
**Radiation protection — Sealed sources
— Leakage test methods**

Radioprotection — Sources scellées — Méthodes d'essai d'étanchéité

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 9978:1992), which has been technically revised. The main changes compared to the previous edition are as follows:

- [Clause 4](#): Revised to add text specifying factors to be considered in designing an effective leak testing regime for a particular type of sealed source;
- [Clause 4](#): Requirement added that personnel performing leak tests be appropriately trained and qualified, informative reference to ISO 9712 added;
- [Clause 4](#): Requirement added that measurement uncertainty shall be considered in sentencing non-binary test results;
- [Table 1](#) — “Threshold detection values and limiting values for different test methods” has been revised for clarity;
- [5.1](#): Informative reference to suitable assay techniques for immersion test liquid samples added: ISO 19361 and ISO 19581;
- [5.1.1](#), [5.1.2](#), [5.1.4](#): Composition of suitable immersion test liquids clarified;
- [5.3](#): Informative reference to suitable wipe testing techniques (ISO 7503-2) added and clarification that acceptance criteria is absolute without correction for wiping efficiency required;
- [6.1](#): Normative reference to ISO 20485 added for methods of helium leak testing and calculation of acceptance limits;
- [6.2](#): Cautionary text added to state that efficacy of tests assume ideal conditions for vision of bubbles;
- [6.2.1](#): Cautionary text added regarding bubble testing of self-heated sources;

- [A.1](#): Text expanded to clarify which tests to use under given circumstances.

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Introduction

The use of sealed sources has become so widespread that standards to guide the user, manufacturer and regulatory agencies are necessary. When establishing these standards, radiation protection is the prime consideration.

The purpose of this document, in conjunction with ISO 2919, is to minimise the risk to the public caused by leakage of radioactive material into the general environment.

Leakage test methods for sealed sources were standardised in the first edition of this document. The experience acquired since this date has necessitated the revision of this document.

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Radiation protection — Sealed sources — Leakage test methods

1 Scope

This document specifies the different leakage test methods for sealed sources. It gives a comprehensive set of procedures using radioactive and non-radioactive means.

This document applies to the following situations:

- leakage testing of test sources following design classification testing in accordance with ISO 2919^[1];
- production quality control testing of sealed sources;
- periodic inspections of the sealed sources performed at regular intervals, during the working life.

[Annex A](#) of this document gives guidance to the user in the choice of the most suitable method(s) according to situation and source type.

It is recognized that there can be circumstances where special tests, not described in this document, are required.

It is emphasized, however, that insofar as production, use, storage and transport of sealed radioactive sources are concerned, compliance with this document is no substitute for complying with the requirements of the relevant IAEA regulations^[2] and other relevant national regulations. It is also recognized that countries can enact statutory regulations which specify exemptions for tests, according to sealed source type, design, working environment, and activity (e.g., for very low activity reference sources where the total activity is less than the leakage test limit).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 20485:2017, *Non-destructive testing — Leak testing — Tracer gas method*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

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 is practical in physical and chemical properties

3.3

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

3.4

leakage

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

3.5

leaktight

term applied to sealed sources which, after undergoing leakage testing, meet the acceptance criteria

Note 1 to entry: The acceptance criteria are given in [Table 1](#).

3.6

model designation

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

3.7

non-destructive test

test used to detect internal, surface and concealed defects or imperfections in materials, using techniques that do not damage or destroy the items being tested

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

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

3.10

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 it contains, in place of the radioactive material, a substance resembling it as closely as possible in physical and chemical properties and trace quantities of radioactive material

Note 1 to entry: The tracer is in a form soluble in a solvent which does not attack the capsule and has the maximum activity compatible with its use in a containment enclosure.

3.11

standard helium leakage rate

helium leakage rate at an upstream pressure of $10^5 \text{ Pa} \pm 5 \times 10^3 \text{ Pa}$ and a downstream pressure of 10^3 Pa or less at a temperature of $296 \text{ K} \pm 7 \text{ K}$ ($23 \text{ °C} \pm 7 \text{ °C}$)

Note 1 to entry: In this document, the unit Pascal cubic meter per second is used¹⁾.

1) $[1 \times 10^{-6} \text{ Pa} \cdot \text{m}^3 \cdot \text{s}^{-1} = 1 \text{ } \mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1} \approx 10^{-5} \text{ atm} \cdot \text{cm}^3 \cdot \text{s}^{-1} \approx 1 \times 10^{-5} \text{ mbar} \cdot \text{l} \cdot \text{s}^{-1} \approx 7,5 \times 10^{-3} \text{ lusec.}]$

3.12**test source**

sample used in the performance tests, having the same material and construction as sealed sources of the model for which classification is being established

Note 1 to entry: A test source may be a simulated sealed source, a dummy sealed source or production source.

Note 2 to entry: The performance tests are described in ISO 2919.

4 Requirements

The tests described in this document are all designed to test and verify that the sealed source is leaktight. However not all tests are applicable in all circumstances. Correct application and choice of test method and testing media is critically important in designing an effective leak test programme. Factors to be considered include:

- the chemical form of the active material if leak test is by radioactive means;
- the type of test liquid used in immersion tests;
- the number of encapsulations;
- the internal void volume when tests are carried out by volumetric means;
- the temperature of the sealed source;
- the suitability of the test method for the environment in which it is being performed;
- the reason for performing the test (integrity testing of a test source, production leakage tests, routine in service testing);
- the required sensitivity and acceptance criteria.

The test programme for test and production sealed sources should be considered as part of the design process and validated or justified as appropriate to demonstrate its effectiveness and sensitivity. This process may include the analysis of historic data.

The tests described in this document shall be designed, validated and carried out by competent and qualified persons who have demonstrable appropriate training in the applied test methods. For test methods by radioactive means, the persons shall also have appropriate training in radiation protection and measurement.

NOTE 1 Qualification and certification methods for non-destructive testing personnel can be found in ISO 9712^[2].

An evaluation should be made of uncertainty in the case of non-binary test results (e.g. radiation measurements on immersion test samples) and taken account of in sentencing the result.

Guidance for choosing suitable tests are specified in [Annex A](#).

According to the test type and the sealed source type, at least one of each of the tests described in [Clauses 5](#) and [6](#) should be carried out [see [Annex A](#) for the choice of the test(s)].

It should be noted that it is best practice to carry out more than one type of leakage test and also to perform a final wipe as a contamination check.

The tests described in this document do not form an exhaustive list, and other test methods may be developed. However, in the case where a special test, which is not described in this document, is carried out (see [Clause 1](#)), the organisation shall validate that the applied method is at least as effective as the corresponding method(s) given in this document in order to be able to claim compliance with this document.

At the conclusion of the performed test(s), the sealed source shall be considered to be leaktight if it complies with the acceptance criteria specified in [Table 1](#).

It has been asserted that there is correspondence between the acceptance criteria for volumetric and radioactive leak tests. Whilst there is no universally accepted basis for this assertion, experience has shown that sources meeting the acceptance criteria shown in [Table 1](#) have not subsequently been found to leak.

NOTE 2 A leakage rate of $10 \mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$ for non-leachable solid contents and a rate of $0,1 \mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$ for leachable solids and liquids was historically considered to be equivalent to the activity release limit of 2 000 Bq ($\approx 50 \text{ nCi}$)^[18].

NOTE 3 A further confirmation of the volumetric acceptance threshold is given by Reference [8]. A leakage rate of $10^{-7} \text{ atm} \cdot \text{cm}^3 \cdot \text{s}^{-1}$ or more based on dry air at 298 K (25 °C) and for a pressure difference of 1 atm against a vacuum of 10^{-2} atm (equivalent to or less) is considered to represent a loss of leaktightness, irrespective of the physical nature of the content.

Table 1 — Threshold detection values and limiting values for different test methods

Test method	Subclause	Threshold of detection ^a	Acceptance criteria	
			Non-leachable content	Leachable or gaseous content
Radioactive methods				
Immersion test (hot liquid)	5.1.1	(10 to 1) Bq	<200 Bq	<200 Bq
Immersion test (boiling liquid)	5.1.2	(10 to 1) Bq	<200 Bq	<200 Bq
Immersion test with a liquid scintillator	5.1.3	(10 to 1) Bq	<200 Bq	<200 Bq
Immersion test at room temperature	5.1.4	(10 to 1) Bq	<200 Bq	<200 Bq
Gaseous emanation test	5.2.1	(4 à 0,4) Bq	<i>Unsuitable</i>	<200 Bq (²²² Rn/12 h)
Emanation test with a liquid scintillator	5.2.2	(0,4 to 0,004) Bq	<i>Unsuitable</i>	<200 Bq (²²² Rn/12 h)
Gaseous emanation test (for krypton-85 sealed sources)	5.2.3	(10 to 1) Bq	<i>Unsuitable</i>	<4 000 Bq (⁸⁵ Kr/24 h)
Wet wipe test	5.3.1	(10 to 1) Bq	<200 Bq	<200 Bq
Dry wipe test	5.3.2	(10 to 1) Bq	<200 Bq	<200 Bq
Non-radioactive methods – Helium tests		Standard helium leakage rate		
Helium test (<i>He filling before sealing</i>)	6.1.1	(10^{-2} to 10^{-4}) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$	<1 $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$	<0,01 $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$
Helium pressurisation test (<i>He bombing after sealing</i>)	6.1.2	(1 to 10^{-2}) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$	<1 $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$	<0,01 $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$
Non-radioactive methods – Bubble tests		Corresponding standard helium leakage rate		
Vacuum bubble test	6.2.1	(10 to 1) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1\text{b}}$	No bubbles observed	<i>Not sensitive enough</i>
Hot-liquid bubble test	6.2.2	(50 to 5) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1\text{b}}$	<i>Not sensitive enough</i>	<i>Not sensitive enough</i>
^a The threshold of detection is expressed as a range; its upper end defines the smallest detectable leak under typical, well controlled industrial leak testing conditions and its lower end indicates the smallest detectable leak under excellent (ideal) industrial leak testing conditions. Smaller leaks than those indicated can be detected under laboratory conditions.				
^b Threshold values shown for bubble tests are rough approximations of the corresponding standard helium leakage rates and are applicable only to single leaks under favourable visual conditions.				

Table 1 (continued)

Test method	Subclause	Threshold of detection ^a	Acceptance criteria	
			Non-leachable content	Leachable or gaseous content
Gas pressurisation bubble test	6.2.3	(10 to 1) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1\text{b}}$	No bubbles observed	<i>Not sensitive enough</i>
Liquid nitrogen bubble test	6.2.4	(10^{-1} to 10^{-2}) $\mu\text{Pa} \cdot \text{m}^3 \cdot \text{s}^{-1\text{b}}$	No bubbles observed	No bubbles observed
Non-radioactive methods – Mass gain		Mass gain of water [μg]		
Water pressurisation test	6.3	10	Mass gain < 50	<i>Not sensitive enough</i>
^a The threshold of detection is expressed as a range; its upper end defines the smallest detectable leak under typical, well controlled industrial leak testing conditions and its lower end indicates the smallest detectable leak under excellent (ideal) industrial leak testing conditions. Smaller leaks than those indicated can be detected under laboratory conditions.				
^b Threshold values shown for bubble tests are rough approximations of the corresponding standard helium leakage rates and are applicable only to single leaks under favourable visual conditions.				

Prior to undergoing the following leakage tests the source shall be subject to a thorough visual examination. The source may have to be cleaned to facilitate this. Any cleaning method should avoid the blocking of any potential leakage path for subsequent tests.

All equipment used for tests shall be suitably maintained and calibrated.

The wipe test should only be considered as a leakage test for some specific types of sources (e.g. sources with very thin windows such as foils for smoke detectors), for periodic inspections and in cases where no other test is more suitable.

Wipe tests or liquid immersion test samples should, wherever possible, be checked immediately on basic contamination measuring equipment; for example, a Geiger counter to establish whether there is any gross contamination prior to final measurement on more sophisticated calibrated equipment.

5 Test methods by radioactive means

5.1 Immersion tests

NOTE Suitable assay techniques for evaluation of the activity in the test liquids for all of these immersion tests may be found in ISO 19361^[3] and ISO 19581^[4].

5.1.1 Immersion test (hot liquid)

Immerse the sealed source in a liquid which does not attack the material of the outer surfaces of the source and which, under the conditions of this test, is considered effective for detection of a leak. Examples of such liquids include distilled water, weak detergent solutions or chelation agents and also slightly alkaline or acid solutions with concentrations of about 5 %. Heat the liquid to $323 \text{ K} \pm 5 \text{ K}$ ($50 \text{ }^\circ\text{C} \pm 5 \text{ }^\circ\text{C}$) and maintain it at that temperature for at least 4 h. Remove the sealed source and measure the activity of the liquid. If a group of more than one source is tested at the same time in the liquid sample, the acceptance criteria for a single source shall be used for the group as all the activity in the liquid sample could be originating from a single leaking source. Further testing shall be performed in such cases on smaller groups, or individual sources, in order to identify the leaking source and positively confirm leak tightness of other sources in the group.

An ultrasonic cleaning method can also be used. In this case, the immersion time in the liquid at $343 \text{ K} \pm 5 \text{ K}$ ($70 \text{ }^\circ\text{C} \pm 5 \text{ }^\circ\text{C}$) can be reduced to approximately 30 min.

5.1.2 Immersion test (boiling liquid)

Immerse the sealed source in a liquid which does not attack the material of the outer surfaces of the source and which, under the conditions of this test, is considered effective for detection of a leak.

Examples of such liquids include distilled water, weak detergent solutions or chelation agents and also slightly alkaline or acid solutions with concentrations of about 5 %. Boil for 10 min, allow to cool, then rinse the sealed source in a fresh batch of liquid. Repeat these operations twice, re-immersing the source in the original liquid. Remove the sealed source and measure the activity of the original liquid. If a group of more than one source is tested at the same time in the liquid sample, the acceptance criteria for a single source shall be used for the group as all the activity in the liquid sample could be originating from a single leaking source. Further testing shall be performed in such cases on smaller groups, or individual sources, in order to identify the leaking source and positively confirm leak tightness of other sources in the group.

5.1.3 Immersion test with a liquid scintillator

Immerse the sealed source for at least 3 h at room temperature in a liquid scintillator solution that does not attack the material of the outer surface of the source. Store away from light to avoid photoluminescence. Remove the sealed source and measure the activity of the liquid by a liquid scintillation counting technique.

5.1.4 Immersion test at room temperature

Immerse the sealed source in a liquid which does not attack the material of the outer surfaces of the source and which, under the conditions of this test, is considered effective for detection of a leak. Examples of such liquids include distilled water, weak detergent solutions or chelation agents and also slightly alkaline or acid solutions with concentrations of about 5 %. After a period of at least 24 h, remove the sealed source and measure the activity of the liquid. If a group of more than one source is tested at the same time in the liquid sample, the acceptance criteria for a single source shall be used for the group as all the activity in the liquid sample could be originating from a single leaking source. Further testing shall be performed in such cases on smaller groups, or individual sources, in order to identify the leaking source and positively confirm leak tightness of other sources in the group.

This test may be useful where hot liquid tests are not practical, however the hot liquid tests are recommended whenever possible since their use has been widely recognized for many years and also because they may be more effective.

5.1.5 Acceptance criteria

The sealed source is considered to be leaktight if the total activity detected in the liquid sample is less than 200 Bq (≈ 5 nCi).

5.2 Gaseous emanation tests

5.2.1 Gaseous emanation test by absorption (for radium-226 sealed sources)

Place the sealed source in a small gas-tight container with a suitable absorbent, for example activated carbon, cotton or polyethylene, and leave it for at least 3 h. Remove the source and close the container. Immediately measure the activity of the absorbent.

5.2.2 Gaseous emanation test by immersion with a liquid scintillator (for radium-226 sealed sources)

Follow the procedure described in [5.1.3](#).

5.2.3 Gaseous emanation test (for krypton-85 sealed sources)

Maintain the sealed source under reduced pressure for 24 h. Analyse the content of the chamber for krypton-85 by a plastic scintillation counting technique. Repeat the test after at least 7 days.

5.2.4 Other gaseous emanation tests

Any other test methods which are equivalent to those described in [5.2.1](#) to [5.2.3](#) may be used.

5.2.5 Acceptance criteria

When the tests described in [5.2.1](#) and [5.2.2](#) are completed, the sealed source is considered to be leaktight if the activity detected is less than 200 Bq (≈ 5 nCi) of radon for a collection time of 12 h. When the test period is shorter than 12 h, appropriate corrections shall be made.

When the tests described in [5.2.3](#) is completed, the sealed source is considered to be leaktight if the activity detected does not exceed 4 kBq/24 h (≈ 100 nCi/24 h).

5.3 Wipe tests

When the wipe test is a means of leakage testing carried out at the manufacturing stage, the sealed source shall be cleaned prior to the test and a 7-day waiting period shall be observed before the test.

Wipe testing is frequently used for periodic leak testing of sealed sources in service. In this case the wipe shall be taken directly from the source or the closest accessible point at which contamination resulting from a leak is likely to occur. The wipe area shall not be pre-cleaned before taking the wipe. See [A.4 b](#)).

NOTE Detailed methods of wipe testing are described in ISO 7503-2^[5].

5.3.1 Wet wipe test

Wipe all the external surfaces of the sealed source thoroughly with a swab of suitable highly absorbent material, moistened with a liquid which does not attack the material of which the external surfaces of the sealed source are made and which, under the conditions of this test, has been demonstrated to be effective in removing radioactive material present. Measure the activity of the swab.

5.3.2 Dry wipe test

This test can be used in situations where it may not be appropriate to use a wet swab.

To carry out the test, thoroughly rub all the external surfaces of the sealed source with a dry swab which, under the conditions of this test, has been demonstrated to be effective in removing radioactive material present. Measure the activity of the swab.

5.3.3 Acceptance criteria

If the activity detected on the swab is less than 200 Bq (≈ 5 nCi), the sealed source is considered to be leaktight. No further adjustment shall be made for wiping efficiency.

6 Test methods by volumetric means

The data given in this document for the relationship between volumetric leakage rates and loss of radioactive material are based on values published in Reference [\[9\]](#) and, although they have not been confirmed absolutely by experimental work, volumetric leakage test methods have been used for many years and experience shows that they can be accepted as valid test methods. Thus it may be assumed that, when volumetric tests are performed in accordance with this document, a volumetric leak rate of less than $1 \times \mu\text{Pa}\cdot\text{m}^3\cdot\text{s}^{-1}$ is equivalent to a radiological leak of less than 200 Bq for sealed sources containing non-leachable contents and a leakage rate of less than $0,01 \mu\text{Pa}\cdot\text{m}^3\cdot\text{s}^{-1}$ is equivalent to a leak of less than 200 Bq for sealed sources containing leachable contents.

Volumetric tests cover a range of sensitivities. Therefore the presence of a gross leak which would escape detection by the primary test method shall be addressed by use of an additional test method suitable for detecting a larger leak than that of the primary test method.

For these tests to be valid, except the one described in 6.3, the free volume inside the sealed source shall be greater than 100 mm³. If these tests are used for sealed sources with a free volume of less than 100 mm³, the test shall be deemed to be a special test as allowed for under [Clause 1](#) and the user shall demonstrate the validity of the test^[15].

Before conducting any of the tests described in 6.1 to 6.3, the sealed source should be in a clean and dry condition.

If sealed sources are cleaned before testing or otherwise subjected to any liquids, special care should be taken to ensure that the drying process used is effective at removing such liquids from potential leak sites/defects where it could be held by capillary action. Prolonged drying above liquid's boiling temperature or vacuum baking may be necessary to ensure the required effectiveness. It is recommended that efficacy of the drying process is verified and confirmed experimentally to ensure that an existing leak is not plugged and rendered undetectable.

Because of their lower detection limit, only those volumetric tests using helium (6.1) are applicable to sealed sources with leachable or gaseous contents.

6.1 Helium mass spectrometer leakage tests

NOTE Appropriate helium leak test methods are described in ISO 20485.

6.1.1 Helium test [equivalent to leak test type B6 in ISO 20485]

Ensure that the free volume inside the sealed source contains a concentration of commercial grade helium of more than 5 %.

Place the sealed source containing helium in a suitable vacuum chamber, which is subsequently evacuated through a helium mass spectrometer. Perform the measurement in accordance with the equipment manufacturer's instructions and the requirements of ISO 20485.

The indicated helium leakage rate according to the previous evaluation divided by the concentration of helium in the free volume gives the actual standard helium leakage rate.

6.1.2 Helium pressurisation test [equivalent to leak test type B5 in ISO 20485]

Place the sealed source in a pressure chamber. Purge the chamber of air. Using helium, pressurise the chamber to a given helium pressure and maintain it for a given period. Depressurise the chamber, clean the sealed source by flushing it with dry nitrogen or rinsing it in a volatile fluorocarbon liquid, and transfer it to a suitable vacuum chamber.

Calculate the reject point based on the appropriate acceptance criteria from [Table 1](#) using the method described in ISO 20485.

Perform the measurement in accordance with the equipment manufacturer's instructions and the requirements of ISO 20485.

NOTE The helium pressurisation test is based on the principle of forcing helium through the potential leak into the void within the capsule, and then measuring the rate of leakage exiting the leak after the pressurisation period. The indicated leak rate is therefore not the actual standard leakage rate, since the partial pressure of helium in the void needs to be considered using the method described in ISO 20485.

6.1.3 Acceptance criteria

When these tests are completed, the sealed source is considered to be leaktight if the actual standard helium leakage rate is less than $1 \mu\text{Pa}\cdot\text{m}^3\cdot\text{s}^{-1}$ for non-leachable contents and $0,01 \mu\text{Pa}\cdot\text{m}^3\cdot\text{s}^{-1}$ for leachable or gaseous contents (see [Table 1](#)).

6.2 Bubble leakage tests

Bubble leakage tests are not applicable for use with sources that have leachable content other than to ensure the absence of gross leaks.

Bubble leakage tests rely on an increase in the internal pressure relative to external pressure. Then gas from internal voids can penetrate any leaks and form visible bubbles in a liquid bath. For one particular leak, the rate of bubbling increases with a decrease in surface tension. Note that sensitivity values indicated in [Table 1](#) were derived from work done under ideal conditions. In applying these tests, users shall take account of operational and environmental factors that may compromise sensitivity and should be able to demonstrate that the chosen test remains sufficiently sensitive to achieve its objective in the circumstances in which it is being used (i.e. it shall be possible to see bubbles emanating from a leak under actual operating conditions – even for smallest leaks claimed as detectable).

For a bubble leak test to be valid, the source shall have been sealed at approximately ambient temperature and pressure as the test is dependent on the pressure gradient across the potential leak to create bubbles.

6.2.1 Vacuum bubble test [equivalent to immersion technique using vacuum in EN 1593]^[6]

By using ethylene glycol, isopropyl alcohol, mineral or silicone oil, or water with a wetting agent as a leakage test fluid in a suitable vacuum chamber, lower the air content of the fluid by evacuating the chamber for at least 1 min at ambient temperature. Re-establish atmospheric air pressure and submerge the sealed source completely to a depth of at least 5 cm below the fluid level. Reduce the absolute pressure in the chamber to between 15 kPa and 25 kPa. Observe any bubbles emanating from the sealed source for a period of at least 1 min.

Special care should be taken when testing high activity, sources which are hot under ambient conditions. Localized heating of the test liquid on the surface of such hot sources can lead to severe bubbling due to boiling at reduced pressures typically used for this test and thus render the test method ineffective. In addition, the temperature of the source needs to be taken account of as, in the event that there is a leakage path, the reduced internal gas pressure as the source is immersed in cool liquid invalidates the test conditions and can block a leak as fluid is drawn into the leak path. This aspect shall be taken into consideration when setting up the vacuum bubble test for high activity sources.

6.2.2 Hot-liquid bubble test [equivalent to immersion technique using liquid at elevated temperature in EN 1593]^[6]

If the source is sealed at close to atmospheric pressure, its internal pressure can be increased by immersing it into hot liquid.

Ensure that the sealed source is at ambient temperature. Immerse it at a depth at least 5 cm below water level in a water bath which is at a temperature between 363 K and 368 K (90 °C and 95 °C). Glycerine at 393 K to 423 K (120 °C to 150 °C) is an acceptable alternative to water. Observe any bubbles emanating from the sealed source for a period of at least 1 min; however a minimum period of 2 min is recommended, whenever possible and particularly for capsules with large thermal mass and poor thermal conductivity.

6.2.3 Gas pressurisation bubble test [equivalent to immersion technique using pressurisation of the object in EN 1593]^[6]

Place the sealed source in a suitable pressure chamber of volume at least twice that of the source and at least five times the free volume inside the source. Pressurise the chamber with helium gas to at

least 1 MPa and maintain it at that pressure for 15 min. Release the pressure, remove the sealed source from the chamber and immerse it 5 cm below the level of ethylene glycol, isopropyl alcohol, acetone or water containing a wetting agent in a bath. Observe for bubbles emanating from the sealed source over a period of at least 1 min.

6.2.4 Liquid nitrogen bubble test

Immerse the sealed source completely in liquid nitrogen for a period of 5 min, then transfer it to the test liquid (normally methanol). Observe for bubbles emanating from the sealed source over a period of at least 1 min.

6.2.5 Acceptance criteria

If no bubbles are observed at the end of the tests described in [6.2.1](#) to [6.2.4](#), the sealed source is considered to be leaktight provided that the required sensitivity is achieved.

6.3 Water pressurisation test

Determine the mass of the sealed source on a sufficiently sensitive balance. Perform the experimental pressure test with water, wipe the sealed source dry and re-determine its mass on the same balance.

If the gain in mass is less than 50 µg, the sealed source is considered to be leaktight but only for non-leachable contents. For this test to be valid, the calculated free volume within the sealed source has to be capable of holding at least five times as much water as the sensitivity of the mass measuring equipment.

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