offers its most vulnerable area to the hammer.

Drop the hammer onto the source.

7.5 Vibration test

7.5.1 Apparatus

Use a vibrating machine capable of performing the tests specified.

7.5.2 Procedure

Fix the source securely to the platform of the vibrating machine so that the source is kept rigidly in contact with the platform at all times.

For classes 2 and 3, subject the sealed source to three complete test cycles for each condition specified. Conduct the test by sweeping through all the frequencies in the range at a uniform rate, from the minimum

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frequency to the maximum frequency, and return to the minimum frequency after 10 min or longer. Test each axis of the source as specified below. In addition, continue the test for 30 min at each resonant frequency found.

For class 4, subject the sealed source to three complete test cycles for each condition specified. Conduct the test by sweeping through all the frequencies in the range at a uniform rate, from the minimum frequency to the maximum frequency, and return to the minimum frequency after 30 min or longer. Test each axis of the source as specified below. In addition, continue the test for 30 min at each resonant frequency found.

For the purposes of these tests, a maximum of three axes shall be used. A spherical source has one axis taken at random. A source with an oval or disc-type cross-section has two axes, one of revolution and one taken at random in a plane perpendicular to the “symmetrical axis”. Other sources have three axes, taken parallel to the significant external dimensions.

7.6 Puncture test

7.6.1 Apparatus

7.6.1.1 Steel hammer, the upper part of which is equipped with a means of attachment, and the lower part of which bears a rigidly fixed pin. The characteristics of this pin shall be as follows:

a) hardness: from 50 to 60 Rockwell C;

b) external (free) height: (6,0 ± 0,2) mm (external to the hammer face);

c) diameter: (3,0 ± 0,1) mm;

d) striking surface: hemispherical.

The centre line of the pin shall be in alignment with the centre of gravity and with the point of attachment of the hammer. The mass of the hammer and pin depends on the test class.

7.6.1.2 Hardened steel anvil, rigidly mounted and with a mass at least ten times that of the hammer. The contact surface between the sealed source and the anvil shall be large enough to prevent deformation of this surface when the puncture test takes place. If necessary, a cradle may be used to maintain the position and point of contact between the test source and the anvil.

7.6.2 Procedure

For the appropriate class, choose the mass of the hammer and pin in accordance with Table 1.

For all drop heights, the distance of the drop is measured between the top of the sealed source positioned on the anvil and the point of the pin in its position prior to release. Normally, this height is 1 m, except as allowed in Table 1 for equivalent imparted energy.

Position the sealed source so that it offers its most vulnerable area to the pin. Drop the hammer onto the sealed source.

If the dimensions and mass of the sealed source concerned do not permit unguided fall, lead the striker to the puncture point in a smooth vertical tube.

7.7 Bending tests

7.7.1 Bending test for sealed sources with $L/D \geq 15$

This bending test shall apply to sealed sources having an L/D of 15 or greater, where L is the active length and D is the minimum outer capsule diameter or dimension taken perpendicular to the major axis of the sealed source over its active length.

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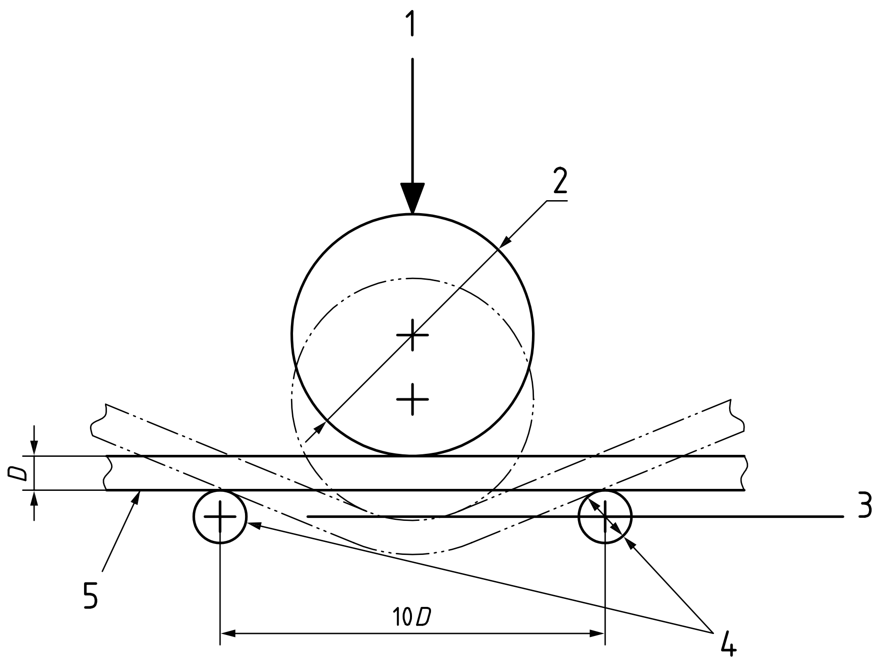
Bending test classification is based on the application of a static force, using the following test parameters and three cylinders, as illustrated in Figure 1. The three cylinders shall not rotate and shall have longitudinal axes that are parallel to each other. The cylinders shall have smooth surfaces and shall be of sufficient length to accommodate the full contact surface of the capsule during the test procedure. All cylinders shall be made of a solid material with a Rockwell C hardness of 50 to 55. Care should be taken not to apply the static force too suddenly as this will increase the effective force.

The static force shall be applied at the most vulnerable part of the sealed source.

The static force to be applied for each class of bending test is given in Table 1.

For flexible sealed sources, the sealed source shall have passed the bending test if it maintains its integrity after being placed in the test jig whilst the centre line of the central cylinder passes through the plane containing the major axes of the two static support cylinders.



Key

1 static force

2 5D — force cylinder

3 plane of support cylinders

4 2D — support cylinders

5 sealed source

Figure 1 — Bending test parameters

7.7.2 Bending test for sealed sources with $L/D \geq 10$ and $L \geq 100$ mm

This bending test shall apply to sealed sources having an L/D of 10 or greater and an L of 100 mm or greater, where L is the active length and D is the minimum outer capsule diameter or dimension taken perpendicular to the major axis of the sealed source over its active length.

The sealed source shall be rigidly clamped in a horizontal position so that half its length protrudes from the face of the clamp.

The orientation of the specimen shall be such that the specimen will suffer maximum damage when its free end is struck by the flat face of a steel hammer. The hammer shall strike the specimen so as to produce an impact equivalent to that resulting from a free vertical fall of 1,4 kg through 1 m.

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The hammer shall have an external diameter of (25 ± 1) mm and a flat striking surface with its outer edge rounded to a radius of (3,0 ± 0,3) mm.

Sealed sources that pass this bending test shall be class 7.

7.7.3 Bending test for brachytherapy sources

This bending test shall apply to sealed brachytherapy sources having an overall length of 30 mm or greater.[2]

The sealed source shall be placed in a suitable device, such that it can be bent to an angle of at least 90° over a radius of (3,0 ± 0,1) mm. The test shall be made by placing approximately one-third of the length of the sealed source in the device, gripping the protruding portion with a suitable tool (e.g. pliers) and exerting the force necessary to bend the source over the specified radius to an angle of at least 90°. The sealed source shall then be straightened again.

Sealed sources that pass this bending test shall be class 8.

8 Source marking

Whenever physically possible, the capsule and the source assembly shall be durably and legibly marked with the following information given in order of priority:

a) the word “radioactive”; where this is not feasible, the symbol for radioactivity in accordance with ISO 361;

b) manufacturer’s name or symbol;

c) serial number;

d) mass number and chemical symbol of the radionuclide;

e) for neutron sources, the target element.

Marking of the capsule shall be carried out before the sealed source is tested.

9 Source certificate

The manufacturer shall provide a certificate with every sealed source or batch of sealed sources.

The certificate shall state in each case:

a) name of manufacturer;

b) classification designated by the code specified in Clause 4;

c) where applicable, the special form approval certificate number;

d) model designation;

e) serial number;

f) brief description, including chemical symbol and mass number of the radionuclide;

g) recommended working life;

h) content activity, estimated from an assay of the radioactive material used or from radiation output measurements and absorption data;

i) radiation output, equivalent assay value according to a reference standard, or statement of content;

j) method used, result and date of test for freedom from surface contamination;

k) method used, result and date of test for freedom from leakage.

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An example of a certificate for a sealed radioactive source is given in Annex B.

NOTE In addition, the certificate can include, as appropriate, a detailed description of the source, in particular:

— for the capsule: dimensions, material, thickness and method of sealing;

— for active contents: chemical and physical forms, dimensions, mass or volume and details of significant quantities of radionuclide impurities.

10 Quality assurance

A quality assurance programme should be established according to ISO 9001 or equivalent standards for the design, manufacture, testing, inspection and documentation of all sealed sources. Each manufacturer shall have developed a quality assurance programme appropriate to the sources being designed and manufactured.

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Annex A
(informative)

Classification of radionuclides

The following classification is based on ICRP Publication 5[8]. In addition, the nuclides ^{125}I, ^{67}Ga, ^{87}Y and ^{111}In have been included.

Information given in parentheses refers to the classification recommended by the 84/466[9] and 84/467[10] Euratom Directives, where (2), (3) and (4) indicate classification into groups 2, 3 and 4, respectively. However, in this International Standard, the grouping (A, B1, B2 or C) given hereafter should be used.

NOTE 1 It is accepted that ICRP Publication 5 is obsolete, but the information obtained from it and given herein is appropriate for use with this International Standard.

NOTE 2 There are other informative national standards and international guidance documents applicable to the classification of radionuclides and sealed sources[12][13][14]. These classification systems are outside the scope of this International Standard.

Group A				
^{227}Ac	^{242}Cm	^{231}Pa	^{241}Pu	^{228}Th
^{241}Am	^{243}Cm	^{210}Pb	^{242}Pu	^{230}Th
^{243}Am	^{244}Cm	^{210}Po	^{223}Ra	^{230}U
^{249}Cf	^{245}Cm	^{238}Pu	^{226}Ra	^{232}U
^{250}Cf	^{246}Cm	^{239}Pu	^{228}Ra	^{233}U
^{252}Cf	^{237}Np	^{240}Pu	^{227}Th	^{234}U

Group B1				
^{228}Ac	^{36}Cl(3)	^{125}I	^{212}Pb	^{160}Tb(3)
^{110m}Ag	^{56}Co(3)	^{126}I	^{224}Ra	^{127m}Te(3)
^{211}At	^{60}Co(3)	^{131}I	^{106}Ru	^{129m}Te(3)
^{140}Ba(3)	^{134}Cs	^{133}I(3)	^{124}Sb(3)	^{234}Th(3)
^{207}Bi(3)	^{137}Cs(3)	^{114m}In	^{125}Sb(3)	^{204}Tl(3)
^{210}Bi	$^{152(13y)}$Eu	^{192}Ir(3)	^{46}Sc(3)	^{170}Tm(3)
^{249}Bk	^{154}Eu	^{54}Mn(3)	^{89}Sr(3)	^{236}U
^{45}Ca(3)	^{181}Hf(3)	^{22}Na(3)	^{90}Sr	^{91}Y
^{115m}Cd	^{124}I	^{230}Pa	^{182}Ta(3)	^{95}Zr(3)
^{144}Ce				

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Group B2				
^{105}Ag	$^{64}Cu(4)$	^{43}K	^{143}Pr	$^{97}Tc(4)$
^{111}Ag	$^{165}Dy(4)$	$^{85m}Kr(4)$	^{191}Pt	^{97m}Tc
^{41}Ar	^{166}Dy	^{87}Kr	$^{193}Pt(4)$	$^{99}Tc(4)$
^{73}As	^{169}Er	^{140}La	^{197}Pt	^{125m}Te
^{74}As	^{171}Er	^{177}Lu	^{86}Rb	$^{127}Te(4)$
^{76}As	$^{152(9,2h)}Eu$	^{52}Mn	^{183}Re	$^{129}Te(4)$
^{77}As	$^{155}Eu(2)$	$^{56}Mn(4)$	^{186}Re	^{131m}Te
^{196}Au	$^{18}F(4)$	^{99}Mo	^{188}Re	^{132}Te
^{198}Au	^{52}Fe	^{24}Na	^{105}Rh	^{231}Th
^{199}Au	^{55}Fe	^{93m}Nb	$^{220}Rn(4)$	^{200}Tl
^{131}Ba	^{59}Fe	^{95}Nb	^{222}Rn	$^{201}Tl(4)$
$^{7}Be(4)$	^{67}Ga	^{147}Nd	^{97}Ru	^{202}Tl
^{206}Bi	^{72}Ga	$^{149}Nd(4)$	^{103}Ru	^{171}Tm
^{212}Bi	^{153}Gd	^{63}Ni	^{105}Ru	^{48}V
^{82}Br	^{159}Gd	$^{65}Ni(4)$	$^{35}S(4)$	$^{181}W(4)$
^{14}C	^{197}Hg	^{239}Np	^{122}Sb	^{185}W
^{47}Ca	^{197m}Hg	^{185}Os	^{47}Sc	^{187}W
$^{109}Cd(2)$	^{203}Hg	^{191}Os	^{48}Sc	$^{135}Xe(4)$
^{115}Cd	^{166}Ho	^{193}Os	^{75}Se	^{87}Y
^{141}Ce	^{130}I	^{32}P	$^{31}Si(4)$	^{90}Y
^{143}Ce	^{132}I	^{233}Pa	$^{151}Sm(2)$	^{92}Y
$^{38}Cl(4)$	$^{134}I(4)$	^{203}Pb	^{153}Sm	^{93}Y
^{57}Co	^{135}I	^{103}Pd	^{113}Sn	^{175}Yb
^{58}Co	$^{115m}In(4)$	^{109}Pd	^{125}Sn	^{65}Zn
$^{51}Cr(4)$	^{190}Ir	^{147}Pm	^{85}Sr	^{69m}Zn
$^{131}Cs(4)$	^{194}Ir	^{149}Pm	^{91}Sr	^{97}Zr
^{136}Cs	^{42}K	^{142}Pr	^{96}Tc	

Group C				
^{37}Ar	^{111m}In	$^{193m}Pt(3)$	^{96m}Tc	natural U
^{58m}Co	^{113m}In	^{197m}Pt	^{99m}Tc	^{131m}Xe
^{134m}Cs	^{85}Kr	^{87}Rb	$^{232}Th(2)$	^{133}Xe
^{135}Cs	^{97}Nb	^{187}Re	natural Th(2)	^{91m}Y
^{71}Ge	^{59}Ni	^{103m}Rh	^{235}U	^{69}Zn
^{3}H	$^{15}O(3)$	^{147}Sm	^{238}U	$^{93}Zr(2)$
^{129}I	^{191m}Os	^{85m}Sr		

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Annex B
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Example of certificate for sealed radioactive source

Manufacturer's name, address, telephone number and fax number

CERTIFICATE FOR SEALED RADIOACTIVE SOURCE

Model designation:	XYZ-1234
Serial number:	1234ABC
Radionuclide:	^{137}Cs (for neutron sources, also give target element)
Radionuclide impurities:	^{134}Cs activity $<$ 1,0 %
Description:	Gamma radiation source, CsCl pellet in double stainless steel capsule
Active length:	15,5 mm
Active diameter:	17,8 mm
Overall length:	26,4 mm
Overall diameter:	21,3 mm

ISO classification: ISO/11/E63636(1)

Special form certificate number: GB/199/S

Recommended working life: 10 years

Estimated content activity: 7 TBq Date: 2011-Apr-07

(For short-lived radionuclides, the time of measurement should also be given.)

Radiation output:	139 $\mu Gy \cdot s^{-1}$
Quantity measured:	Air kerma rate at 1 m from the centre of the source in a radial direction, i.e. perpendicular to the symmetrical axis of the source

Date: 2011-Apr-07

Test for freedom from surface contamination:

Method: Dry wipe test (see ISO 9978:1992, 5.3)

Result: passed Date: 2011-Apr-07

Test for freedom from leakage:

Method 1: Vacuum bubble test (see ISO 9978:1992, 6.2)

Result: passed Date: 2011-Apr-07

Method 2: Helium test (see ISO 9978:1992, 6.1)

Result: passed Date: 2011-Apr-07

This certificate and the information contained herein complies with the requirements of ISO 2919

Approval:

Signature: Date: ....

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Annex C
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General information on adverse environmental conditions

C.1 Corrosion evaluation

The most commonly found conditions causing corrosion are:

— atmospheres containing SO_2, H_2S, Cl_2, CO_2 or HCl;

— fluids containing salts, especially chloride anions;

— moisture;

— dissimilar metals;

— ionized air due to high levels of radiation from a source.

Manufacturers should ensure that materials used for capsules are compatible with the surroundings, e.g. holders, devices, environment, etc. in which they are to be used.

Users should ensure that, when sources are used in corrosive environments, inspection and test frequencies are adequate. Users should be particularly aware of the potential of generating corrosive environments when sources are used in close proximity to halogenated plastics.

Wherever potential corrosive environments exist, the manufacturer and user should agree to the programme of appropriate tests performed.

C.2 Fire evaluation

Wherever a potential for fire exists, the manufacturer and user shall agree on a programme of appropriate tests to be carried out. In some cases, one of the temperature tests given in this International Standard will be considered appropriate.

C.3 Fatigue failure

The potential for fatigue failure shall be considered if the test source is subject to thermal cycling, bend cycling, vibration, cyclic loading, embrittlement, or mechanical shock over time.

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Annex D
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Additional tests

D.1 General

This annex gives examples of additional test methods jointly developed by the user and the manufacturer. They are not obligatory in order for sealed sources to meet ISO classification, but some of them may be required to meet national regulations.

D.2 Corrosion tests

See ISO 7384[4].

D.3 Sulfur dioxide corrosion test

See ISO 11845[7].

D.4 Neutral salt spray test

See ISO 9227[6].

D.5 Fire test

See ISO 834-1[3].

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[2] ANSI N44.1-1973, *Integrity and test specifications for selected brachytherapy sources* (R. 1984)

[3] ISO 834-1, *Fire-resistance tests — Elements of building construction — Part 1: General requirements*

[4] ISO 7384:1986, *Corrosion tests in artificial atmosphere — General requirements*

[5] ISO 9001:2008, *Quality management systems — Requirements*

[6] ISO 9227:2006, *Corrosion tests in artificial atmospheres — Salt spray tests*

[7] ISO 11845:1995, *Corrosion of metals and alloys — General principles for corrosion testing*

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[11] ANSI/HPS N43.6-2007, *Sealed radioactive sources — Classification*

[12] IAEA-TECDOC-1344, *Categorization of Radioactive Sources*, July 2003

[13] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, Annex 1

[14] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure

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