
**Radiological protection — Sealed
radioactive sources — General
requirements and classification**

*Radioprotection — Sources radioactives scellées — Exigences
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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

ISO 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

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

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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

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)".

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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.

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 98 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 <i>LID</i> > 15	Test 7.7.1 500 N (51 kg) for <i>LID</i> > 15	Test 7.7.1 1 000 N (102 kg) for <i>LID</i> > 15	Test 7.7.1 2 000 N (204 kg) for <i>LID</i> > 15	Test 7.7.1 4 000 N (408 kg) for <i>LID</i> > 15	Test 7.7.2 for <i>L</i> > 100 mm and for <i>LID</i> > 10	Test 7.7.3 for brachy- therapy needle with <i>L</i> > 30 mm	Special test

^a 1 g = 9,8 m/s².

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.

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 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 defined in Table 3.

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