INTERNATIONAL STANDARD

ISO 2919

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Radiation protection — Sealed radioactive sources — General requirements and classification

Radioprotection — Sources radioactives scellées — Prescriptions générales et classification

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

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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.

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.

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.*

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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.