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AERB Standard Specification No: 4

RADIOLOGICAL SAFETY IN THE DESIGN AND MANUFACTURE OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

Approved by the Board on April 2, 1991.

Atomic Energy Regulatory Board
Vikram Sarabhai Bhavan
4th floor, North Wing
Anushaktinagar
Bombay-400094
India

FOREWORD

1. A wide range of consumer products containing radioactive substances are extensively used in the public domain. Many of these products are now-a-days manufactured in the country. The users in general, are unaware of the presence of radioactivity in these products as well as the potential harm they may produce as a result of radiation exposure in case of careless or improper use. Therefore, it is necessary to ensure that the consumer products contain as little radioactivity as practicable and in addition the products themselves are assessed and approved before they are manufactured and supplied to the public. This will ensure that even if these products are handled in any manner and disposed off in domestic refuse, the radiation doses to individual members of the public are small and hence constitute only negligible radiation risk. Under these circumstances, no special regulatory controls would be required to protect the public from radiation exposure arising due to the consumer products.

2. In May 1990, the Task Group constituted by the Atomic Energy Regulatory Board with Dr. I.S. Sundara Rao as Convener, set the criteria for approving the consumer products before they are released to the public. As a sequel to the work of the Task Group, a Working Group constituted by Atomic Energy Regulatory Board with Shri P. Gangadharan as Convener, has developed the standard specifications for consumer products. These standards are meant for compliance by the manufacturers of consumer products in order to meet the requirement of keeping the radiation dose to individual members of the public as low as reasonably achievable.

   These standard specifications will provide an important step towards design and production of safer consumer products for public use.

(S.D. Soman)
Chairman, AERB

STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN THE DESIGN AND MANUFACTURE OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

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STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN THE DESIGN AND MANUFACTURE OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SDBSTANCES

1. INTRODUCTION

1.1 This document is concerned with "Manufactured Products or appliances or miscellaneous items in which radionuclides have been intentionally or adventitiously incorporated and which can be supplied to members of the public without special surveillance".

1.2 It is recognised that, in general practice, manufacturers should inform the consumer on the correct use of their products. The manufacturer should also explain how to avoid damaging the integrity of the radioactive substance with a view to prevent unnecessary exposure. This will help to reduce the probability of accidents or misuse. In any case, a consumer cannot be statutorily obliged to follow instructions given by manufacturer.

1.3 It is impossible to ensure that consumer items containing radioactive substances, once they have been supplied, would be used in the manner intended by the manufacturer, or that they would be disposed off in any recommended manner.

1.4 Normal .use, misuse and accidents may lead to radiation exposure - both of those benefiting from the product and of others who receive no direct benefit. Disposal may also cause radiation exposure of persons who receive no benefit. Therefore, the consumer products are essentially beyond further control for purposes of radiation protection by the competent authority once they have been supplied.

1.5 The specifications given in this document apply to all consumer products regardless of the purpose for which the radionuclide is added. The purpose may be to make use of the ionizing radiation emitted by the substance in the product itself (e.g. radioluminescent devices, antistatic devices, ionization chamber smoke detectors), or to make use of some other property of the material where the presence of radioactivity in the final product is merely adventitious {e.g. incandescent gas mantles).

1.6 This standard does not cover the products containing natural radioactive materials, which have not been intentionally added, such as building materials. Also products contaminated with radioactive substances during production, either due to the use of radioactive substances as tracers or accidentally, due to leakage of radioactive source, are beyond the scope of this standard.

1.7 This standard does not cover medical use of radionuclides such as nuclear powered cardiac pacemakers, and radiation emitting devices such as television receivers and video display terminals.

1.8 This standard is concerned with the exposure of the public arising from the use of consumer products. The radiation protection of workers involved in the manufacture of consumer products is covered in the AERB Safety Guide on the manufacture of consumer products (AERB/SG/CP1). Protection of persons engaged in handling and servicing of the products is also covered in the Safety Guide.

1.9 The manufacture and supply of consumer products containing radioactive substances for use in public domain is subject to authorisation by the competent authority.

1.10 An authorisation for manufacturing a consumer product should be contingent upon adequate demonstration that the product perform a function which can be fulfilled only by using a radioactive substance or that the use of radioactive substance to fulfill the function has evident advantages over any other practical method. This function shall be met by one or more of the following criteria:

i) Possible saving of life
ii) Protection against personal injury
iii) Improving reliability or dependability of a product in respect of its safety functions
iv) The fulfilling of an advantage not covered by (i) to (iii) above but judged to be of equal importance.

1.11 An authorisation for manufacture and approval of the use of a consumer product is subject to an adequate demonstration that the use, misuse and disposal of the product do not give rise to unacceptable radiation doses to individual members of the public and the population at large. The effective dose to an individual member of the public should not exceed 1.0 mSv in a year even in a worst scenario arising due to gross misuse or accident, and under normal circumstances. of use, the individual doses do not exceed a fraction of this. The collective dose to the entire population should not exceed 1 person Sv in any year.

1.12 The intrinsic safety of a consumer product is an important consideration for approval of a product for public use. The intrinsic safety should be demonstrated both for normal use conditions and also for severe accident conditions.

1.13 The Procedures described in this standard specify the essential requirements for the design and construction of consumer products containing radioactive substances, so that when the product is designed and constructed in accordance

with this standard and demonstrated compliance with the test requirements, the product can be accepted with reasonable confidence that the public are adequately protected from unacceptable radiation exposure.

1.14 The manufacturers shall carry out the tests prescribed in this standard, submit an application along with the test results and obtain pre-marketing approval for the product from the competent authority.

1.15 Such approved products can only be marketed or supplied to users, in accordance with the terms and conditions stipulated in the approval granted by the competent authority under the provisions of the Radiation Protection Rules (1971) issued under the Atomic Energy Act (1962).

1.16 This standard covers only those consumer products containing radioactive substances, which are commercially manufactured and extensively used in India. Certain other products which are either manufactured or supplied in a limited way and those imported and used for special purposes are not included in this document. Manufacturers or distributors of such products are advised to apply to the competent authority with relevant technical details and radiation safety aspects for special approval granted on a case-by-case basis.

2. RADIOLUMINOUS TIMEPIECES

STANDARD SPECIFICATIONS FOR MANUFACTURE

1. Scope

This standard specifies the radiation safety requirements of luminous timepieces. The specifications include optical and mechanical characteristic of radioluminous deposits on dials and hands together with the test methods.

2. Definition of terms

2.1 Radioluminescence : Luminescence caused by the radiation emitted by the radionuclide within crystalline powders (ZnS, Zn_2SiO_4, etc.)

2.2 Radioluminescent deposit : A radioluminous substance in powder form mixed with a binder and fixed on a support.

2.3 Special timepieces : Timepieces designed for uses which require considerable luminosity. They are generally used or worn intermittently.

3. Specification and test methods for timepieces

3.1 Legibility

3.1.1 For watches using radioluminous substances, the following criteria shall apply :

a) At least four hour markings shall be used except when an aperture is provided on the dial. These markings shall be 3,6,9 and 12.
b) The 12 shall be differentiated from other markings.
c) If only four markings are used, the minimum value of luminous intensity inclusive of the hands and markings shall be 25 ncd (nanocandelas).
d) If more than four markings are used, the luminous intensity shall be increased by 3 ncd per additional marking.
e) The pair of hands, taken in isolation, shall have a luminous intensity of at least 10 ncd.

3.1.2 For timepieces not worn on persons, the minimum value of luminous intensity shall be doubled.

3.2 Nature of radionuclides

3.2.1 Only the following radionuclide shall be used.
Tritium (H-3) or Promethium (Pm-147)

3.2.2 Radium (Ra-226) shall not be used on timepieces.

3.2.3 The use of different radionuclides on the same time-piece is not allowed.

3.3 Total radioactivity of the timepiece.

The maximum quantity of radioactivity specified in terms of maximum activity per timepiece is expressed as average of the total activities of the timepieces taken at random from a given lot produced within a given factory from the beginning to the end of a production cycle, without entailing changes in methods of production, materials of construction, or type and brand of radioluminous material. The maximum total activity of any isolated timepiece shall not exceed the values given below:

a) Timepieces worn on person

Radionuclide	Maximum activity per timepiece in a lot	Maximum activity per isolated timepiece.
H-3	200 MBq	300 MBq
Pm-147	4 MBq	6 MBq

b) Timepieces not worn or carried on person

Radionulcide	Maximum activity per timepiece in a lot	Maximum activity per isolated timepiece.
H-3	300 MBq	400 MBq
Pm-147	6 MBq	8 MBq

c) Special timepieces

Radionuclide	Maximum activity per isolated timepiece
H-3	1 GBq
Pm 147	20 MBq

3.4 Protection against radiation

The timepiece shall be covered on all sides by a case, glass or acrylic plastic and the deposit covered with protective

varnish, such that the user is protected against any direct contact with the components treated with radioluminescent material and the low energy ß radiation is sufficiently absorbed. Any deposit of a radioluminous material shall be protected by a film of transparent non-radioactive material of thickness not less than 50 mg cm^{-2}.

The mechanical strength of the protective covering shall be sufficient to withstand the stresses encountered under normal conditions of use and as far as reasonably practicable, during possible accidents. Perfect water tightness shall be ensured for watches.

3.5 Checking of radioactivity

The activity shall be checked on the timepiece fitted with its normal protective glass or acrylic plastic. A method based on photometric measurement is permitted. If the measurement of the bremsstrahlung is used, account shall be taken of the attenuation due to the glass or acrylic plastic and to the deposit itself. The thickness of the glass or acrylic plastic and the deposit are measured and the activity of the deposit is either measured or estimated after correcting for self-absorption.

When uncertainity resulting from the above mentioned methods of checking makes it impossible to guarantee that the requirement specified under 3.3 are complied with, a destructive method shall be used to measure the activity. Such a destructive method shall consist in isolating the radionuclide from other constituents of the luminescent substance or from the deposit, and converting it into a form suitable for accurate measurement. For example, a suitable method for tritiated substance consists in destruction of the luminescent deposit by combustion, collection of the liberated water and measurement of its activity with a suitable liquid scintillator.

3.6 Adhesion

3.6.1 Swipe test for dials

The luminous painted dials shall be dried and kept in an oven at 50°c for 15 min. After cooling to room temperature, the luminous markings shall be wiped gently using dry surgical cotton or brush No. zero. There shall be no spread of the paint.

3.6.2 Bending test for hands

a) Hands with a length of 15 mm or less shall be bent round a cylinder with a radius of 12.5 mm.

b) Hands with a length of over 15 mm shall be bent round a cylinder with a radius equal to the length of the hand, with a tolerance of $\pm$ 1 mm.

3.6.3 Estimation of the adhesion

Following the swipe test and bending test, examine the dials and hands as well as their immediate surroundings. The presence of alterations such as splits and cracks or of perceptible debris shall be considered grounds for rejection. Such rejected items should be disposed off as radioactive waste. Detached particles are revealed by means of an ultra-violet lamp.

3.7 Marking

The marking specified below is obligatory only for special timepieces. It is intended for the information of the horologist as well as the user. It shall be effected, legibly and indelibly with a non-radioactive paint, on the dial of the time piece. It shall comprise of one of the following indications:

T1G for deposits activated by tritium
Pm20M for deposits activated by promethium

The indications give the maximum authorised radioactivity value in becquerel for tritium and promethium deposits.

3.8 Checking of the marking

The marking shall be checked by visual inspection.

4. **Specifications and test methods for radioluminescent deposits**.

The specification relating to the deposits shall be checked unless special restrictions are indicated. These shall be checked:

(a) on the finished products
(b) on the dials
(c) on a sample placed on a stand and support made of stainless steel having a reflectivity between 0.2 and 0.3, comprising a circular coupelle containing a circular cup having a surface area of 1 cm^2,intended to hold 50 mg of powder.
(d) on standard hands
(e) on the rectangular support defined for checking of the colours.

4.1 Colours

4.1.1 Standardised colours

1 - White
3 - Yellow
5 - Greenish-yellow
7 - Green
9 - Blue-Green

The list is not restrictive and on agreement between manufacturer and the user, other colours may also be used.

4.1.2 Checking of the colours

The colours of the deposit shall be checked by visual examination in daylight, without sun, on samples defined in 4 (c). The colours shall be compared with those of reference standards consisting of 50 mg of non-radioactive luminescent powder deposited on a surface of 1 cm at one end of a standard support made of stainless steel having a reflectivity between 0.2 and 0.3. The standards must be stored in the dark.

4.2 Specific luminous intensity

The quality of the deposits is characterised by their luminous intensity per unit mass of powder when they are examined in layers of 50 mg of powder per square centimetre, on a support having a reflectivity between 0.2 and 0.3. The specific luminous intensities expressed in micro-candelas per gram of powder (ucd/g) may vary from 2.5 to 80.

4.2.1 Checking of specific luminous intensity.

The deposit shall be applied on a standard support as specified in 4(c).

The luminous intensity shall be checked after the luminous deposit has been kept in darkness for at least 3 hours. The luminous intensity is measured with a photometer equipped with photomultiplier tube showing a S-11 response or any other equipment assuring of equivalent response.

The characteristics of the standards used for this measurement and the radioluminescent deposits shall be similar. The stability should be periodically checked. The luminous intensity shall be evaluated in relation to the mass of the powder deposit.

4.3 Resistance to aging

4.3.1 Nature of the test

It is considered that simultaneous exposure to heat; humidity and activating light constitutes a test of accelerated ageing, which validly simulates the conditions of real ageing.

4.3.2 Procedure

The deposit should be placed in a crystallizer (a glass container, in the form of a cylinder with a flat bottom and straight sides, the height of which should be equal to approximately half of the diameter) containing water at normal temperature. The support should not be immersed. The crystallizer should be covered with a 0.1 mm thick sheet of polyethylene and placed under a 300 W ultra-violet lamp.

Prior to switching on the lamp, the crystallizer should be brought to 55 ± 2°C. Maintaining this temperature, It should be exposed to ultra-violet radiation of 300 nm for 3 h.

4.3.3 Estimation of the resistance to ageing

The luminous intensity of the deposit should be measured before and after the test. The loss in luminous intensity shall be less than 10%.

4.4 **Insolubility**

4.4.1 Procedure

The deposit should be immersed to a depth of at least 3 mm for 24 h in distilled water, at a temperature between 18°C and 25°C., The activity of the water shall then be measured. For 50 mg of the deposit, it shall be less than:

3.7 MBq for tritium deposits
0.2 MBq for promethium deposits

4.4.2 Checking of the insolubility

The checks should be carried out on standard deposits as defined in 4(c) which have been prepared in accordance with the instructions of the manufacturer of the luminous powder and which have undergone the test specified in 3.6.1.

Quality control may also be carried out on luminous components (dials and hands) which have undergone the tests specified in 3.6. The mass of the powder in the deposit shall then be measured or calculated, assuming that the activity in water is proportional to the mass of the powder in the deposit regardless of its activity.

References

1. International Standard - Radioluminescence for time measurement instruments - Specifications-ISO 3157-1975(E)

2. Radiation Protection Standards for Radioluminous Timepieces. Recommendations of the European Nuclear Energy Agency and the International Atomic Energy Agency IAEA Safety Series No.23 (1967).

3. Requirements for Radioluminescence for time keeping instruments, IS 9275: 1979; Bureau of Indian Standards.

3. GASEOUS TRITIUM LIGHT SOURCES

STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN DESIGN AND MANUFACTORE

1. **Scope**

Gaseous Tritium Light Sources (GTLSs) are self-energised luminous sources consisting of a sealed glass container filled with tritium gas and coated internally with a phosphor. The glass envelop shal1 prevent the transmission of low energy beta particles emitted by tritium. Any external radiation from a GTLS is therefore solely due to bremsstrahlung. GTLSs shall not be supplied directly to members of the public unless they are incorporated into some instrument or other object, which provides considerable shielding. GTLSs shall not be used in toys, personal adornment and for frivolous purposes. No GTLS shall be directly accessible.

2. **Design and construction**

2.1 The quantity of tritium in any single GTLS shall be as low as practicable, but shall not exceed 75 GBq. The tritium shall be only in the form of H_2 or H^3H.

2.2 The content of oxygen or water vapour in the tritium gas shall not exceed 2% of the total tritium activity in the GTLS.

2.3 The thickness of glass container shall not be less than 0.6 mg/cm (the range of tritium betas in glass) and shall be at least 20% of the outer diameter.

2.4 The tritium filling pressure for general purpose GTLSs shall be less than 1 atmosphere. For special purpose GTLSs requiring high luminous intensity, the tritium filling pressure may be increased upto 2.5 atmospheres.

2.5 The glass container shall be covered externally with an elastic transparent sleeve made of plastic or soft resin. The thickness of the sleeve shall not be less than 2.0 mm and should snugly fit onto the glass container.

2.6 The radiation level on the surface of a GTLS shall not exceed 1 microsievert per hour per GBq of tritium.

3. **Tests on prototype sources**

The procedures described below are recommended for conducting performance tests on prototypes. Procedures demonstrated to be at least equivalent to these are also acceptable.

Tests shall be carried out consecutively on the same GTLS, in the order shown below.

3.1 Discolouration test : The sources shall be exposed for 12 hours to the light from an S-4 lamp filtered by a Corex D filter, at a distance of 20 cm from the lamp. The tests shall be performed in air at an ambient temperature of 27°C and a relative humidity of 95-100%. The samples shall be irradiated with the light impinging on the translucent surface of the source.

The test sources shall be examined visually and any discolouration observed. The light spectrum and output after the test shall be compared with those prior to the test. When measured with a visual photometer, the loss of luminosity shall not be greater than 20%.

3.2 Temperature test: The GTLS shall be heated in air to a temperature of +80°C within 5 min, kept at this temperature for one hour, then cooled to -20°C in less than 45 min and kept at this temperature for 1 hour. For special purpose GTLSs intended for use at extremely low temperatures, a separate test at –45°C is necessary. The requirement of this test shall be decided by the manufacturer and the user.

3.3 Vibration test: The GTLS shall be subjected to five complete cycles in the range 25 Hz to 500 Hz at 5 g. The test shall be conducted by sweeping through all the frequencies in the range at an uniform rate from the minimum to maximum and return to the minimum frequency in 10 min. or longer. The test shall also dwell 30 min. at each resonance frequency found.

3.4 External pressure test: The GTLS shall be put into a test chamber and subjected to air pressures of 25 kPa and 200 kPa of duration 15 min each, the pressure being returned to atmosphere between each period. This shall be repeated ten times.

3.5 Immersion test: The GTLS shall be immersed in a cold bath at O.C for 15 minutes. Within one minute, transfer to a hot bath at 65°C and keep it in the hot bath for 15 minutes- within one minutes transfer again to the cold bath. This shall be repeated for two cycles.

4. **Evaluation of test results**

After each test, the GTLS shall be examined by visual inspection or luminosity control. The loss of tritium or loss of luminosity shall not be greater than 20% after completion of all the tests.

5. **Leak test on each source**

Each source shall be soak tested for 24 hour in a volume of water equal to about 10 times the volume of the source. The source shall be removed and the activity in the solution measured using liquid scintillation counter. The activity in the solution shall not exceed 185 Bq.

References

1. Classification of Radioactive Self-luminous light sources. American National Standard ANSI N540-1975 (N.B.S. 116).

4. GASEOUS TRITIUM LIGHT DEVICES

STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN THE DESIGN AND CONSTRUCTION

1. Scope

This standard specifies the safety features to be incorporated in the design and construction of Gaseous Tritium Light Devices (GTLDs) in order to ensure adequate safety to the members of the public from gaseous tritium light sources (GTLSs). The hazard to members of the public from GTLSs is virtually limited to internal contamination arising from the accidental breakage of a source. The hazard of external exposure is negligible in practice. This standard is applicable to GTLDs containing GTLSs and not to GTLSs themselves, which should not be made available to the general public unless contained in a device.

As far as possible GTLDs shall be used to serve a safety function. GTLSs should not be used in toys, personal adornment or for frivolous purposes. No GTLS shall be directly accessible.

2. **Definition of terms**

2.1 Gaseous Tritium Light Source (GTLS): A GTLS consists of a sealed glass container filled with tritium gas and coated internally with a phosphor.

2.2 Gaseous Tritium Light Device (GTLD): A GTLD is an instrument, a piece of equipment, article or sub-assembly containing one or more GTLSs.

2.3 Activity: This term is used as the radioactivity measured at the time of manufacture of the GTLS.

3. **Design and construction**

3.1 The GTLD shall comprise characters which are luminously self powered by GTLS(s), permanently assembled and protected within an outer assembly. The front face of the assembly shall be of plastic material or glass and the sides and back shall be of plastic material or of metal.

3.2 The activity of tritium used in a GTLD should be as low as practicable. For an exit sign, the activity of tritium in the device shall not exceed 925 GBq. The maximum activity for other GTLDs depends on the nature of GTLD and shall not exceed the value specified by the Competent Authority on case-by-case basis.

3.3 The radiation level on any accessible surface of the assembled device shall not exceed 2.5 uSv per hour.

3.4 The GTLD shall be so constructed that it cannot readily be dismantled and that the tritium cannot be released under the severest accident conditions that are likely to be encountered in the normal handling of the device.

3.5 When GTLDs are constructed by mounting GTLSs within an outer case, the case shall be perforated for internal ventilation by a hole 2 mm to 3 mm diameter in each of the shorter edges. These holes shall be placed either on the centre line of, the case or equidistant above and below the central line, and in such a way that the GTLSs are not exposed.

3.6 The GTLD shall be constructed so that it can be held rigidly in position by mounting on a surface of a wall or suspended from brackets or from a ceiling or soffit or can be fitted in an instrument. The means of suspension shall be firmly attached or fastened to the back of the assembly such that the GTLD will not fall under normal circumstances.

3.7 The GTLD shall incorporate means for secure and rigid fixing of such a type that a special tool or procedure is required for the removal of GTLS from the device.

3.8 The external surface of the GTLD facing the observer shall have a matt or semi-matt surface to prevent specular reflection. The colour of this front surface shall be such that an effective contrast with the characters is achieved when the GTLD is viewed in daylight or artificial light.

4. Lettering or character.

The letters or characters shall have clearly defined edges, equivalent to the appearance of letters illuminated through metal stencil.

5. Prototype tests

The manufacturer of GTLD shall demonstrate to the competent authority that the sources will not become detached or suffer loss of tritium under the following test condition. These tests shall be carried out on the same prototype device, in the order given below:

5.1 Temperature test: The GTLD shall be heated in air to a temperature of +80°C within 5 min, kept at this temperature for one hour, then cooled to -20°C in less than 45 min and kept at this temperature for 1 hour. For special devices intended for use at extremely low temperatures, a separate test at -45°C is required.

5.2 Vibration test: The GTLD shall be subjected to three complete cycles in the range 25 Hz to 500 Hz at 5 g. The test shall be conducted by sweeping through all the frequencies in the range at an uniform rate from the minimum to maximum and return to the minimum frequency

in 10 min. or longer. Each axis of the GTLD shall be tested. In addition, the test shall dwell 30 min. at each resonance frequency found.

5.3 Drop test: The GTLD shall be dropped either on its face, back or a side from 1 m on to a smooth, hard rigid surface so as to cause maximum damage.

5.4 External pressure test: The GTLD shall be put into a test chamber and exposed in air to pressures of 25 kPa and 200 kPa of duration 15 min. each, the pressure being returned to atmosphere between each period. This shall be repeated four times.

5.5 Bump test: The device shall be subjected to 2000 bumps from a height of 5 cm on a hard surface.

6. **Examination after tests**

After each test, the GTLS shall be examined by visual inspection or luminosity control.

a) There shall be no evidence of structural failure, which would adversely affect the mechanical strength or integrity of the GTLD.

b) The loss of tritium or loss of luminosity after completion of all the tests shall not be greater than 20%.

7. **Marking and labelling**

7.1 Each GTLD shal1 be indelibly marked so that the marking can be seen from the front, with the basic trefoil radiation symbol, and adjacent to this symbol in letters and figures, the date upon which the useful life will end.

7.2 Each GTLD shall bear a label on the exterior of the device in a manner that the information is observable, and on the label the following information shall be given in permanent lettering.

(a) The word 'TRITIUH' and activity on date of manufacture.

(b) A serial number

(c) The words -"This GTLD complies with AERB/SS-4(1991)

(d) The following wordings

"Do not Open"-

"When the device is to be discarded, it has to be returned to the manufacturer for safe disposal."

(e) The manufacturer's Name and Address.

References

1. Radiation Protection Standards for Gaseous Tritium Light Devices OECD/NEA(1973)
2. British Standard Specifications for Self Luminous Exit Signs as 4218 (1978)

5. IONIZATION CHAMBER SMOKE DETECTORS

STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN THE DESIGN AND MANUFACTURE

1. **Scope**

Two types of smoke detectors are commercially available in the market. One is of ionization chamber type and the other of photoelectric type. Ionization type smoke detectors (ICSDs) are more widely used for an early warning of fire hazards in public, commercial and residential premises, and contain a radioactive source. This standard specifies the built-in safety features and test procedure of ICSDs for compliance by the manufacturer for grant of pre-marketing approval from the competent authority.

2. **Design and construction**

2.1 The radioactive source used in ICSDs shall be Am-241. The source shall comply with the requirements of C 32222 classification as per AERB Standard Specification for classification and testing of sealed radioactive sources (AERB-SS-3) 1990. The activity of Am-241 in the source shall not exceed 40 kBq.

2.2 The radioactive source shall be firmly incorporated in a suitable inactive matrix or sealed in a suitable inactive container having adequate mechanical strength so as to prevent dispersion or contamination. This requirement is also applicable to cutfoil sources where such sources are employed in ICSDs.

2.3 The sealed radioactive source shall be housed in a manner to provide adequate shielding so as to limit radiation levels on any ex2ernal accessible surface. The dose rate averaged over 10 cm^2 area of any accessible region shall not exceed 1 u Sv/hr at 0.1 m from the surface of the ICSD.

2.4 The sealed radioactive source shall not be directly accessible under normal use. The ICSD shall be sufficiently tamper proof.

2.5 Access to the radioactive source, whenever necessary, shall be only by means of special tools available to authorised service and maintenance personnel and shall require special procedure.

2.6 The materials of construction shall be to ensure reliable performance during its useful life under adverse environmental conditions, such as high humidity, dust, chemical vapours etc.

2.7 The ICSD shall be constructed so that it can be held rigidly in position by mounting on a ceiling or suspended from brackets. The means of mounting or suspension shall be firmly attached or fastened to the body of the ICSD such that it will not fall under any normal circumstances.

2.8 The level of radioactive contamination on the external surfaces and those accessible during maintenance oper~2ion of the ICSD shall not exceed a mean value of 0.04 Bq cm^{-2} .

3. **Tests on prototype**

These tests are intended to demonstrate that the sources will not become detached or suffer loss of integrity under normal conditions of use as well as possible accident situations.

These tests shall be carried out consecutively on the same ICSD in the order given below.

3.1 Temperature: The ICSD shall be cooled to -25° C and kept at this temperature for one hour. Then it shall be allowed to return to ambient temperature for one hour. It shall then be heated to 100°C, kept at this temperature for one hour and then allowed to return to ambient temperature.

3.2 Vibration test The ICSD shall be subjected to five complete cycles in the range 25 Hz to 500 Hz at 5 g. The teat should be conducted by sweeping through all frequencies in the range at an uniform rate from the minimum to the maximum and returning to the minimum frequency in 10 min. or longer. The test shall also dwell 30 min. at each resonance frequency found.

3.3 Drop test: The ICSD shall be dropped from a height of 4 m onto a hard surface so as to suffer maximum damage.

3.4 Impact test: A steel hammer weighing 0.5 kg shall be dropped from a height of 0.5 m onto the ICSD which is Positioned on a steel anvil so as to suffer maximum damage.

3.5 Accidental condition fire test: This test shall be carried out on a separate ICSD complete with the source or on the source(s) mounted in the source holders in the presence of part of the ICSD which are sufficiently representative of the whole ICSD. This shall be placed in a furnace and air shall be passed through the furnace for the duration of the test at a flow rate of 1 to 5 l/min. and condensed and filtered before release to atmosphere. The ICSD (or the parts thereof) shall be heated from room temperature to 600°C and kept at this temperature for one hour. If the total activity released from the source exceeds 185 Bq per source, then the source shall be considered to result in unacceptable level of contamination.

3.6 High temperature industrial fire, and incineration test: The competent authority must be satisfied that the source(s) In an ICSD will not result in an unacceptable release of activity to atmosphere in the event of a high temperature fire (for industrial ICSDs) or of incineration of waste (for single station (ICSDs). A high temperature fire and incineration test shall therefore be carried out on the complete ICSD or on the source(s) mounted in their source holders in the presence of parts of the ICSD which are sufficiently representative of the whole ICSD. A separate ICSD should be used for this test. The procedure shall be the same as that described in paragraph 3.5 except that the ICSD (or the parts thereof) shall be heated to 1200^{o}C and retained at this temperature for one hour.

If the activity released from the source exceeds 1 per cent of the activity of the source, then the source shall be considered to result in an unacceptable release of activity to atmosphere.

4. **Evaluation of teat results**

After each test specified in 3.1 to 3.4, the ICSD shall be examined for physical damage, increase in external radiation level and damage of source resulting in increase of contamination of the device. There shall be no increase in radiation level and no increase in contamination.

5. **Marking and labelling**

5.1 Each ICSD shall be indelibly marked so that the markings can be seen when mounted, with the basic trefoil radiation symbol, and adjacent to this symbol in letters and figures, the date upon which the useful life will end.

5.2 Each ICSD shall bear a label on the exterior of the device in a manner that the information is observable, and on the label the following information shall be given in permanent lettering:

(a) The word Am-241 and activity on the date of manufacture

(b) A serial number

(c) The words "This ICSD complies with AERB/SS-4 (1991)"

(d) The following wordings "Do not open" -

"When the device is to be discarded, it has to be returned to the manufacturer for safe disposal."

(e) The manufacturer's Name and Address.

Reference

Smoke detectors for use in automatic electrical fire alarm system. IS: 11360:1985; Bureau of Indian Standards.

6.FLUORESCENT LAMP STARTERS

STANDARD SPECIFICATIONS FOR RADIOLOGICAL SAFETY IN THE DESIGN AND MANUFACTURE

1. **Scope**

The radioactive material introduced into fluorescent lamp starter bulbs is either in the form of a mixture of radioactive gas with a carrier gas (Kr-85 in Argon) or as a dot of radioactive suspension or paint (Titanium-Tritium suspension or Thorium Paint), This Standard specifies the essential requirements for the design and manufacture of the starters so that the members of the public are adequately protected against exposure or intake of radioactivity due to normal handling and use and possible accidents.

2. **Design and construction**

2.1 The quantity of radioactivity in any single lamp starter device shall be as low as practicable. The maximum activity and quantity for Krypton-85, Tritium, Promethium-147 and Thorium shall be 5 Bq, 40 kBq, 20 kBq and 0.05 mg respectively.

2.2 The thickness of the glass bulb shall not be less than 0.6 mg cm^{-2}(range of tritium betas in glass).

2.3 The glass bulb shall be enclosed in an outer container made of metal or polycarbonate material.

2.4 The enclosure should have adequate mechanical rigidity to prevent the breakage of the glass bulb or prevent loss of radioactivity under normal handling and use.

3. **Teats on prototype**

3.1 Teats on glass bulb :
The testing procedures given below are recommended. Procedures demonstrated to be at least equivalent are also acceptable.

The tests shall be carried out consecutively on the same glass bulb in the order shown below:

3.1.1 Temperature Test: The glass bulb shall be heated in " air to a temperature of +80°C within 5 min., kept at this temperature for one hour, then cooled to -20°C in less than 45 min. and kept at this temperature for one hour.

3.1.2 External Pressure Test: The glass bulb shall be put in a test chamber and subjected to air pressure of 25 kPa and 200 kPa for a duration of 15 min. the pressure being returned to atmosphere between each period.

3.1.3 Immersion Test: The glass bulb shall be immersed in a cold bath at 0°C for 15 minutes. Within one minute, transfer to a hot bath at 65°C and keep it in the hot bath for 15 minutes. Again, within one minute transfer to the cold bath.

3.2 Tests on complete device

3.2.1 Drop Test: The device shall be dropped from a height of 4 meters on a hard surface.

3.2.2 Bump Test: The device shall be subjected to.2000 bumps from a height of 5 cm on a hard surface.

4. **Evaluation of test results**

After carrying out the tests specified under 3.1 and 3.2, the glass bulb shall be examined for breakage and loss of radioactivity. There shall not be any release of radioactivity.

Reference

Starters for fluorescent lamps (third revision) IS 2215: 1983; Bureau of Indian Standards.

7. INCANDESCENT GAS MANTLES

STANDARD SPECIFICATIONS FOR MANUFACTURE

1. **Scope**

Thorium as thorium nitrate is used in the manufacture of incandescent gas mantles. The quantity of thorium per mantle depends on the rated candle power of the gas mantle.

2. Specification of average quantity of thorium in a mantle

Candle Power	Average Quantity of Thorium per mantle
upto 400	600 mg
> 400	800 mg

3. Individual mantles shall be packed in a sealed weather-proof sachet prior to distribution and retail outlet.

4. **Tests on manufactured product**

4.1 Wipe test: Wipe the external surface of the gas mantle 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 gas mantle and which, under conditions of the test, has been demonstrated to be effective in removing any radioactive material present. Measure the activity of the swab. This activity shall be less than 185 Bq.

4.2 Immersion test: Immerse the gas mantle in distilled water and heat the water to 50°C and hold it at this temperature for 5 hours. Remove the gas mantle and measure the activity in the water. The activity released into water shall be less than 185 Bq.

5. **Marking and labelling**

On the satchet containing individual gas mantle the following instructions shall be printed.

* Always light and use gas mantle in well ventilated area - Keep safe distance while lighting the gas mantle.

* Keep gas mantle and ash out of reach of children Ash should not be swallowed.

* Do not keep mantles or ash near skin for prolonged periods - Dispose off ash in trash - Wash hands after handling gas mantle and ash.

Reference

Gas mantles (first revision)

IS 2788: 1987; Bureau of Indian Standards.

8. ANTISTATIC DEVICES

STANDARD SPECIFICATIONS FOR MANUFACTURE

1. **Scope**

Antistatic devices contain Po-2lO as ceramic microspheres. The standard specifies the radiation safety requirements for the design and manufacture of static eliminators so that members of the public are adequately protected against exposure or intake of radioactivity due to normal handling, use and possible accidents.

2. **Design and construction**

2.1 The activity of Po-210 adsorbed in ceramic microspheres incorporated in a device shall not exceed 5 MBq. The average activity of a microsphere taken randomly from a lot shall be 3.7 MBq. Each device shall not incorporate more than one microsphere.

2.2 The average diameter of the microsphere shall be 40 um.

2.3 The microspheres shall be rigidly fixed on a backing Plate with a binder or resin.

2.4 The source mount shall be covered with a wire mesh to prevent direct physical contact with the source.

3. Tests on prototype and evaluation of test results

The following tests shall be conducted on the prototype source assembly. Procedures demonstrated to be equivalent are also acceptable.

3.1 Swipe test: The exterior surface of the source assembly shall be swiped with dry cotton and tested for transfer of contamination. The activity on the cotton swab shall be less than 0.04 Bq cm^{-2} of area swiped.

3.2 The prototype source assembly shall be placed in a glass tube through which air is allowed to flow at a rate of 1 to 5 l/minute and condensed and filtered before release to atmosphere. The device shall be heated to 600°C and kept at this temperature for one hour.

The activity removed from the Source shall not exceed 185 Bq.

3.3 Immersion test: The source assembly shall be immersed completely in water or detergent or chelating agents for 24 hours. Heat the liquid to 50°C and hold it at this temperature for 5 hours. The sealed source shall be removed and the activity in the liquid shall be measured. If the detected activity is less than 185 Bq, the sealed source is considered to be leak-free.

3.4 Impact teat: The source assembly shall be positioned on a steel anvil and a steel hammer weighing 5O gm shall be dropped on to the source from a height of 1 meter. The source integrity shall be tested by the swipe test.

4. **Marking and labelling**

Each device shall be indelibly marked on the exterior of the device with the following:

(a) The trefoil symbol, the word Po-21O, and activity on the date of manufacture.

(b) A serial number

(c) The words "This Device complies with AERB/SS-4(1991)"

(d) The following words :

"Do not open"

(e) The manufacturer's Name and Address.

9. OTHER CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

1. Some other consumer products used in the country also contain radioactive substances. These include (a) tungsten are electrodes containing thorium for special welding Jobs,

(b) ceramic or porcelain ware, glazed with uranium (c) opthalmic glasses and camera lenses containing K-40 and thorium, and (d) gemstones irradiated by neutrons to improve their quality and value. The amount of radioactivity in such products is small and hence may not pose any serious radiation hazard due to their use, misuse and normal methods of disposal.

2. Manufacturers and distributors of such items are also required to seek prior approval from the competent authority for manufacture and supply to users. The concerned parties are advised to apply to the competent authority in the prescribed format with the particulars of product and an assessment of radiation safety associated with the handling, use and disposal of the product by members of the public. The competent authority shall grant approval for manufacture and marketing of these products on a case-by-case basis.

APPENDIX- I

CONSUMER PRODUCTS REQUIRING PRIOR APPROVAL

	Product	Radionuclide	Maximum Activity or mass per product
l(a)	Radioluminous Timepieces (General)	H-3	300 MBq (worn on person) 400 MBq (not worn on person)
		Pm-147	6 MBq (worn on person) 8 MBq (not worn on person)
(b)	Special timepieces	H-3	1 GBq
		pm-147	20 MBq
2.	Gaseous Tritium Light Sources(GTLSs)	H-3	75 GBq
3.	Gaseous Tritium Light Devices (GTLDs)	H-3	925 GBq (Exit signs)
4.	Ionization Chamber Smoke Detectors(ICSDs)	Am-241	40 kBq
5.	Fluorescent Lamp Starters	Kr-85	5 Bq
		H-3	40 kBq
		Th	0.05 mg
6.	Incandescent Gas Mantles	Th	600 mg (upto 400CP) (Average) 800 mg (> 400 CP) (Average)
7.	Antistatic devices	Po-210	5 MBq

Appendix -II

Government of India

Atomic Energy Regulatory Board

Vikram Sarabhai Bhavan.
4tb Floor, North wing,
Anushaktinagar,
Bombay 400 094.

Ref: AERB/RSD/TA/450-CP/ **Date:**

APPLICATION FOR PRE-MARKETIHG APPROVAL OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES

A. DETAILS OF MANUFACTURER

1. Name and address of the applicant:

2. Name and address of the manufacturer of the consumer product:

3. Name and address of the manufacturer/supplier of radioactive material:

4. Persons to be contacted regarding this application:

5. Name, Type and Model designation of the consumer product requiring type approval:

B. **DOCUMENTATION FOR GRANTING APPROVALS**

The following information in appropriate detail, shall be given by the manufacturer to the competent authority for issuing prior approval.

a) A description of the product, its intended use, its expected useful life and the function served by the radionuclide(s).

b) The identification, concentration and total activity of the radionuclide(s) used in the product.
(The applicant should justify the choice of radionuclide, particularly in relation to other radionuclides of lower radiotoxicity or more appropriate half-life that could be used.)

c) The justification for the use of the radioactive substance in the product making comparisons with any non-radioactive alternatives.

d) The chemical and physical form of the radionuclides to be applied to or incorporated in the product.

e) Details of the desi9n and construction of the product, particularly as related to the containment and shielding of the radionuclide under normal and adverse conditions of use and disposal, and the accessibility of the radioactive substance to unauthorised persons (detailed drawings should be provided).

f) Details of manufacturing process. Give flow chart.

g) The organisation of quality control and the quality control tests to be applied to radiation source and other components and to the finished products.

h) The external radiation level from the product and the method of measurement.

i) The activity of the total amount of radioactive material (s) expected to be distributed in the products annually and an indication of the importance of the market including a description of the future avenues of distribution or resale in second-hand market.

j) Instructions for use, installation and maintenance as appropriate.

k) Information on the possible consequences of misuse, damage or failure.

l) A description and the results of tests for demonstrating the radiological integrity of the product in normal use, misuse and accidental damage.

m) Details of information (in advertising material, technical brochures, maintenance instructions, guarantee certificates, etc...) on the radionuclide(s) incorporated and the total amount of activity in the product.

n) Information on how it is intended to label the product, e.g. name of product, date of manufacture identification and activity of radionuclide(s).

I certify that the information furnished by me is correct to the best of my knowledge and belief.

Place: Signature . . . . . .

Date : Name . . . . . .

Designation . . . . . .

GUIDELINES FOR RADIATION SAFETY IN MANUFACTURE OF CONSUMER PRODUCTS

These guidelines are provided as general information to manufacturers. For further details, the manufacturers may consult the AERB Safety Guide on the subject

1. The Layout of the manufacturing facility shall be in accordance with the guidelines provided by the Division of Radiological Protection, BARC. The plans shall be approved by DRP, BARC prior to commencement of radiation work.

2.(a) Handling of radioluminous paint shall be carried out in glove box or ventilated box. All dusty operations and mixing of paint shall be carried out in glove box. Painting on time pieces shall be done in ventilated box. The glove box shall be maintained at a negative pressure of about 200 Pa. The ventilated box shall be connected to an exhaust system to remove radioactive vapours away from occupied areas. The exhaust system should be made 'ON' at least 30 minutes prior to commencement of work.

(b) Filling of GTLS and Fluorescent Lamp Starter bulbs with radioactive gas shall be carried out in well ventilated fumehood to prevent contamination of working environment. The fumehood should be under negative pressure. The ventilation system shall provide 6-8 air changes per hour.

(c) All operations involving thorium powder and thorium solution shall be done in well ventilated rooms provided with exhaust. The ventilation system shall provide 6-8 air changes per hour.

3. The walls and floors of rooms where radioluminous paints or thorium solutions are handled shall be lined with impervious strippable paint and smooth tiling to facilitate easy decontamination.

4. Contamination of work surfaces, floor and walls and items used in the work areas shall be checked periodically and if found contaminated, shall be promptly decontaminated.

5. All radioactive wastes arising from day-to-day operations shall be collected in polythene bags and kept segregated in a separate room. Any unwanted or unused radioactive material shall also be treated as waste. Low levels of liquid wastes can be disposed off by dilution and flushing in sanitary sewage. Low level solid wastes can be buried underground. Guidance from DRP, BARC should be sought on the method of disposal. The disposal procedures will depend on the nature of waste and level of activity.

While collecting the wastes, solid wastes should be segregated. Organic solvents and other liquids should also ii be segre9ated in separate bottles. Activity limits for disposal of radioactive wastes through sanitary sewage and land burial are given in the Table. I and II.

Table I. Activity limits for disposal through sanitary sewerage systems

Radio-nuclide	Maximum limit on total discharge per day	Average monthly concentration of radioactivity in the discharge
	MBq	MBq m^{-3}
H-3	92.5	3700.0
Pm-147	4.00	22.0

Note: If the flow of water is 2 x 10^5 litres per day, this will dilute the activity to authorised concentration.

Table II. Activity limits for disposal by ground burial

Radionuclide	Maximum activity in a pit
	MBq
H-3	9250.0
Pm-147	40.0

GLOSSARY OF TERMS USED IN THE STANDARD

i) "Absorbed Dose"' means energy absorbed per unit mass. Its unit is the joule per kilogram which is given the special name gray (Gy).

ii) "Activity" -See Radioactivity.

iii) "Competent Authority" means any officer or authority appointed by the Central Government by Notification under the Radiation Protection Rules -1971. Chairman, Atomic Energy Regulatory Board has been notified as the Competent Authority.

iv) "Contamination" means the presence of a radioactive substance on surface in quantities in excess of O.4 Bq cm^{-2} for beta and gamma emitters or 0.04 Bq cm^{-2} for alpha emitters.

v) "Effective Dose" means the weighted sum of the equivalent doses in all the tissues and organs of the body. Equivalent Dose means the absorbed dose averaged over a tissue or organ and weighted for the radiation quality of interest. The radiation weighting factor is selected for the type and energy of radiation incident on the body or in the case of sources within the body, emitted by the source. The unit of effective dose is the joule per kilogram, which is given the special name Sievert (Sv), 1 mSv is 10^{-3} Sv. The sum of the effective doses of all members in an exposed group of individuals is called the collective dose and is expressed as person sievert (person Sv).

vi) "Ionizing radiation" in the context of consumer products means, alpha particles, electrons or beta particles and gamma photons emitted by radioactive nuclei during the decay process. These radiations are capable of producing ion pairs (electrically positive or negative ions) when they interact with atoms and molecules of matter.

vii) "Radioactivity or Activity" is the spontaneous disintegration of unstable nuclei accompanied by the emission of one or more types of radiation. Redionuclides are isotopes of atoms having the property of radioactivity. Radioactive substance is a substance having radionuclide in it. The unit of radioactivity is, disintegrations per second which is given the special name becquerel (Bq). 1 Bq = 1 disintegration per second. 1 kBq=lOOO Bq and 1 "I MBq=lO^{6} Bq, 1 GBq=lO^{9} Bq.

viii)"Sealed Source-: Radioactive source sealed in a capsule or having a bonded cover being strong enough to prevent contact with and dispersion of the radioactive material under condition of use and wear for which the sealed source was designed.

ix) "Sealed Source Holder": Mechanical support for the sealed source.

FORMAT OF APPROVAL CERTIFICATE

AERB/445/TAC/CP **Date:**

APPROVAL CERTIFICATE FOR CONSUMER PRODUCT CONTAINING RADIOACTIVE SUBSTANCE

1. The Atomic Energy Regulatory Board hereby approves the (name of the consumer product} Model No . . . . manufactured by M/s.XYZ for supply to the public in India.

2. The (name of the consumer product) incorporating _____ Bq of (radioactive substance) complies with the AERB Standard Specifications for Radiological Safety in the design and manufacture of consumer product containing radioactive substances -AERB-SS-4 11991).

3. Any change in the specifications or in the manufacturing process shall be implemented only with the prior approval of the Competent Authority.

4. M/s. XYZ shall keep AERB informed about the total quantity of radioactive substance and the total number of item of the approved model supplied to the public in each year. Such information shall be in the form of reports to AERB in the month of January of the following year.

5. Kindly acknowledge the receipt of the certificate.

COMPETENT ATHORITY

M/s.XYZ _____

MEMBERSHIP OF THE TASK AND THE WORKING GROUP

Membership of the Task Group to prepare Radiation Safety Criteria for the Approval of Consumer Products Containing Radioactive Substances.

Dr. I.S. Sundara Rao	-	Convener	-	Atomic Energy Regulatory Board, Bombay.
Dr, S.K. Mehta	-	Member	-	Health Physics Divn., Bhabha Atomic Research Centre, Bombay.
Shri S.R.K. Iyer	-	Member	-	Board of Radiation & Isotope Technology, Bombay.
Shri S.P. Agarwal	-	Member	-	Division of Radio-logical Protection, Bhabha Atomic Research Centre, Bombay.

Membership of the Working Group to Prepare Standard Specifications for Design and Manufacture of Consumer Products Containing Radioactive Substances. (AERB 55-4)

Shri P.Gangadharan	-	Convener	-	Division of Radio-logical Protection, Bhabha Atomic Research Centre, Bombay.
Shri S.V. Achrekar	-	Member	-	Indian Gas Mantle Manufacturers Association, Bombay
Smt. S. Cherian	-	Member	-	Board of Radiation & Isotope Technology, Bombay
Shri V.V. Gokhale	-	Member	-	Peico Electronics & Electricals Ltd., Thane.
Shri M. Subramanyam	-	Member	-	IIMT Watch Factory-IV, Tumkur.
Dr. I. S. Sundara Rao	-	Member	-	Atomic Energy Regulatory Board, Bombay.

The Task Group and Working Group received assistance from Smt. R. N. Vadiwala (AERB) in the preparation and finalisation of the documents.