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GOVERNMENT OF INDIA

AERB SAFETY STANDARD

TESTING AND CLASSIFICATION OF SEALED RADIOACTIVE SOURCES

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY STANDARD NO. AERB/SS/3 (Rev. 1)

TESTING AND CLASSIFICATION OF SEALED RADIOACTIVE SOURCES

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This document is subject to review, after a period of one year from the date of issue, based on the feedback received.

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FOREWORD

Widespread utilisation of ionising radiation for multifarious applications in medicine, industry, agriculture, research etc. has brought in its wake the need for exercising regulatory controls to ensure safety of users, members of the public and the environment. The Atomic Energy Regulatory Board (AERB), constituted under the Atomic Energy Act, 1962 by the Government of India, is entrusted with the responsibility of developing and implementing appropriate regulatory measures aimed at ensuring radiation safety in all applications involving ionising radiation. One of the ways to meet these responsibilities is to develop and enforce specific codes and standards dealing with radiation safety aspects of various applications of ionising radiation to cover the entire spectrum of operations, starting from design of radiation equipment, their installation and use, to their ultimate decommissioning/disposal.

In view of the fact that regulatory standards and requirements, techniques of radiation safety engineering and type of equipment change with time, it becomes necessary to review and revise codes and standards from time to time to incorporate these changes.

The first AERB Standard (Specification) entitled "Testing and Classification of Sealed Radioactive Sources, AERB/SS/3" issued in 1990 has been useful to the manufacturers of sealed radioactive sources as well as to the designers of radiation equipment and devices for selecting right classification of the source required in specific applications. Although the Standard covered sources used in most applications, certain special tests for brachytherapy sources as well as tests and classification requirements for long sources used in high intensity irradiators were not covered. Similarly, the Standard did not provide guidance on tests to be conducted on metallic as well as sealed radioactive sources to qualify them as a special form radioactive material as required by the regulations for safe transport of radioactive material. Since the specifications for these categories are relevant in the present context of extensive use of sealed radioactive sources in the country, the above Standard has now been revised by a task group (Task Group IX) constituted by AERB.

The Standing Committee for Review and Revision of AERB's Radiation Safety Documents, constituted by Chairman, AERB, has scrutinised and finalised this

Standard. The revised Standard, approved for issuance on October 5, 2001 by the Atomic Energy Regulatory Board, is effective from its date of issue and replaces the earlier Standard of 1990.

AERB wishes to thank all individuals and organisations who helped in the revision of the Standard. The names of persons who participated in the preparation of the earlier Standard and its present revision are listed, along with their affiliations, for information.

Suhas P. Sukhatme

(Suhas P. Sukhatme)
Chairman, AERB

DEFINITIONS

Dummy Sealed Source

Facsimile of a radioactive sealed source, the encapsulation 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 practicable in physical and chemical properties.

Encapsulation

Protective envelope used to prevent leakage of radioactive material.

Non-leachable

Form of radioactive material contained in the source, which is virtually insoluble in water and is not convertible into dispersible products.

Quality Control

Quality assurance actions which provide a means to control and measure the characteristics of an item, process or facility in accordance with established requirements.

Note: Tests and procedures shall be so designed as to establish the ability of the sealed source to comply with the performance characteristics for that source as prescribed in Table-1 of this Standard.

Radiation Output

Number of particles and/or photons of ionising radiation emitted per unit time from a source in a defined geometry. Radiation output may also be stated in terms of air kerma rate at a specified distance from the source of radiation.

Sealed Source

Radioactive source material that is (a) permanently sealed in a capsule or (b) closely bounded and in solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, as also under foreseeable mishaps.

Simulated Source

Facsimile of a radioactive sealed source, the encapsulation 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 mechanical, 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 shall be in a form soluble in a solvent which does not attack the encapsulation and has the maximum activity compatible with its use in a glove box. For example, the following activity levels are acceptable:

^{90}Sr + ^{90}Y as soluble salt	:	2 MBq
^{60}Co as soluble salt	:	1 MBq

(1 Ci = 3.7×10^{10} Bq)

Source Holder

A device used to support and retain the sealed source in position.

Source in Device

Sealed source which remains captive in a device, thereby having mechanical protection from damage during use.

Unprotected Source

Sealed source which, for use, is removed from a device, and hence may not have mechanical protection from damage during use.

SPECIAL DEFINITIONS

Container

General term used to designate any enclosure which may surround the sealed source.

Device

Any equipment or apparatus or device designated to incorporate sealed source(s).

Leakage

Transfer of radioactive material from the sealed source to the environment.

Model or Type

Descriptive term or number to identify a specific sealed sources design.

Prototype Source

Original of a model of a sealed source, which serves as a pattern for the manufacture of all sealed sources, identified by the same model or type designation.

Prototype Testing

Performance testing of a new radioactive sealed source before a sealed source of such design is put into actual use.

CONTENTS

1. INTRODUCTION

1.1 General

Widespread utilisation of sealed radioactive sources in medicine, industry, agriculture and research has brought in its wake the need for exercising regulatory control and standardisation to ensure radiological safety to users and the general public. The Atomic Energy Regulatory Board (AERB) is entrusted with the responsibility of developing and implementing appropriate regulatory measures aimed at ensuring radiation safety.

This Standard specifies the characteristics of a sealed radioactive source as well as essential performance and safety criteria and tests relevant to specific applications of sealed sources in order to achieve and maintain their integrity under all conditions of use and anticipated accidents. This Standard is a performance standard based on the intended use of source, and hence does not attempt to establish design requirements. The manufacturers of sealed radioactive sources shall follow this Standard, which classifies sources by performance specifications and verify the performance of sources by subjecting them to specified tests. Upon satisfactory demonstration of compliance with the requirements of this Standard, the manufacturers shall obtain type approval from the Competent Authority. Users shall ensure that only type approved sealed sources are procured and used.

This Standard is based on international standards on classification of sealed sources, performance tests, markings, certification and leak tests. The national and international standards have been consulted in the preparation of this document.

1.2 Purpose and Scope

This Standard establishes a system of classification of sealed radioactive sources based on performance specification. It stipulates a set of tests by which the manufacturer can evaluate the safety of sources under conditions of normal use or anticipated accidents and demonstrate compliance with this Standard for type approval. It is also intended that by considering the radiological safety aspects arising due to release of radioactive material from the encapsulation of sealed source(s), the user can select the type of source(s) suitable for his application.

The tests include the exposure of source to abnormally high and low temperatures and subjecting it to a variety of mechanical tests. Each test can be applied in several degrees of severity. The criterion for "pass or fail" depends on integrity of containment or extent of leakage of radioactive contents of the source. Methods of assessing the sources for leakage after each test are also given in this document. The leak test methods described here are primarily applicable to prototype testing. However, these procedures may also be used for leak testing in routine production. All tests specified in this Standard are not necessarily applicable or appropriate to all types of sealed sources. It is necessary to select a suitable test or a combination of tests relevant for a particular use.

Appendix-III of this Standard includes a list, which is not necessarily comprehensive, of typical applications of sealed radioactive sources with recommended test schedule for each application. These schedules are minimum requirements corresponding to applications in the broadest sense. Factors to be considered for applications under more severe conditions are listed in sections 3.2.2 and 3.2.3.

This Standard makes no attempt to specify the requirements for the design of sources and method of construction or their calibration in terms of radiation output. Radioactive materials inside a nuclear reactor and fuel elements are not included. This Standard also specifies general requirements, production tests, marking and certification for sealed radioactive sources used for medical, industrial and other applications.

2. SOURCE MARKINGS

Wherever physically possible, the encapsulation of sealed source and sealed source container shall be durably and legibly marked with the following information, in the given order of priority:

(a) mass number and chemical symbol of the radionuclide;

(b) serial number of the source;

(c) for neutron sources, the target element; and

(d) manufacturer's name or symbol.

Marking of the capsule shall be done prior to testing the sealed source.

3. RADIOACTIVE SOURCES - CLASSIFICATION

3.1 Classification Designation

Classification of sealed sources shall be as designated by an alphanumeric code consisting of a letter and five digits.

The letter shall be either C or E. C denotes that the activity level of sealed source does not exceed the limit specified in Appendix-II. E denotes that the activity of sealed source exceeds the limit.

The first digit following the letter C or E shall be the class number, which describes the performance for temperature as specified in Appendix-III.

The second digit shall be the class number, which denotes the performance for external pressure.

The third digit shall be the class number, which denotes the performance for impact.

The fourth digit shall be the class number, which denotes the performance for vibration.

The fifth digit shall be the class number, which denotes the performance for puncture.

3.2 General Considerations

Appendix-I classifies radionuclides into four groups according to their relative radiotoxicity.

Appendix-II establishes the maximum activity of sealed sources, for each of the four radiotoxicity groups in Appendix-I, below which a separate evaluation of specific usage and design is not required.

Sealed sources containing more than the maximum activity specified in Appendix II shall be subject to further evaluation for specific usage and design. The activity level of sealed sources for purposes of classification according to Appendix-II shall be that at the time of its manufacture.

Appendix-II also specifies the physical, chemical and geometrical forms of radionuclides used to determine these properties. They shall be the same as physical, chemical and geometrical forms of radioactive material contained in the sealed source.

Some typical applications of sealed sources or devices containing sealed source along with minimum performance requirements are given in Appendix-III. These requirements take into account their normal usage and anticipated accidents but do not include exposure to fire or explosion. For all these applications, the class numbers specify the test to which only the sealed sources shall be subjected, except that for the category of ion generators where complete source-device combination may have to be tested.

If any particular usage or accidental conditions are likely to be more severe than is considered in Appendix-III, the specification of sealed source shall be considered on an individual basis. The manufacturer shall submit such specification based on user's special requirement to AERB for approval. The numbers shown in Appendix-III refer to class numbers used in Table-1.

3.2.1 Classification of Sealed Source Performance Standard

The environmental test conditions to which a sealed source may be subjected are given in Table-1. The tests are arranged in increasing order of severity.

The classification of each sealed source type shall be determined by actual testing of at least two sources (sealed prototype, dummy or simulated) taken randomly from a batch of sources manufactured under same conditions of that type for each test in Table-1, or by deriving from previous tests which demonstrate that the source would pass the test if tests were actually performed. Different specimens may be used for each of the tests.

Compliance with tests shall be determined by the ability of sealed source to maintain its integrity after each test is performed. A source with more than one encapsulation shall be deemed to have complied with a test, if it can be demonstrated that at least one encapsulation has maintained its integrity after the test.

For leak testing of a simulated source, the sensitivity of chosen method shall be adequate to detect and measure the leakage of material.

3.2.2 Fire, Explosion or Corrosion

The manufacturer or user should consider the likely consequences when the sealed source or device containing the sealed source is subjected to fire, explosion or corrosion. The following factors should be considered:

(a) quantity of radioactive material contained in the sealed source;

(b) radiotoxicity;

(c) chemical and physical form of material and the geometrical shape;

(d) environment in which it is to be used;

(e) protection afforded by encapsulation and containment of device; and

(f) consequences of loss of activity.

3.2.3 Radiotoxicity and Solubility

Except as required by section 3.2.2, the radiotoxicity shall be considered only when the activity of sealed source exceeds the values shown in Appendix-II. If the activity exceeds the limit as shown in Appendix-II, the specification of sealed source has to be considered on an individual basis. If the activity of radionuclide is within the limit, the performance requirements specified in Appendix-III can be applied without further consideration of either radiotoxicity or solubility.

3.2.4 Quality Control

A quality assurance and control programme shall be established in both design and manufacture of sealed sources to ensure that sealed sources manufactured according to quality assurance programme will have the performance at least equal to that of the prototypes tested as per this Standard. An important aspect of quality assurance programme is the documentation covering design review and procedures for inspection, records of traceability of materials as well as the test results specified in this Standard.

3.3 Procedure to Establish Classification and Performance Requirements

3.3.1 Radiotoxicity shall be established from Appendix-I.

3.3.2 The quantity of activity allowed shall be determined from Appendix-II.

3.3.3 If the desired quantity does not exceed the allowable quantity in Appendix-II an evaluation for fire, explosion or corrosion hazard shall be made. If no significant hazard exists, the sealed source classification may be taken from Appendix-III. If a significant hazard exists, factors listed in section 3.2.2 shall be evaluated with particular attention to temperature and impact requirements.

3.3.4 If the desired quantity exceeds the allowable quantity of Appendix-II, fire, explosion or corrosion hazard shall be evaluated in addition to separate evaluation of specific sealed source usage and sealed source design.

3.3.5 After the required classification of sealed source for the particular application or usage has been established the performance standard can be obtained directly from Table-1.

3.3.6 Alternatively, the sealed source class can be determined from Table-1 and for any specific application selected from Appendix-III.

3.4 Testing Procedures

3.4.1 General

Testing procedures for temperature, external pressure, impact, vibration and puncture given in Table-2 shall be performed for determining the performance classification numbers. All the criteria specified are minimum requirements. Procedures that can be demonstrated to be at least equivalent are acceptable. All tests except temperature tests shall be at ambient temperature.

3.4.2 Temperature Test

3.4.2.1 Equipment

Heating or cooling equipment shall have a test zone volume of at least five times the volume of test specimen. If a gas or oil-fired furnace is used for temperature test, an oxidising atmosphere shall be maintained throughout the test.

3.4.2.2 Procedure

All tests shall be performed in air, except in the case of low temperature test, where an atmosphere of carbon dioxide is permitted to enable the use of solid carbon dioxide (dry ice). All test sources shall be held at the maximum test temperature for at least 1 h and at the minimum test temperature for at least 20 min.

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

Sources to be subjected to temperatures above ambient shall be heated to test temperature at least as rapidly as indicated in the Table below:

TEMPERATURE-TIME RELATIONSHIP FOR TEMPERATURE TEST

Temperature (^{O}C)	**Time (minutes)**
Ambient	0
80	5
180	10
400	25
600	40
800	70

For classes 4,5 and 6, test sources shall also be subjected to a thermal shock test. The source used in the temperature test may be used for this test provided the source has passed the temperature test. A separate test source may also be used instead.

For thermal shock test, the source shall be heated to the maximum test temperature (required for that particular class) and held at that temperature for at least 15 min. The test source shall be transferred in 15 s or less to water at a maximum temperature of 20^{O}C. Water shall be flowing at a rate of at least ten times the source volume per minute, or if the water is stationary, it shall have a volume of at least twenty times the source volume.

3.4.2.3 Evaluation

The source shall be examined visually after the test and subjected to an appropriate leak test such as that described in section 5.

3.4.3 External Pressure Test

3.4.3.1 Equipment

Pressure gauge used for this test shall have been calibrated within six months prior to the date of the test and should have a pressure range at least 10% greater than the test pressure. The vacuum gauge shall read to a pressure of at least 20 kPa absolute. Different test chambers may be used for the low and high pressure tests.

3.4.3.2 Procedure

Test source shall be placed in the chamber and exposed to test pressure for two periods of 5 min each. The pressure shall be returned to atmospheric between the periods. Low pressure test shall be conducted in air and high pressure test for Class 6 by a hydraulic method using water as the medium in contact with source. High pressure test for classes 3, 4 and 5 shall preferably be conducted by the same procedure. Oil shall never be used as hydraulic medium in contact with the source. Oil in contact with the source may block small leaks. However, the source may be in water in a flexible bag sealed from hydraulic oil in the test chamber.

3.4.3.3 Evaluation

Test source shall be examined visually and then subjected to an appropriate leak test such as that described in section 5.

3.4.4 Impact Test

3.4.4.1 Equipment

3.4.4.1.1 A steel hammer shall be designed with an upper part suitable for hold and release attachment and the lower part having a flat striking surface of 25 mm diameter, with its edge rounded to a radius of 3 mm.

The centre of gravity of the hammer shall lie on the axis of the circle which defines the striking surface, and this axis shall pass through the point of attachment. The mass of hammer depends on the test class.

3.4.4.1.2 Steel anvil, the mass of which shall be at least ten times that of the hammer, shall be rigidly mounted so that it does not deflect during impact. It shall have a flat top surface, large enough to take the whole of the source.

3.4.4.2 Procedure

The mass of hammer shall be chosen according to the class as specified in Table-1.

The drop height shall be adjusted to 1 m measured between the top of source positioned on the anvil and the base of hammer in the release position.

The source shall be so positioned as to cause maximum damage on impact, and drop the hammer on to the source.

3.4.4.3 Evaluation

Test sources shall be examined visually and then subjected to an appropriate leak test such as that described in section 5.

3.4.5 Vibration Test

3.4.5.1 Equipment

A vibrating machine capable of performing the tests specified.

3.4.5.2 Procedure

The source shall be fixed securely to the platform of vibrating machine so that the source will always remain in contact with the platform.

For classes 2 and 3, the source shall be subjected to three complete test cycles for each condition specified. The test shall be conducted by sweeping through all frequencies in the range at a uniform rate from the minimum frequency to the maximum and returning back to the minimum frequency in 10 min, or longer. Tests shall be carried out on each axis of the source. In addition, the test shall be continued for 30 min at each resonance frequency found.

For class 4, the source shall be subjected to three complete test cycles for each of the conditions specified. The test shall be conducted by sweeping through all frequencies in the range at a uniform rate from the minimum frequency to the maximum and returning to the minimum frequency in 30 min, or longer. Tests shall be carried out on each axis* of the source. In addition, the test shall be continued for 30 min at each resonance frequency found.

3.4.5.3 Evaluation

Test sources shall be examined first visually and then subjected to an appropriate leak test as described in section 5.

3.4.6 Puncture Test

3.4.6.1 Equipment

3.4.6.1.1 Hammer, the upper part of which shall be equipped with means of attachment, and the lower part of which bears a rigidly fixed pin, having the following specifications:

(a) hardness in the range of 50 to 60 HRC;

(b) free height of 6 mm;

(c) diameter 3 mm; and

(d) lower surface hemispherical.

The centre line of the pin shall be aligned with the centre of gravity and with the point of attachment of the hammer. Mass of the hammer and pin depends on the test class.

3.4.6.1.2 Hardened steel anvil rigidly mounted and with a mass at least ten times that of the hammer. The contact surface between source and anvil shall be large enough to prevent deformation of this surface when puncture takes place. If necessary, a cradle of suitable form may be provided between source and anvil.

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* 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 axis of revolution. Other sources have three axes, taken parallel to the significant external dimensions.

3.4.6.2 Procedure

Mass of the hammer and pin shall be chosen according to the class as specified in Table-1.

The drop height shall be adjusted to 1 m measured between the top of source positioned on the anvil and the point of the pin in release position.

The source shall be positioned so that it offers its most vulnerable area to the pin so as to cause maximum damage in the test.

The hammer shall be dropped on to the source.

If the dimensions and mass of source do not permit unguided fall, the striker shall be led to the puncture point through a smooth vertical tube.

3.4.6.3 Evaluation

The test source shall be examined visually and subjected to an appropriate leak test such as that described in section 5.

4. ADDITIONAL TESTS ON MANUFACTURED SOURCES

The following tests shall be carried out on each sealed source by the manufacturer.

4.1 Tests for Surface Contamination

Method 1

All exposed external surfaces of the sealed source shall be wiped thoroughly with a piece of filter paper or other suitable material of high absorbent capacity, moistened with a liquid which will not attack the material of the external surfaces of the capsule and which, under the conditions of this test, has been demonstrated to be effective in removing any radioactive material from the surface. The activity on paper or other material used shall be measured. If the detected activity is less than 185 Bq (5 nCi), the sealed source is considered to be free from surface contamination.

Method 2

The sealed source shall be immersed in a liquid which will not attack the material of the external surfaces of the capsule and which, under conditions of this test, has been demonstrated to be effective in removing any radioactive material from the surface. Examples of such liquids include distilled water and weak solutions of detergents or chelating agents. The liquid shall be heated to 323 ± 5 K (50° ± 5° C) and held at this temperature for 4 h. The sealed source shall be removed and the activity in the liquid measured. If the detected activity is less than 185 Bq (5 nCi), the sealed source is considered to be free from surface contamination.

4.1.1 In the case of sealed sources the characteristics of which (dimensions, chemical composition, etc.) do not allow for such a test, another equivalent method may be adopted with prior approval of the competent authority.

4.2 Leak Test Requirements

The tests described in section 5 shall be carried out by a competent and qualified person who has had appropriate training in radiation protection.

According to the control type and sealed source type, at least one of the tests described in clause 7.1 and 7.2 should be carried out {(see Annexure-I for the choice of test(s)}

However, where a special test not described in this Standard is carried out, the user should be able to demonstrate that the applied method is at least as effective as the corresponding method(s) given in this standard.

It is the normal practice to carry out more than one type of tests and to perform a final wipe test as a contamination check.

At the conclusion of the performed test(s), the sealed source shall be considered to be leak-tight if it complies with limiting values specified in Table-2.

If there is no direct correspondence between levels of measurement of different methods, the results will depend on measuring equipment and procedures.

A leakage rate of 10 $\mu Pa.m^3s^{-1}$ for non-leachable solid contents and a rate of 0.1$\mu Pa.m^3s^{-1}$ for leachable solids, liquids and gases would, in most cases, be considered to be equivalent to the activity release limit of 2 kBq (50 nCi).

A further confirmation of volumetric acceptance threshold is given in Table-2. A leakage rate of 10^{-7} $atm.cm^3.s^{-1}$ or less based on dry air at 25°C and for a pressure difference of 1 atmosphere against a vacuum of 10^{-2} atm. or less is considered to represent a loss of leak-tightness, irrespective of physical nature of the content.

Prior to any testing, except in the case of recurrent inspections, the sealed source shall be thoroughly cleaned and shall undergo a thorough visual examination.

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

Where applicable, the following parameters should be specified, whenever possible:

- pressure;
- temperature; and
- proportionality factor between the volume of sealed source and the volume of test enclosure used for certain tests, as well as the volume of liquid used to cover the sealed source to be tested.

Wipe test should not be considered as a leakage test, except for some specific types of sources (e.g. sources with thin windows), for recurrent 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 equipment.

5. LEAK TEST METHODS

5.1 Radioactive Methods

Tests for surface contamination specified under section 4.1 shall be carried out before the leak test. Any surface-contaminated source shall not be subjected to leak tests unless the surface of the source is cleaned and found to be free from any removable contamination. Leak test shall be repeated allowing at least 7 days after cleaning the surface to establish whether there is a leak.

5.1.1 Immersion Tests

5.1.1.1 Immersion Test (hot liquid)

Sealed source shall be immersed in a liquid which will not attack the material of the external surfaces of the sealed source and which, under the conditions of this test, has been demonstrated to be effective in removing the radioactive material from the surface. Examples of such liquids include distilled water, and weak detergent solutions, or chelating agents, or acid solutions with concentrations of about 5%. The liquid is heated to 323 K ± 5 K (50°C ± 5°C) and held at this temperature for 5 h. The sealed source shall be removed and the activity in the liquid measured.

Note: An ultrasonic cleaning method can also be used. In this case, the immersion time in liquid at 343 K ± 5 K (70°C ± 5°C) can be reduced to 30 min.

5.1.1.2 Immersion Test (boiling liquid)

Sealed source shall be immersed in a liquid which will not attack the material of the external surfaces of the sealed source and which, under conditions of this test, has been demonstrated to be effective in removing radioactive material from the surface. After the liquid has been boiled for 10 min and allowed to cool, the sealed source shall be rinsed in a fresh batch of liquid. These operations shall be repeated twice (a total of three times), re-immersing the source in the original liquid. Sealed source shall be removed and the activity in the liquid measured.

5.1.1.3 Immersion Test with Liquid Scintillation

Sealed source shall be immersed for 3 h at room temperature in a liquid scintillator solution, which does not attack the material of the external surfaces of the sealed source. The solution is stored in dark to avoid photoluminescence. Sealed source shall be removed and the activity of the liquid determined by liquid scintillation counting technique.

5.1.1.4 Immersion Test at Room Temperature

Sealed source shall be immersed in a liquid which does not attack the material of the external surfaces of the sealed source and which, under conditions of this test, is considered to be effective for removal of all traces of radioactive material from the surface. (This test may be useful where hot liquid tests are not practical: however the latter are recommended whenever possible since their use has been widely recognised for many years and also because they may be more effective.)

Sealed source shall be immersed in a liquid at room temperature 293 K ± 5 K (20°C ± 5°C) and maintained at this temperature for 24 h. Sealed source shall be removed and the activity of the liquid measured.

5.1.1.5 Approval Criteria

Sealed source shall be considered to be leak-tight if the activity detected does not exceed 200 Bq.

5.1.2 Gaseous Emanation Tests

5.1.2.1 Gaseous Emanation Test by Absorption (for ^{226}Ra sealed sources)

Sealed source to be tested shall be placed into an appropriate small, gas-tight container together with a suitable absorbent, such as activated carbon, or cotton-wool, and allowed to remain for at least 3 h. Sealed source shall be removed and the container closed tightly. The activity of the absorbent shall be measured immediately.

5.1.2.2 Gaseous Emanation Test by Immersion in a Liquid Scintillator (for ^{226}Ra sealed sources)

Sealed source shall be immersed for 3 h at room temperature in a liquid scintillator solution, which does not attack the material of the external surfaces of the sealed source. The solution is stored in dark to avoid photoluminescence. Sealed source shall be removed and the activity of the liquid determined by liquid scintillation counting technique.

5.1.2.3 Gaseous Emanation Test (for ^{85}Kr sealed sources)

The sealed radioactive source shall be maintained at reduced pressure for 24 h. The content of the chamber is analysed for krypton-85 by plastic scintillation counting technique. The test is repeated after at least 7 days.

5.1.2.4 Other Gaseous Emanation Tests

Any other test method equivalent to those described in sections 5.1.2.1 to 5.1.2.3 may be used.

5.1.2.5 Approval Criteria

When the tests described in sections 5.1.2.1 or 5.1.2.2 are completed, sealed source shall be considered to be leak-tight if the activity detected does not exceed 200 Bq of radon for a collection time of 12 h. When the collection time is shorter than 12 h, appropriate corrections shall be made.

When tests described in sections 5.1.2.3 or 5.1.2.4 are completed, the sealed source shall be considered to be leak-tight if the activity detected does not exceed 4 kBq/24 h.

5.1.3 Wipe Test

If a wipe test is used to determine leak tightness after mechanical or thermal prototype testing, the sealed source to be tested shall be cleaned (decontaminated) prior to leak tests.

When the wipe test is intended to test leakage 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.

In case of wipe test methods, it is necessary to consider the technique used, the instrumentation, and pressure applied, because the method used may not give sufficiently accurate reproducibility guarantees.

5.1.3.1 Wet Wipe Test

All external surfaces of the sealed source shall be wiped thoroughly with a swab of filter paper, or other suitable material of high absorbent capacity, moistened with a liquid which will not chemically attack the material of external surface of the sealed source and which, under conditions of the test, has been demonstrated to be effective in removing any radioactive material present. The activity of the swab shall be measured.

5.1.3.2 Dry Wipe Test

This test can be used in situations where it may not be appropriate to use a wet swab, for example, for high activity cobalt-60 sources or in some recurrent inspections.

To carry out the test, all external surfaces of sealed source shall be thoroughly rubbed with a dry swab of filter paper and the activity of the swab shall be measured.

5.1.2.3 Approval Criteria

If the activity detected does not exceed 85 Bq, the sealed source is considered leak-tight.

5.2 Non-radioactive Methods

Before conducting any of the tests prescribed in sections 5.2.1.1 to 5.2.1.3, the sealed source should be thoroughly cleaned and dried.

It shall be ensured that there are no gross defects which might invalidate the subsequent test results, for example, by visual inspection or by a method less sensitive than that of the subsequent test. For these tests to be valid, except that described in section 5.2.1.3, the free volume inside sealed source shall be greater than 0.1 cm^3. If this test is used for a sealed source with a free volume less than 0.1 cm^3, the user shall be able to demonstrate the validity of the test.

Because of their lower detection limit, only those tests using helium (section 5.2.1.1) are applicable to sealed sources with leachable or gaseous contents.

5.2.1 Helium Mass Spectrometer Leakage Test

5.2.1.1 Helium Test

Sealed source shall be placed in a suitable vacuum chamber containing helium. The chamber shall be evacuated through a helium mass spectrometer and the helium leak rate shall be evaluated in accordance with the recommendations of the manufacturer of leak testing equipment.

It shall be ensured that the free volume inside sealed source contains a concentration of commercial grade helium of more than 5%. The helium leakage rate indicated in the previous evaluation divided by the concentration of helium in free volume gives the actual standard helium leakage rate.

5.2.1.2 Helium Pressurisation Test

Sealed source shall be placed in a pressure chamber. The chamber shall be purged of air using helium, and the chamber pressurised to a given helium pressure for a given period. After depressurising the chamber, the sealed source shall be cleaned by flushing it with dry nitrogen or rinsing it in a volatile fluorocarbon liquid and transferring it to a suitable vacuum chamber. Helium leak rate shall be measured as described in section 5.2.1.1.

With the indicated helium leakage rate Q the actual standard helium leakage rate L can be evaluated by using the equation,

$$Q = \frac{L^2.p.t}{p_0^{\,2}.V} \quad (1)$$

where p_0 = 1.01325x10^5 Pa

Note-1: With helium pressure p in megapascals (in practice between 0.5 MPa and 10 MPa) maintained for a conditioning time t, in hours, a delay time between pressurisation and measurement of less than 10 min. and taking into account the free volume, V, in cubic centimetres greater than 0.1 cm^3 inside the sealed source, the conventional test parameters may be chosen and the test results evaluated using the following relationship:

$$Q = 0.35 \times \frac{L^2.p.t}{V} \quad (2)$$

where,

Q is the indicated leak-rate ($\mu Pa.m^3.s^{-1}$);

L is the standard helium leak rate ($\mu Pa.m^3.s^{-1}$) in the range between the acceptance thresholds 1 $\mu Pa.m^3.s^{-1}$ and 10^{-2} $\mu Pa.m^3.s^{-1}$.

$L \leq 1.7$ Ö (QV/pt)

Note-2: Equation (2) is valid in the case of molecular flow through one or more leaks. In the case of high percentage of viscous laminar flow, this equation leads to a moderate over-estimation of the actual standard helium leakage rate, but this factor only slightly influences the test result.

5.2.1.3 Approval Criteria

When these tests are completed, the sealed source is considered to be leak-tight if the actual standard helium leakage rate is less than 1 $\mu Pa.m^3.s^{-1}$ for non-leachable and 10^{-2} $\mu Pa.m^3 s^{-1}$ for leachable or gaseous contents (see Table-2).

5.2.2 Bubble Leakage Tests

Bubble leakage tests rely on an increase in internal pressure with increase in temperature. Gas from internal voids can then penetrate any leaks and form visible bubbles in a liquid bath. For one particular leak, the bubbling rate increases with decrease in surface tension.

5.2.2.1 Vacuum Bubble Test

By using ethylene glycol, isopropyl alcohol, mineral or silicone oil, or water with a wetting agent as leakage test fluid in a suitable vacuum chamber, the air content of the fluid is lowered by evacuating the chamber for at least 1 min. When atmospheric air pressure is re-established, the sealed source shall be completely submerged to a depth of at least 5 cm below the fluid level. The absolute pressure in the chamber shall be reduced to between 15 kPa and 25 kPa. Any bubbles emanating from the sealed source are observed for a period of at least 1 min.

5.2.2.2 Hot-liquid Bubble Test

Sealed source shall be at ambient temperature prior to being immersed 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 and 150°C) is an alternative to water. Any bubbles emanating from the sealed source are observed for at least 1 min. However, a minimum period of 2 min. is recommended whenever possible, and particularly when capsules with large thermal mass and poor thermal conductivity are involved.

5.2.2.3 Gas Pressurisation Bubble Test

Sealed source shall be placed in a suitable pressure chamber of volume at least twice that of the sealed source and at least five times the free volume inside the sealed source. The chamber shall be pressurised with helium gas to at least 1 MPa and maintained at that pressure for 15 min. After releasing the pressure, the sealed source shall be removed from the chamber and immersed 5 cm below the level of glycol, isopropyl alcohol, acetone or water containing wetting agent for bath. Bubbles emanating from the sealed source are observed over a period of at least 1 min.

5.2.2.4 Liquid Nitrogen Bubble Test

Sealed source shall be immersed completely in liquid nitrogen for 5 min. It shall then be transferred to the test liquid (normally methanol). Bubbles emanating from sealed source are observed over a period of at least 1 min.

5.2.2.5 Approval Criteria

If no bubbles are observed at the end of the tests described in 5.2.2.1 to 5.2.2.4, the sealed source is considered to have a leakage rate of less than 1 $\mu Pa.m^3s^{-1}$ and to be leak-tight only if the contents are non-leachable.

5.2.3 Water Pressurisation Test

The mass of sealed source shall be determined on a balance and the external pressure test shall be performed with water. The sealed source shall be wiped and dried and its mass shall be re-determined on the same balance. If the gain in mass is less than 50 mg, the sealed source is considered to be leak-tight 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. This test is applicable particularly in evaluating the external pressure test for classes 3, 4, 5 and 6 of Table-1.

The above test is necessary for long sources only.

6. SPECIAL TESTS

Additional tests, as specified in this section, are to be performed for certain sources.

6.1 Brachytherapy Sources

Sealed radioactive gamma sources in the form of tubes, capsules or seeds and needles used for interstitial, intracavitary and surface applications in brachytherapy, and beta sources used for ophthalmic, nasopharyngeal and surface applicators shall be subjected to the following tests:

TESTS TO BE PERFORMED FOR BRACHYTHERAPY SOURCES

Form of source	**Tests**
Tubes	Temperature Impact Percussion
Needles	Temperature Impact Percussion Bending Tensile
Beta applicators	Temperature Impact Percussion Puncture

6.1.1 Test Methods

The temperature and impact tests shall be of classes 6 and 4 respectively.

6.1.1.1 Percussion Test: The prototype shall be placed on a sheet of lead supported by a smooth solid surface and struck by the flat face of a mild steel bar to produce an impact equivalent to that resulting from a free drop of 1.4 kg through 1 m.

The lower part of the bar shall be 25 mm in diameter with edges rounded off to a radius of 3.0 (± 0.3) mm. The lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 25 mm thick, shall cover an area greater than that covered by the prototype.

A fresh surface of lead shall be used for each impact. The bar shall strike the prototype so as to cause maximum damage.

6.1.1.2 Bend Test: The prototype shall be subjected to a bend of 900 over 3mm. radius. The prototype shall then be straightened to original configuration.

6.1.1.3 Tensile Test: A mass of 11 kg shall be suspended from the eyelet of needle for at least 60s.

6.1.1.4 Puncture Test: A 0.8 mm diameter steel ram shall exert a static force of at least 1400 kg/cm^2 against face or window of the prototype source.

6.1.2 Evaluation: Each of the sources shall be examined visually after the tests and subjected to an appropriate leak test described in section 5.

6.2 Tests for Long Sources

6.2.1 Bend Test

The bend test shall apply to sources having an *L/D* of 15 or more, where *L* is active length and *D* the minimum outer capsule diameter of active length or smallest cross-sectional dimension of non-circular sources.

Bend test classification is based on applied static force in the arrangement shown in Figure-1.

The three cylinders shall have longitudinal axes parallel to each other and shall not rotate during test. The cylinders shall be solid, shall have smooth surfaces and shall be of sufficient length to accommodate the full contact of the capsule surface during the test. Cylinder hardness shall be ROCKWELL 'HR_C' 50-55.

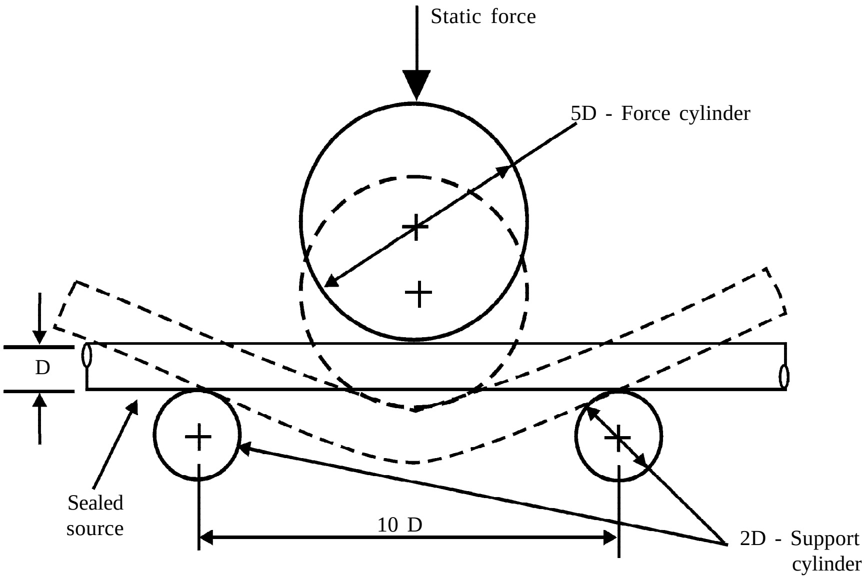

Fig.1: ARRANGEMENT FOR BEND TEST

The static force shall be applied at the most vulnerable part of the sealed source, and shall not be applied suddenly as this will increase the effective force.

Bend test performance classification and sealed source performance requirements for long sources used in different categories of irradiators are given in Tables-3 and 4 respectively.

6.2.2. Evaluation of Bend Test

A source shall be deemed to have complied with bend test if the source, due to its flexibility, passes through the test rig (the centre of force cylinder passes through the centre line of the two support cylinders) and maintains its integrity.

6.2.3 Evaluation: The source shall be examined visually after the test and subjected to an appropriate leak test described in section 6.

6.3 Special Form Radioactive Material

Indispersible solid radioactive material or an ordinarily unbreakable metallic sealed capsule containing radioactive material shall meet the following requirements (AERB Code No. SC/TR-1):

(a) the special form radioactive material shall have at least one dimension not less than 5 mm;

(b) the special form radioactive material shall be of such nature or shall be so designed that a prototype would not:

  (i) break or shatter under impact, percussion and bend; and

  (ii) melt or disperse under heat;

(c) when a sealed capsule constitutes a part of the special form radioactive material, the capsule shall be so constructed that it can be opened only by destroying it.

6.3.1 Demonstration of Compliance

6.3.1.1 Sealed sources meeting requirements of temperature test class 6 and impact test class 4 specified in section 3 shall be deemed to have complied with the performance standard as specified in 6.3 (b).

6.3.1.2 Alternatively, tests to be performed in lieu of 6.3.1.1 are:

(i) the prototype of special form radioactive material shall be subjected to impact test, percussion test, bending test, and heat test;

(ii) a different prototype may be used for each of the tests;

(iii) the prototype shall be prepared as normally presented for transport. The radioactive material shall be simulated as closely as practicable;

(iv) the prototype shall not break or shatter when subjected to impact, percussion or bending tests;

(v) the prototype shall not melt or disperse when subjected to the heat test; and

(vi) after impact test, percussion test, bending test and heat test, a leaching assessment or volumetric leakage test shall be performed on the prototype by a method no less sensitive than the methods given in para 6.3.3.1 for indispersible solid material and in para 6.3.3.2 for encapsulated material.

6.3.2 Test Methods

6.3.2.1 Impact Test: The prototype shall drop on to a rigid target from a height of 9 m. The target shall be a flat horizontal surface of such character that any increase in its resistance to displacement or deformation upon impact by the prototype would not significantly increase the damage to the prototype.

6.3.2.2 Percussion Test: The test prescribed under section 6.3.1.1 shall apply.

6.3.2.3 Bending Test: The test shall apply only to long, slender sources with both a minimum length of 10 cm and a length-to-minimum width ratio of not less than 10. The prototype 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 prototype shall be such that the prototype will suffer maximum damage when its free end is struck by the flat face of a steel bar. The bar shall strike the prototype so as to produce an impact equivalent to that resulting from a free vertical drop of 1.4 kg through 1 m. The lower part of the bar shall be 25 mm in diameter with edges rounded off to a radius of 3.0 (± 0.3) mm.

6.3.2.4 Thermal Test: The prototype shall be heated in air to a temperature of 800 ^{o}C and held at that temperature for 10 min and then allowed to cool in ambient temperature.

6.3.3 Leaching and Volumetric Leakage Assessment Methods

6.3.3.1 Prototype of solid indispersible material shall be subjected to leaching assessment after each test as follows:

(i) the prototype shall be immersed for 7 days in water at ambient temperature. The volume of water to be used in the test shall be sufficient to ensure that at the end of the test period the free volume of the unabsorbed and unreacted water remaining shall be at least 10% of the volume of the solid test sample itself. Water shall have an initial pH of 6-8 and a maximum conductivity of 1 mS/m at 20 ^{o}C;

(ii) water with prototype shall then be heated to a temperature of 50 (± 5) ^{o}C and maintained at this temperature for 4 h;

(iii) the activity of water shall then be determined;

(iv) the prototype shall then be stored for at least 7 days in still air at not less than 30 ^{o}C and relative humidity at not less than 90%;

(v) the prototype shall then be immersed in water of the same specification as in (i) above and the water with prototype heated to 50 (± 5) ^{o}C and maintained at this temperature for 4 h; and

(vi) the activity of water shall then be determined.

The activity shall not exceed 2 kBq.

6.3.3.2 Simulated radioactive material enclosed in a sealed capsule shall be subjected to either leaching assessment or volumetric leakage assessment.

Leaching assessment shall consist of the following steps:

(i) the prototype shall be immersed in water at ambient temperature. Water shall have an initial pH of 6-8 and a maximum conductivity of 1 mS/m at 20 ^{o}C;

(ii) water with prototype shall then be heated to a temperature of 50 (± 5) ^{o}C and maintained at this temperature for 4 h;

(iii) the activity of water shall then be determined;

(iv) the prototype shall then be stored for at least 7 days in still air at not less than 30 ^{o}C and relative humidity not less than 90% at 30 ^{o}C; and

(v) the processes as in (i), (ii) and (iii) shall be repeated.

Volumetric assessment shall be carried out as given in section 6.3.3.1.

6.4 Low-Dispersible Radioactive Material

Low-dispersible radioactive material shall be such that the total amount of this radioactive material in a package shall meet the following requirements:

(i) the radiation level at 3 m from the unshielded radioactive material does not exceed 10 mSv/h;

(ii) if subjected to enhanced thermal test and impact test, the airborne release in gaseous and particular forms of up to 100 mm aerodynamic equivalent diameter would not exceed 100 A2. A separate prototype may be used for each test; and

(iii) if subjected to the test specified in 6.3.3.1 (i) the activity in water would not exceed 100 A2. In the application of this test, the damaging effects of tests specified in (ii) shall be taken into account.

6.4.1 Test Methods

6.4.1.1 Enhanced Thermal Test: The prototype shall be in thermal equilibrium under conditions of an ambient temperature of 42 ^{o}C, subject to solar insolation conditions specified in Table S2.1 of Safety Code for Transport of Radioactive Material (AERB Safety Code, SC/TR-1) and subject to the design maximum rate of internal heat generation within the package from radioactive contents. Alternatively, any of these parameters are allowed to have different values prior to and during the test, provided due account is taken of them in the subsequent assessment of package response.

The thermal test shall consist of:

(i) exposure of a prototype for 60 min to a thermal environment which provides a heat flux at least equivalent to that of a hydrocarbon fuel/air fire in sufficiently quiescent ambient conditions to give a minimum average emissivity coefficient of 0.9 and an average temperature of at least 800 ^{o}C, fully engulfing the specimen, or with a surface absorptivity coefficient of 0.8, or the value that the package may be demonstrated to possess if exposed to the fire specified, followed by;

(ii) exposure of specimen to an ambient temperature of 42 ^{o}C, subject to solar insolation conditions specified in Table S2.1 and subject to the design maximum rate of internal heat generation by the radioactive contents for a sufficient period to ensure that temperatures in the specimen are decreasing everywhere and/or are approaching initial steady state conditions. Alternatively, any of these parameters are allowed to have different values following cessation of heating, provided due account is taken of them in subsequent assessment of the package.

During and following the test the specimen shall not be artificially cooled and any combustion of materials of the specimen shall be permitted to proceed naturally.

6.4.1.2 Impact Test: The prototype shall be subjected to an impact on target at a velocity not less than 90 m/s at such an orientation as to suffer maximum damage. The target shall be as defined in 6.3.2.1.

7. ACCOMPANYING DOCUMENTS AND CERTIFICATES

7.1 Accompanying Documents

The manufacturer shall ensure that each sealed radioactive source, or batch of sealed sources, supplied to a user is accompanied by document(s) containing details of source production, if any, and a certificate. The certificate shall in every case state:

(a) name of manufacturer;

(b) classification designated by the code established in this Standard;

(c) serial number and brief description, including chemical symbol and mass number of the radionuclide, dimensions, materials, thickness of encapsulation and the method of encapsulation;

(d) chemical and physical form of radioactive contents, dimensions and mass or volume, percentage of undesirable radionuclides, from the point of view of the end use of sealed source;

(e) equivalent activity, and/or radiation output in terms of air kerma rate, as appropriate, on a specified date;

(f) method used and the result of test for freedom from radioactive contamination;

(g) leak test method used and test result; and

(h) reference to type approval granted by the Competent Authority.

7.2 Certificate of Compliance

The manufacturer shall ensure that each sealed radioactive source supplied to a user is accompanied by a certificate of compliance giving results of various tests specified in Appendix-IV. This certificate of compliance shall specify the classification of each source in accordance with section 3.1. The format of the application for approval of the classification of sealed source is given in the Appendix-V.

APPENDIX-I

CLASSIFICATION OF RADIONUCLIDES ACCORDING TO RADIOTOXICITY

High Toxicity

Group A

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

Medium Toxicity

Group B1

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

CLASSIFICATION OF RADIONUCLIDES ACCORDING TO RADIOTOXICITY (continued)

Medium Toxicity

Group B2

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

CLASSIFICATION OF RADIONUCLIDES ACCORDING TO RADIOTOXICITY (continued)

Low Toxicity

Group C

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

APPENDIX-II

ACTIVITY LEVELS

Radionuclide group (Refer Appendix-I)	Maximum Activity in TBq (Ci)	
	Leachable[1] and/or highly reactive[3]	Non-leachable[2] and not highly reactive[4]
A	0.01 (approx. 0.3)	0.1 (approx. 3)
B1	1 (approx. 30)	10 (approx. 300)
B2	10 (approx. 300)	100 (approx. 3000)
C	20 (approx. 500)	200 (approx. 5000)

1 Leachable - greater than 0.01% of the total activity in 100 ml in still H_2O at 20 ^{O}C in 48 h.

2 Non-leachable - less than 0.01% of the total activity in 100 ml in still H_2O at 20 ^{O}C in 48 h.

3 Highly reactive - highly reactive in ordinary atmosphere or water (metallic, Na, K, U and Cs, etc.)

4 Not highly reactive - not highly reactive in ordinary atmosphere or water (Au, Ir, ceramics, etc.)

APPENDIX-III

SEALED SOURCE PERFORMANCE REQUIREMENTS FOR TYPICAL USAGES

Sealed source usage		Sealed source test and class				
		Temperature	Pressure	Impact	Vibration	Puncture
Radiography - Industrial	Unprotected source	4	3	5	1	5
	Source in device	4	3	3	1	3
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
	Interstitial and intracavitary appliances[1]	5	3	2	1	1
	Surface applicators	4	3	3	1	2
Gamma gauge (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 for X-ray fluoroscence analysis (excluding gas-filled sources)		3	3	2	2	2
Oil well logging		5	6	5	2	2
Portable moisture and density gauge (including dolly-transported)		4	3	3	3	3
General neutron source application (excluding reactor start-up)		4	3	3	2	3
Calibration sources Activity greater than 1 MBq		2	2	2	1	2
Gamma irradiation sources	Unprotected	4	3	4	2	4
	Source in device	4	3	3	2	3
Ion generators[2]	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors	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 Source-device combination may be tested.

APPENDIX-IV

FORMAT OF "CERTIFICATE FOR SEALED RADIOACTIVE SOURCE" (as required under section-7)

1. Manufacturer's name and address: ....
....

2. Manufacturer's identification mark: ....

3. Source S.No: .... 4. Date of manufacture:...........................

5. Source classification number: C/E ....

6. Radionuclide: ....
Mass number and chemical symbol: ....
Target element for neutron sources ....

7. Chemical and physical form: .... Mass/volume ....

8. Maximum % of other radionuclides:................... % on ....(date)
(specify the radionuclide and ....% on ....(date)
percentage ....% on .... (date)

9. Equivalent activity GBq (Ci): ± .... %:...............on ....(date)
and/or radiation output:...on ....(date)
(specify fluence rate for radioactive neutron sources)

10. External dimensions:................Minimum encapsulation thickness:..............................
Material of construction:......................Method of sealing:...
Number of encapsulations:...

11. Freedom from surface contamination: Method of test: ....
Date of test: .... Result of test: ....

12. Freedom from leakage : Method of test: ....
Date of test: .... Result of test: ....

13. Type approval number: AERB/445/.....................on ....(date)

14. Certification number: IND/......./S.......................on ....(date)
for special form radioactive material

15. The sealed source conforming to classification C/E ....and free from surface contamination and radioactive leakage (less than 185 Bq.) can be used for....................................(purpose)

Date: .... Signature: ....

Designation:.................. Name: ....

APPENDIX-V

FORMAT OF "APPLICATION FOR APPROVAL OF CLASSIFICATION OF SEALED SOURCE"

(a) State whether it is fresh application or renewal.

(b) State whether the approval is for sealed source/special form radioactive material/ low dispersible radioactive material

A. General

1. Name and address of the applicant: ....
....
....
....
PIN..
Telephone with STD code: .... Telex:...
Fax:.. E-mail:...

2. Name and address of the: manufacturer ....
....
....
....
PIN..
Telephone with STD code: .... Telex:...
Fax:.. E-mail...

3. Person to be contacted regarding the application: ....
Telephone with STD code:......................... Telex:...
Fax:.. E-mail:...

B. Details of Sealed Source

4. Radioactive: ....

5. Other radionuclides present (nature and quantity):...

6. Target element in case of neutron source: ....

7. Chemical and physical form: ....

8. Mass/volume (mm^3): ....

9. Maximum activity (GBq/Ci): ....

10. Material(s) of construction : ....

11. External dimension (cm): ....

12. Active dimension (cm): ....

13. Thickness of wall/covering/cladding (mm): ....

14. Method of sealing: ....

15. Number of encapsulation(s): ....

16. Freedom from surface contamination:
    (a) Test method (specify): ....
    (b) Result(s): ....

17. Manufacturer's identification mark: ....

18. Tests for source classification :

Number of random samples for testing:

S.No.	**Test***	**Classification number**
1	Temperature (3.4.2)	
2	Pressure (3.4.3)	
3	Impact (3.4.4)	
4	Vibration (3.4.5)	
5	Puncture (3.4.6)	
6	Bend (6.2.1)	
7	Impact (6.3.2.1)	
8	Percussion (6.3.2.2)	
9	Bending (6.3.2.3)	
10	Heat (6.3.2.4)	
11	Enhanced thermal (6.4.1.1)	
12	Impact (6.4.1.2)	

* Numbers given in brackets refer to relevant sections in this Standard

19. Source classification: C/E..

20. Results of leak test

 (a) Radioactive method(s) (specify): ....

 (b) Non-radioactive method(s) (specify): ....

21. Anticipated useful life of the sealed source: ....years

22. Intended use of sealed source: ....

Place: .... Signature:...

Date: .... Name: ....

Designation: ....

(Office seal)

Attachments:

1. A copy of quality assurance (QA) programme during manufacturing of sealed radioactive sources and procedures to demonstrate that the manufactured sources are identical to the prototype.

2. A copy of test report describing the method and results.

3. A copy of the certificate as required under section 4.

4. Publicity material regarding the intended use of sources.

TABLE-1: CLASSIFICATION OF SEALED SOURCE PERFORMANCE STANDARDS

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 400°C to 20°C	-40°C (20 min), +600°C (1 h) and thermal shock 600°C to 20°C	-40°C (20 min), +800°C (1 h) and thermal shock 800°C 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	200 g from 1 m	2 kg from 1 m	5 kg from 1 m	20 kg from 1 m	Special test
Vibration	No test	3 times 10 min 25 to 500 Hz at 49 m/s^2 (5 g)*	3 times 10 min 25 to 500 Hz at 0.635 mm amplitude peak-to-peak and 90 to 500 Hz at 98 M/S^2 (10 g)*	3 times 30 min 25 to 80 Hz at 1.5 mm amplitude peak-to-peak and 80 to 2000 Hz at 196 m/s^2 (20 g)*			Special test
Puncture	No test	1 gram from 1 m	10 gram from 1 m	50 gram from 1 m	300 gram from 1 m	1kg from 1 m	Special test

* Peak acceleration amplitude.

TABLE 2: THRESHOLD DETECTION VALUES AND LIMITING VALUES FOR DIFFERENT TEST METHODS

Test method	Sub-clause in text	Threshold detection value	Limiting value: Non-leachable content	Limiting value: Leachable or gaseous content
		Activity (Bq)		
Immersion test (hot liquid)	5.1.1.1	10 to 1	200	200
Immersion test (boiling liquid)	5.1.1.2	10 to 1	200	200
Immersion test with liquid scintillator	5.1.1.3	10 to 1	200	200
Gaseous emanation test	5.1.2.1	4 to 0.4	...*	200 (^{222}Rn/12 h)
Emanation test with a liquid scintillator	5.1.2.2	0.4 to 0.04	... *	200 (^{222}Rn/12 h)
Wet wipe test	5.1.3.1	10 to 1	200	200
Dry wipe test	5.1.3.2	10 to 1	200	200
		Standard helium leak rate (µPa.m^3.s^{-1})		
Helium test	5.2.1.1	10^{-2} to 10^{-4}	1	10^{-2}
Helium pressurisation test	5.2.1.2	1 to 10^{-2}	1`	10^{-2}
Vacuum bubble test	5.2.2.1	1**	1	... ***
Hot liquid bubble test	5.2.2.2	1**	1	... ***
Gas pressurisation bubble test	5.2.2.3	1**	1	... ***
Liquid nitrogen bubble test	5.2.2.4	1**	1	... ***
		Mass gain of water (µg)		
Water pressurisation test	5.2.3	10	50	... ***

* Unsuitable
** These detection limits apply only to single leaks under favourable visual conditions
*** Not sensitive enough

TABLE 3: BEND TEST PERFORMANCE CLASSIFICATION FOR LONG SOURCES

Bend test	Class					
	1	2	3	4	5	6
Static force	No test	100 N (10.2 kgf)	500 N (51 kgf)	1000 N (102 kgf)	2000 N (204 kgf)	4000 N (408 kgf)

TABLE 4: SEALED SOURCE PERFORMANCE REQUIREMENTS FOR GAMMA IRRADIATORS

Gamma irradiator category*	Sealed source test and class					
	Temperature	Pressure	Impact	Vibration	Puncture	Bend
II, III, IV	4	3	4	2	4	5
I	4	3	4	2	3	4

* Category I : Self-contained dry source storage
Category II : Panoramic dry source storage
Category III : Self-contained wet source storage
Category IV : Panoramic wet source storage

Details of other requirements for categories II, III, and IV irradiators are given in AERB Standard Specifications for Radiological Safety for the Design and Installation of Land-Based Stationary Gamma Irradiators (AERB-SS-6, 1993).

ANNEXURE-I

GUIDANCE FOR THE CHOICE OF TEST TO BE CARRIED OUT ACCORDING TO CONTROL AND SEALED SOURCE TYPE

This annexure (including Table A1) provides a guide to assist in selection of the most suitable tests for carrying out quality control, production control and recurrent inspection, taking into account the sealed source type (design, characteristics etc.)

Table A.1 is not comprehensive; however it covers a wide range and can act as a guide for many sealed source designs. It gives the preferred test and second choice test.

A.1 Leakage test for production of sealed sources

The most appropriate leakage test for production of sealed sources containing a radionuclide can be determined from Table A.1, according to their particular source design and technology.

A.2 Leakage test for prototype sealed sources

Leakage tests allowing validation of required tests for determining the classification of a prototype sealed source according to this Standard may be carried out on:

- prototype sealed source with nominal radioactive content; or
- simulated sealed sources; or
- dummy sealed sources.

For the last case, it will be clearly necessary to use a non-radioactive leakage test method.

The most appropriate leakage test will depend on the sealed source technology and design and can be determined from Table A.1.

A.3 Recurrent inspections

It is obviously necessary to test sealed sources at regular intervals after the manufacturer has supplied it to a user, to check that they have not developed a leak. Many countries follow statutory regulations to specify the frequency of tests. The time interval between tests may vary according to the sealed source type and design, and also the working environment.

These tests are not necessarily the same as those which are appropriate during manufacture. It is important to take into account the utilisation conditions of the sealed source and of any specific risks that it might encounter during its working life.

Thus several conditions may be encountered in practice when considering recurrent tests:

(a) The sealed source can only be tested at the site where it is used and it is practical to carry out a wipe test on the nearest accessible surface. In this case, a wipe test (5.1.3) is chosen. A visual examination of the source should also be carried out if possible;

(b) The source can only be tested at the site where it is used, but direct access to source is not possible or not desirable because of the unjustified exposure of persons carrying out the test, for example high activity teletherapy sources or other sources in sealed housings. In this case, wipe tests should be carried out on the nearest accessible surface; and

(c) Where facilities are available to test the sealed source by other methods, for example in certain hospitals, by return to the manufacturer or by other suitable laboratories, the methods recommended for production sources in Table A.1 should be used. A visual examination of sealed source should also be carried if possible.

Warning:

1. If the activity is found to be present, even if below the limiting value of 200 Bq, action should be taken to establish whether this arises from source leakage. One procedure would be to repeat the tests at regular intervals to determine whether the activity detected is increasing.

2. When carrying out recurring test, it is essential to ensure that radiation exposure levels are within accepted limits.

TABLE-A1: SELECTION OF LEAKAGE TEST METHODS RELATED TO MANUFACTURING TECHNOLOGY

Source type	Tests for production sources		Tests to establish classification of source	
	Preferred	**Second choice**	**Preferred**	**Second choice**
A Sealed source containing radioactive material A1 A single integral window. e.g. smoke detectors A2 Low-activity reference sources. e.g. encapsulated in plastic	Immersion (5.1.1)	Wipe (5.1.3)	Immersion (5.1.1)	Wipe (5.1.3)
A3 Single-or double-encapsulated sources (excluding ^{3}H and ^{226}Ra) for gauging, radiography, and brachytherapy	Immersion (5.1.1) Helium (5.2.1)	Bubble (5.2.2)	Immersion (5.1.1) Helium (5.2.1)	Bubble (5.2.2)
A4 Single-or double-encapsulated ^{226}Ra and other gaseous sources	Gaseous emanation (5.1.2)	Immersion (5.1..1)	Gaseous emanation (5.1.2)	Immersion (5.1.1)
A5 Double-encapsulated sources for teletherapy and high activity irradiator sources	Helium (5.2.1)	Wipe (5.1.3.2)	Immersion (5.1.1) Helium (5.2.1)	Bubble (5.2.2)
B Simulated sealed sources of types A3, A4 and A5			Immersion (5.1.1) Helium (5.2.1)	Bubble (5.2.2)
C Dummy sealed sources			Helium (5.2.1)	Bubble (5.2.2)

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2. International Standard, ISO-1677 - Sealed Radioactive Sources - General - June 1977.

3. International Standard. ISO-9978 - Radiation Protection - Sealed Radioactive Sources - Leak Test Methods - February 1992.

4. American National Standard, N542: Sealed Radioactive Sources, Classification, ANSI N542-1977

5. International Atomic Energy Agency (IAEA), Safety Standard Series, Regulations for Safe Transport of Radioactive Material, ST-1, (1996)

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NOTES

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