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Radiation protection — Sealed radioactive sources — General requirements and classification

*Radioprotection — Sources radioactives scellées — Prescriptions
générales et classification*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

International Standard ISO 2919 was prepared by Technical Committee ISO/TC 85, *Nuclear energy*, Subcommittee SC 2, *Radiation protection*.

This second edition cancels and replaces the first edition (ISO 2919:1980) and ISO 1677:1977, which have been technically revised.

Annexes A to E of this International Standard are for information only.

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Introduction

Safety is the prime consideration in establishing any standard for 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 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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Radiation protection — Sealed radioactive sources — General requirements and classification

1 Scope

This International Standard establishes a system of classification of sealed radioactive sources based on test performance and specifies general requirements, performance tests, production tests, marking and certification.

It provides a set of tests by which the manufacturer of sealed radioactive sources can evaluate the safety of his products in use and by which the user 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 may also be of 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 1 Leakage test methods are given in ISO 9978.

A list of the main typical applications of sealed radioactive sources with a suggested test schedule for each application is given in table 4. The tests are 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.

NOTE 2 Manufacturers and test organizations should prepare their own programme for quality assurance, in accordance with the requirements of ISO 9000 to ISO 9004 or an equivalent national standard.

This International Standard makes no attempt to classify either the design of sources and 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 standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of the publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 361:1975, *Basic ionizing radiation symbol*.

ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*.

ISO 9000-2:1997, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*.

ISO 9000-4:—¹⁾, *Quality management and quality assurance standards — Part 4: Guide to dependability programme management*.

¹⁾ To be published. (Revision of ISO 9000-4:1993)

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation, and servicing.*

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 9004-1:1994, *Quality management and quality system elements — Part 1: Guidelines.*

ISO 9004-2:1991, *Quality management and quality system elements — Part 2: Guidelines for services.*

ISO 9004-3:1993, *Quality management and quality system elements — Part 3: Guidelines for processed materials.*

ISO 9004-4:1993, *Quality management and quality system elements — Part 4: Guidelines for quality improvement.*

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

3 Definitions

For the purposes of this International Standard, the following definitions apply. These are given in alphabetical order.

3.1

capsule

protective envelope used to prevent leakage of radioactive material

3.2

dummy sealed source

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

3.3

fluence rate

number of particles and/or photons of ionizing radiation emitted per unit time from the sealed source in defined geometry

NOTE This is best expressed in terms of radiation fluence rate.

3.4

leakage

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

3.5

leaktight

term applied to sealed sources which, after leakage testing, have met the limiting values given in table 1 of ISO 9978:1992

3.6

model designation

unique term (number, code or combination of these) which is used to identify a specific type of sealed source

3.7

non-leachable

term used to convey that the radioactive material in the form contained in the sealed source is virtually insoluble in water and is not convertible into dispersible products

3.8**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

3.9**quality assurance**

all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality

3.10**radiotoxicity**

the ability of a radionuclide to produce injury by virtue of its emitted radiations, when incorporated in the human body

3.11**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

3.12**simulated sealed source**

facsimile of a sealed source, the capsule of which has the same construction and is made with exactly the same materials as those of the sealed source that it represents but containing, in place of the radioactive material, a substance with physical and chemical properties as close as possible to those of the radioactive material and containing radioactive material of tracer quantity only

NOTE The tracer should be soluble in a solvent which does not attack the capsule and it should have a maximum activity compatible with its use in a test environment (e.g. approximately 1 MBq caesium 137).

3.13**source assembly**

sealed source contained within or attached to a source holder

3.14**source holder**

fixed or removable mechanical device to hold up or to support the source

3.15**source in device**

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

4 Classification and designation**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 3;
- E indicates that the activity of the sealed source exceeds the level specified in table 3.

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 2.

If required, a number is inserted between the parentheses describing the type of bending test the source has passed. Such bending tests, required for some particularly shaped sources (long slender sources, brachytherapy needles), are established 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/98/C43515(1)” or “ISO/98/C43515”;
- a typical brachytherapy source design would be designated “ISO/98/C53211(8)”;
- a typical irradiator source design would be designated “ISO/98/C53424(4,7)”.

Table 1 — Bending test class

Bending test class									
	1	2	3	4	5	6	7	8	X
Reference	No test	B. Test 7.7.1.	B. Test 7.7.1	B. Test 7.7.1	B. Test 7.7.1	B. Test 7.7.1	B. Test 7.7.2	B. Test 7.7.3	Special test
Static force S.F. =		100 N (10,2 kg)	500 N (51 kg)	1 000 N (102 kg)	2 000 N (204 kg)	4 000 N (408 kg)			

4.2 Classification

The classification levels are given in tables 1 and 2. Table 2 provides a list of environmental test conditions with class numbers arranged in increasing order of severity. The classifications given in table 4 do not consider the effects of fire, explosion and corrosion. In the 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 in determining the need for special testing are:

- a) consequences of loss of activity;
- b) quantity of radioactive material contained in the sealed source;
- c) radiotoxicity;
- 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.

The user and manufacturer should jointly decide the additional tests to which the sealed source shall be subjected, if any.

Annex D contains examples of special tests.

Table 2 — Classification of sealed source performance (5 digits)

Test	Class						
	1	2	3	4	5	6	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	Special test
External pressure	No test	25 kPa absolute to atmospheric	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	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	Special test
Vibration	No test	3 times 10 min 25 to 500 Hz at 49 m/s ² (5 g _n) ¹⁾	3 times 10 min 25 to 50 Hz at 49 m/s ² (5 g _n) ¹⁾ and 50 to 90 Hz at 0,635 mm amplitude peak to peak and 90 to 500 Hz at 98 m/s ² (10 g _n) ¹⁾	3 times 30 min 25 to 80 Hz at 1,5 mm amplitude peak to peak and 80 to 2 000 Hz at 196 m/s ² (20 g _n) ¹⁾	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	Special test

1) Acceleration maximum amplitude

4.3 Determination of classification

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

- actual testing of two sealed sources (specimen, dummy or simulated) of that type for each test in table 2;
- derivation from previous tests which demonstrate that the sealed source would pass the test if the test was performed.

Different specimens may be used for each of the tests.

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

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.

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 3 for each of the four radiotoxicity groups given in annex A.

Sealed sources containing more than the specified activity shall be subject to further evaluation of the specific usage and design. For purposes of classification, the activity level of a sealed source according to table 3 shall be considered at the time of its manufacture.

Except if required, evaluation of the effect of fire, explosion, corrosion and radiotoxicity of the radionuclide shall be considered only when the activity of the sealed source exceeds the value shown in table 3. If the activity exceeds this value, the specifications of the sealed sources shall be considered on an individual basis. If the activity does not exceed the values shown in table 3, table 4 may be used without further consideration of either radiotoxicity or solubility.

Table 3 — Specified activity level according to radionuclide group

Radionuclide group (from annex A)	Specified activity TBq (Ci)	
	Leachable ¹⁾	Non-leachable ²⁾
A	0,01 (about 0,3)	0,1 (about 3)
B1	1 (about 30)	10 (about 300)
B2	10 (about 300)	100 (about 3 000)
C	20 (about 500)	200 (about 5 000)

1) Leachable: greater than 0,01 % of the total activity in 100 ml in still H₂O at 50 °C for 4 h conforming to 5.1.1 of ISO 9978:1992.
2) Non-leachable: less than 0,01 % of the total activity in 100 ml in still H₂O at 50 °C for 4 h conforming to 5.1.1 of ISO 9978:1992.

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.

All sealed sources shall be measured after manufacture to determine their radiation output.

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.

Specimen 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, etc. 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 it can be shown that the sealed source is leaktight.

The tracer in a simulated sealed source shall be soluble in a solvent which does not attack the capsule and it shall have a maximum activity compatible with its use in a test environment (e.g. approximately 1 MBq ¹³⁷Cs).

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 given in table 4.

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

For test sources having an active length (L) to minimum outer capsule diameter (D) ratio 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, and for category II, III and IV irradiators, class 5 is required.

For test sources having an active length (L) to minimum outer capsule diameter (D) ratio of 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) 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.

Table 4 — Sealed source classification (performance) requirements for typical usage

Sealed source usage		Sealed source class, depending on test				
		Temperature	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 [6] ¹⁾	5	3	2	1	1
	Surface applicators ²⁾	4	3	3	1	2
Gamma gauges (medium and high energy)	Unprotected source	4	3	3	3	3
	Source in device	4	3	2	3	2
Beta gauges and sources for low-energy gamma gauges or X-ray fluorescence analysis ²⁾		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 [3], [5]	Category I ²⁾	4	3	3	2	3
	Categories II, III and IV ³⁾	5	3	4	2	4
Ion generators ³⁾	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors ²⁾	3	2	2	2	2

1) Sources of this nature may be subject to severe deformation in use. Manufacturers and users may wish to formulate additional or special test procedures.

2) Excluding gas-filled sources.

3) "Source in device" or a "source assembly" may be tested.

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 4, 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 conditions relating to potential accidents do not match the classification specified in table 4, the manufacturer and user shall consider making appropriate tests on an individual basis.

The numbers shown in table 4 refer to the class numbers used in table 2.

NOTE IAEA tests for special form radioactive material [1] are not of general application, but may be relevant when formulating additional tests.

6.3 Procedure to establish classification and performance requirements

6.3.1 Establish the radiotoxicity group from annex A.

6.3.2 Determine the specified activity value in accordance with table 3.

6.3.3 If the sealed source activity does not exceed the specified activity given in table 3, an evaluation of hazards due to fire, explosion, corrosion, etc. shall be made. If no significant hazard is identified, the minimum classification required for the sealed source and its application may be used (see 6.2). If significant hazards are identified, then a full evaluation of the tests required shall be made (see 4.2), paying particular attention to the temperature and impact requirements.

6.3.4 If the sealed source activity exceeds the allowable level given in table 3, a separate evaluation of the tests required shall be made which shall include source design and specific usage as well as hazards due to fire, explosion, corrosion, etc.

6.3.5 After the required minimum classification for the sealed source for the particular application or usage has been established, the performance standards required can be obtained directly from tables 1 and 2.

6.3.6 Alternatively, the sealed source class can be determined from tables 1 and 2 and suitable applications may be selected from table 4.

Since table 2 is arranged in order of increasing severity from class 1 through to class 6, sealed sources of an established classification may be used in any suitable application having the same or less stringent specific performance requirements.

7 Test methods

7.1 General

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

Criteria for compliance with this International Standard after testing are given in 4.3.

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. If a gas- or oil-fired furnace is used, an oxidizing atmosphere shall be maintained throughout the test.

7.2.2 Procedure

Perform all tests in air.

NOTE In the low-temperature test an atmosphere of carbon dioxide ("dry ice") is a permitted alternative, with which a temperature lower than that required will be achieved.

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 to the test temperature within the maximum time limit specified in table 5.

Table 5 — Temperature-time relationship for tests at temperatures above ambient

Temperature °C	Maximum time limit min
80	5
180	10
400	25
600	40
800 ¹⁾	70

1) Part of this test for class 6 is similar in principle to the test given by IAEA [1].

For classes 2 and 3, retain sealed sources at the upper test temperature for at least 1 h and then allow 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 and then subject to thermal shock by transferring them, within 15 s, to water at ambient temperature (about 20 °C) and at 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.

7.3 External pressure test

7.3.1 Apparatus

The pressure gauge shall have been recently calibrated and should have a pressure range at least 10 % greater than the test pressure. The vacuum gauge shall read to a pressure at least as low as 20 kPa absolute. Different test chambers may be used for the low and high pressure tests.

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.

NOTE 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 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 $(3,0 \pm 0,3)$ 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 2.

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 2.

Adjust the drop height to 1 m, measured between the top of the sealed source positioned on the anvil and the face of the hammer in its position prior to release.

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

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 at all times the source will be rigidly in contact with the platform.

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 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 resonance 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 resonance 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 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: $(6,0 \pm 0,2)$ mm (external to the hammer face);

- c) diameter $(3,0 \pm 0,1)$ mm;
- d) striking surface hemispherical.

The centreline 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 of suitable form may be placed between the sealed source and the anvil.

7.6.2 Procedure

For the appropriate class, choose the mass of the hammer and pin in accordance with table 2.

Adjust the drop height to at least 1 m measured between the top of the sealed source positioned on the anvil and the point of the pin in its position prior to release.

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

If the sealed source has more than one vulnerable area, carry out the test on each of them.

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 $L/D \geq 15$

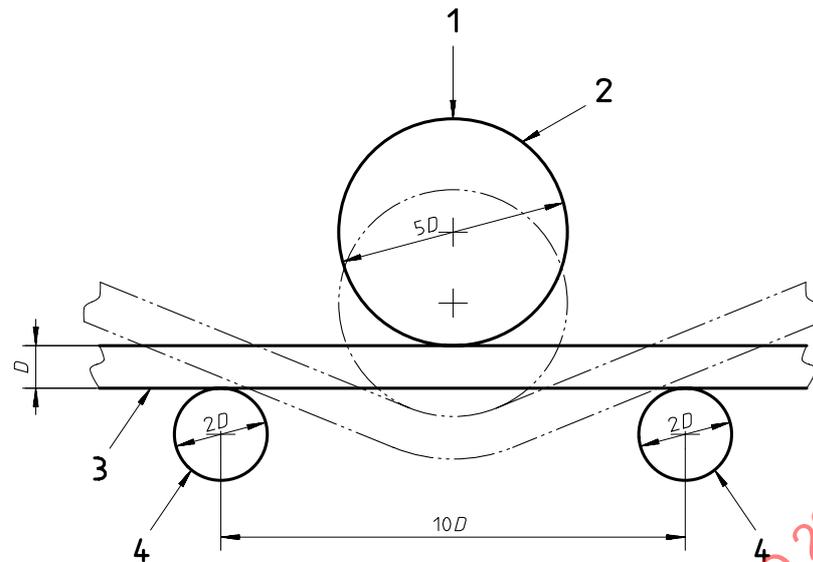
This bending test shall apply to sealed sources having an L/D of 15 or greater, where L is the active length and D is the minimum outer capsule diameter or dimension taken perpendicular to the major axis of the sealed source over its active length.

Bending test classifications are based on applying a static force, using the following test parameters and three cylinders as illustrated in figure 1. All 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 are to be of a solid material with a hardness of Rockwell 50 to 55. In applying the static force, care should be taken not to apply this force 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 having been placed in the test jig whilst 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 Sealed source
- 4 $2D$ - Support cylinders

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 one-half of 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.

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 $(3,0 \pm 0,3)$ mm.

Sealed sources passing this bending test shall be class 7.

7.7.3 Bending test for brachytherapy needles

This bending test shall apply to sealed sources in the form of brachytherapy needles having an overall length of 30 mm or greater [6].

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 $(3,0 \pm 0,1)$ 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 passing 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 (see 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 in every case state:

- a) name of manufacturer;
- b) classification designated by the code specified in clause 4 and where applicable the special form approval certificate number;
- c) serial number and brief description, including chemical symbol and mass number of the radionuclide;
- d) content activity, estimated from assay of radioactive material used or from radiation output measurements and absorption data;
- e) radiation output, for example, fluence rate or for gamma radiation sources: air kerma rate at 1 m and in a specified direction;
- f) method used, result and date of test for freedom from surface contamination;
- g) method used, result and date of test for freedom from leakage.

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

NOTE In addition, the certificate may 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 shall be established according to ISO 9000 to ISO 9004 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.

Annex A (informative)

Classification of radionuclides according to their radiotoxicity

The following classification is based on ICRP publication 5. 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 and 84/467 Euratom Directives, where (2), (3) and (4) indicate classification into group 2, 3 or 4 respectively. However, the classification as given below should be used with this International Standard.

NOTE 1 In accordance with the recommendations of ICRP Publications 5 and 6, ^{90}Sr has been reallocated from group A to group B1.

NOTE 2 The references given in this annex are accepted as being obsolete, but the information obtained from them and given herein is appropriate for use with this International Standard.

Group A: High toxicity		(Group 1: Very high toxicity)		
^{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 B: Medium toxicity				
Subgroup B1		(Group 2: High toxicity)		
^{228}Ac	$^{36}\text{Cl}(3)$	^{125}I	^{212}Pb	$^{160}\text{Tb}(3)$
$^{110\text{m}}\text{Ag}$	$^{56}\text{Co}(3)$	^{126}I	^{224}Ra	$^{127\text{m}}\text{Tl}(3)$
^{211}At	$^{60}\text{Co}(3)$	^{131}I	^{106}Ru	$^{129\text{m}}\text{Te}(3)$
$^{140}\text{Ba}(3)$	^{134}Cs	$^{133}\text{I}(3)$	$^{124}\text{Sb}(3)$	$^{234}\text{Th}(3)$
$^{207}\text{Bi}(3)$	$^{137}\text{Cs}(3)$	$^{114\text{m}}\text{In}$	$^{125}\text{Sb}(3)$	$^{204}\text{Tl}(3)$
^{210}Bi	$^{152(13\text{y})}\text{Eu}$	$^{129}\text{I}(3)$	$^{46}\text{Sc}(3)$	$^{170}\text{Tm}(3)$
^{249}Bk	^{154}Eu	$^{54}\text{Mn}(3)$	$^{89}\text{Sr}(3)$	^{236}U
$^{45}\text{Ca}(3)$	$^{181}\text{Hf}(3)$	$^{22}\text{Na}(3)$	^{90}Sr	^{91}Y
$^{115\text{m}}\text{Cd}$	^{124}I	^{230}Pa	$^{182}\text{Ta}(3)$	$^{95}\text{Zr}(3)$
^{144}Ce				