RI - DNMS Licensee Event Report Disposition

Licensee: Mercy Hospital of Pittsburgh

Event Description:

License No: 37-01321-02 Docket No: 03002182 MLER-RI: 2006-025

Event Date: 07/05/06 Report Date: 07/06/06 HQ Ops Event #:

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [X] Other 10 CFR 35.3067
- [ ] 10 CFR 30.50 Report
- [ ] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [ ] Telephone Inquiry — Inspector/Date
- [ ] Preliminary Notification/Report
- [ ] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [X] Review at Next Inspection

3. REPORT EVALUATION

- [X] Description of Event
- [X] Levels of RAM Involved
- [N/A] Cause of Event
- [X] Corrective Actions
- [X] Calculations Adequate
- [N/A] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

N/A

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality

N/A

- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

N/A

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

☐ Non-Public

☒ Public ~~SIGI~~ SUNSI REVIEW COMPLETE

Inspector Signature: [signature] Date: 7-13-06

Branch Chief Initials: [signature] Date: 7/18/06

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05

Mercy Hospital of Pittsburgh
1400 Locust Street
Pittsburgh, PA 15219-5166

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 6, 2006

RECEIVED
REGION I
2006 JUL 10 PM 12: 20

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Document Control Desk
Director
Washington, DC 20555-0001

To Whom It May Concern:

Mercy

The Mercy Hospital of Pittsburgh (License # 37-01321-02) is notifying the U.S. Nuclear Regulatory Commission via this report in accordance with 10 CFR 35.3067. On July 5, 2006 it was determined that a Cs-137 brachytherapy sealed source, manufactured by Medi Physics, Inc., model # CDCT1, serial # CY 389, revealed the presence of 0.003 uCi of removable contamination at a photopeak identified as Cs-137. The full spectrum counts noted an activity of 0.006 uCi of removable contamination. These measured amounts either approached or slightly exceeded the identified contamination limit of 0.005 uCi. Subsequent leak tests identified reduced contamination.

Mercy Hospital immediately withdrew the source from use. The source has been segregated, shielded and secured to prevent any further use of the source. Medi Physics, Inc. will be contacted and we will request that they accept return of the source. In the event that the manufacturer refuses to accept the return of the source it will be transferred to a licensed disposal company. Copies of the leak test evaluations and the source calibration certificate are attached for reference.

If you need further information, please me at 412-232-8130 or David Wonderly, Medical Physicist, at 412-232-7352.

Sincerely,

Barbara Bookser

Barbara Bookser, B.S., CNMT
Radiation Safety Officer

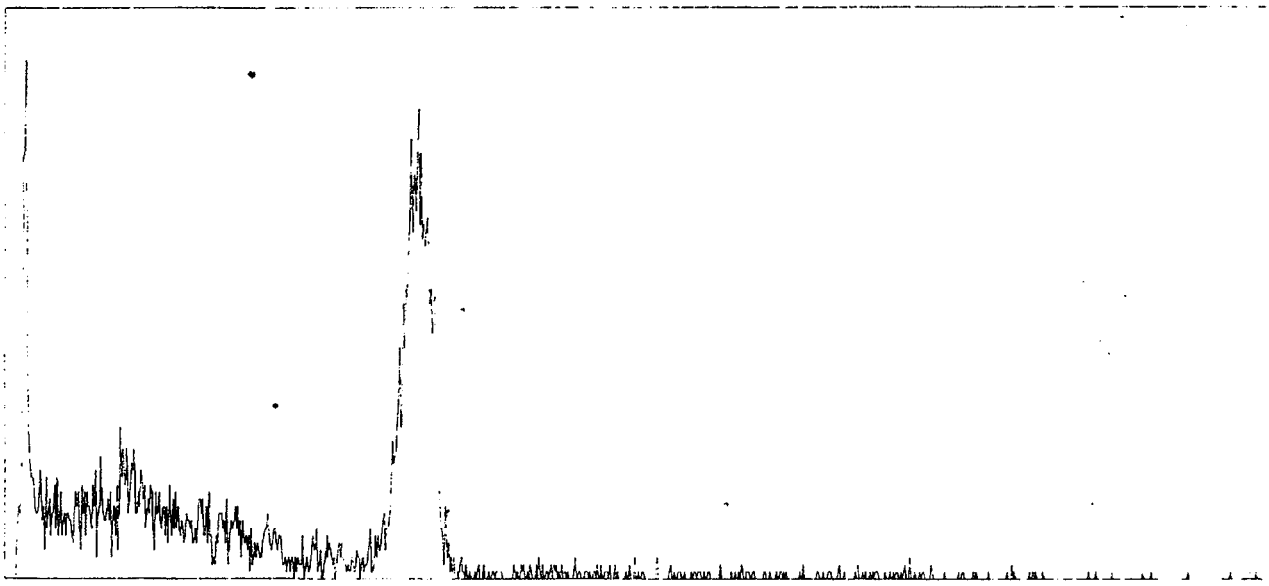
Cc: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B

Mercy Hospital of Pittsburgh

Department of Nuclear Medicine
Captus 2000 s/n=cnv-063

WIPE TEST ANALYSIS

Jul 5, 2006 17:25:44



Wipe Location: Cs-137 SN CY389 7/3/06 1st wipe
Trigger Level: 22000 dpm
Count Time: 60 seconds

Energy (keV)	Net Counts (cpm)	Region of Interest (min)	(max)	Isotope	Activity (µCi)
32.5	336.0	11	22	I125	
192.0	224.0	86	110		
660.5	1.492 k	309	352	Cs137	0.003

Full Spectrum Total Counts (cpm) = 4.065 k
Full Spectrum Net Counts (cpm) = 3.316 k at Efficiency of 24.10 %
Gives Activity of 0.006 (µCi)

Full Spectrum Background Counts (cpm) = 749.0

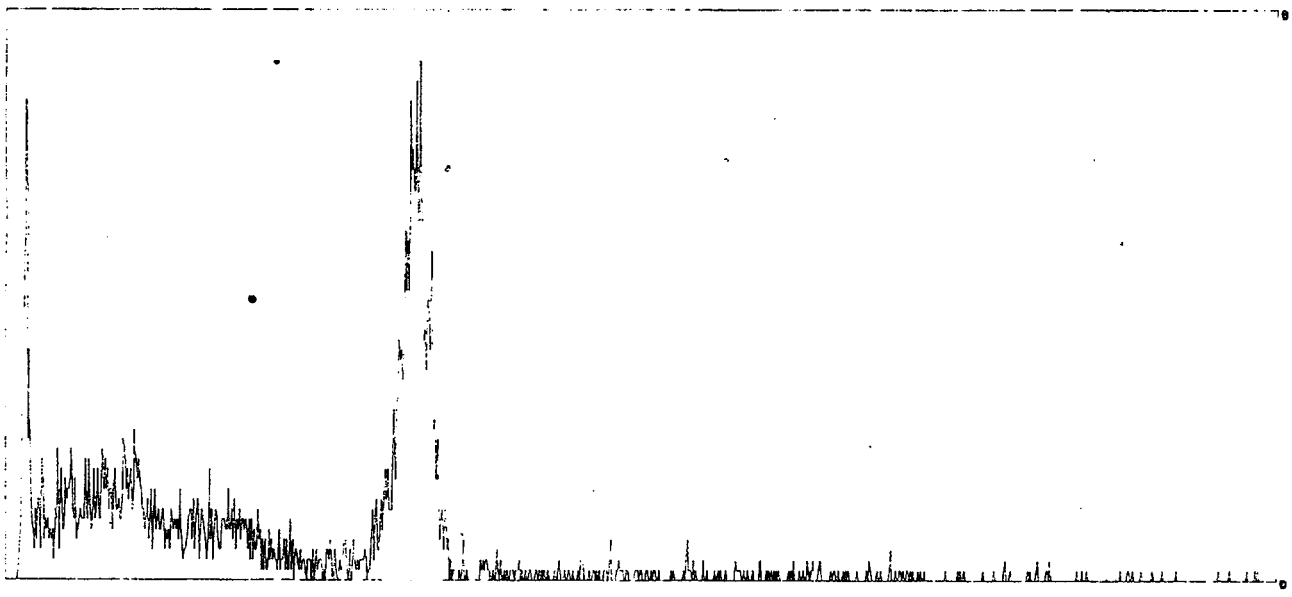
** Indicates Trigger Level Exceeded

Mercy Hospital of Pittsburgh

Department of Nuclear Medicine
Captus 2000 s/n=cnv-063

WIPE TEST ANALYSIS

Jul 5, 2006 17:27:42



Wipe Location: **Cs-137 SN CY389 7/3/06 2nd wipe**
Trigger Level: **22000 dpm**
Count Time: **60 seconds**

Energy (keV)	Net Counts (cpm)	Region of Interest (min)	(max)	Isotope	Activity (µCi)
32.1	220.0	11	22	I125	
94.7	100.0	40	56		
200.8	148.0	90	114		
658.5	1.047 k	308	351	Cs137	0.002

Full Spectrum Total Counts (cpm) = 3.020 k
Full Spectrum Net Counts (cpm) = 2.271 k at Efficiency of 24.10 %
Gives Activity of 0.004 (µCi)

Full Spectrum Background Counts (cpm) = 749.0

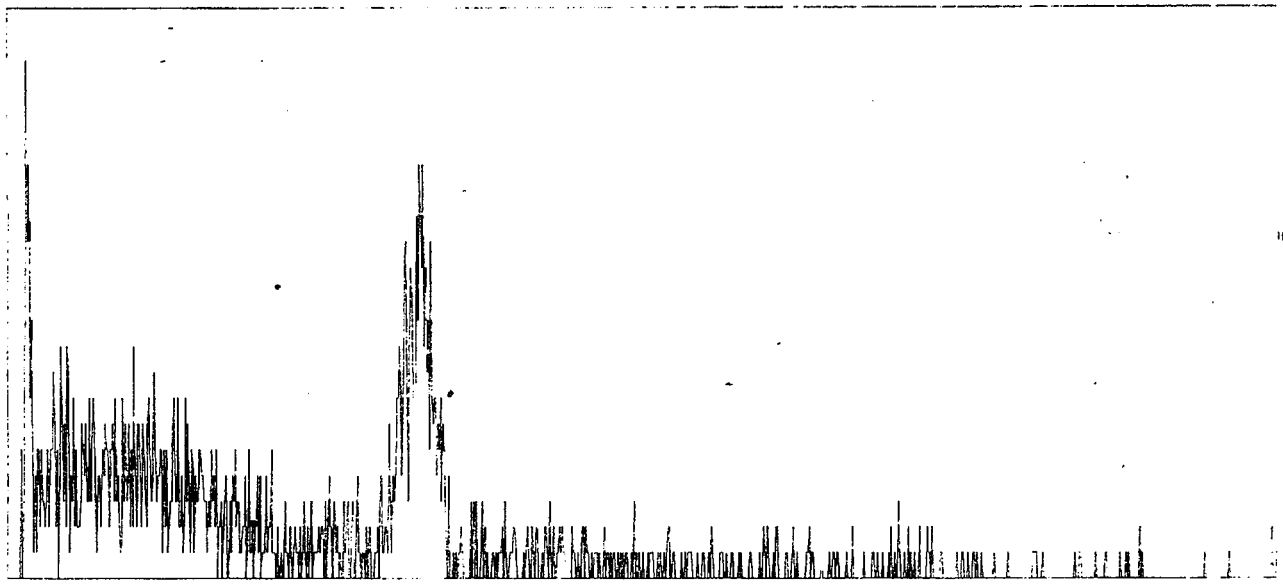
** Indicates Trigger Level Exceeded

Mercy Hospital of Pittsburgh

Department of Nuclear Medicine
Captus 2000 s/n=cnv-063

WIPE TEST ANALYSIS

Jul 5, 2006 17:29:32



Wipe Location: **Cs-137 SN CY389 7/5/06 3rd wipe**
Trigger Level: **22000 dpm**
Count Time: **60 seconds**

Energy (keV)	Net Counts (cpm)	Region of Interest (min)	(max)	Isotope	Activity (µCi)
32.7	83.00	11	22	I125	
658.6	312.0	308	351	Cs137	0.001

Full Spectrum Total Counts (cpm) = 1.483 k
Full Spectrum Net Counts (cpm) = 734.0 at Efficiency of 24.10 %
Gives Activity of 0.001 (µCi)

Full Spectrum Background Counts (cpm) = 749.0

** Indicates Trigger Level Exceeded

Sealed Radioactive Source Test Report

Model No.: CDCT1
Product Code No.: CDCS J2
Description: Tube Source
ANSI Classification C64344

Radioisotope: Cs-137
Nominal activity: (Please refer to notes below)
Capsule: XN241/XN242
Special Form Certificate No.: None

Classifications are based on the testing of specimen sources and give the levels expected from production sources.

Recommended working life: 10 Years
See other side for explanation

Source Serial number	Measurement AKR µGy per hr at 1 m 7 Jul 93	Measurement date	Leakage test type L date passed	Leakage test type D date passed	Contamination test type A date passed
			See other side for description of tests		
CY 326	78.3 76.98	27 Oct 92 22 Jul 93	09 Nov 92	09 Nov 92	12 Oct 94
CY 380	82.2 81.06	14 Dec 92 22 July 93	27 Jan 93	27 Jan 93	12 Oct 94
CY 389	82.3 81.06	14 Dec 92 22 Jul 93	27 Jan 93	27 Jan 93	12 Oct 94
CY 394	77.9 76.82	14 Dec 92 22 Jul 93	27 Jan 93	27 Jan 93	12 Oct 94
CY 847	78.9	22 Jul 93	13 Aug 93	13 Aug 93	12 Oct 94
CY 850	78.8	22 Jul 93	13 Aug 93	13 Aug 93	12 Oct 94
CY 851	79.4	22 Jul 93	13 Aug 93	13 Aug 93	12 Oct 94
CY 853	79.3	22 Jul 93	13 Aug 93	13 Aug 93	12 Oct 94

Notes Batch No. None
Medi-Physics, Inc., does not report Nominal Activity for medical gamma-emitting sources. Nominal values could lead to misleading dosimetric results when these sources are used clinically. To convert AKR values to equivalent millicurie activity of Cs-137, multiply the AKR value by 0.347. To convert AKR values to mg Ra eq, multiply the AKR value by 0.138.

AEA Technology 888 272 2242

Customer: Mercy Hospital
Customer's Order No.: 50513

Internal Order No.: 11069

Signed: TR 742
Date: 13 Oct 94

Medi Physics, Inc.,
2636 S. Clearbrook Drive
Arlington Heights, Illinois 60005
Client Services: 1-800-MEDI-123 (1-800-633-4123)

In Canada call:
1-416-847-1166 / 1-800-387-7160 (Ont/Que)
1-800-387-7146 (rest of Canada)

medi+physics®

Quality control

Testing for leakage and contamination

Stringent tests for leakage are an essential feature of radioactive sources production. The methods adopted depend on the design and intended application of the source, and also on statutory requirements. Where necessary, tests can be specially modified to meet particular requirements.

The standard methods used for testing radiation sources are listed below.

Wipe test A

The source is wiped with a swab or tissue, moistened with ethanol or water; the activity removed is measured. Limit: 185 Bq, 0.005 μCi.

Wipe test B

The source is wiped with a swab or tissue, moistened with ethanol or water; the activity removed is measured. Limit: 1.85 kBq, 0.05 μCi.

Bubble test D

The source is immersed in a suitable liquid (ethanediol) and the pressure in the vessel reduced to 100 mm of mercury. No bubbles must be observed.

Immersion test F

The source is immersed in water at 50 °C for 8 hours and the activity in the water measured.
Limit: 1.85 kBq, 0.05 μCi.

Immersion test L

The source is immersed in water at 50 °C for 4 hours and the activity in the water measured.
Limit: 185 Bq, 0.005 μCi.

Immersion test M

The source is immersed in water which is raised to 100 °C and held at that temperature for 10 min. The water is then removed, the source cooled, and the procedure repeated twice. Sources are passed if the activity extracted in the final procedure does not exceed 185 Bq, 0.005 μCi.

Helium mass spectograph test H

Limit: leak rate of 10^{-8} standard cm^3/sec.

Emanation test K
(scintillation counting test for radon)

The appliance is immersed in a solution of a phosphor in an organic liquid under vacuum; the leakage of radon is measured by liquid scintillation counting. (DWIGHT, D.J. Radiochemical Centre Report R. 176). The limit corresponds to about 1.85 Bq, 5×10^{-11} Ci per 24 hours.

IAEA Special Form

'Special Form' is a test specification for sealed sources given in the IAEA transport regulations.
(IAEA Safety Series No. 6, 1967/1973 revised edition†).

The required tests are:
impact test
percussion test
bending test (only for long, slender sources)
heat test
After each test the source must be subjected to leak testing.

Source working life

The *'recommended working life'* is our recommendation of the period within which the source should be replaced. The period given has been assessed on the basis of such factors as, toxicity of nuclide, total initial activity, source construction (eg capsule design, source insert type, etc), half-life of nuclide, typical application environments, operational experience, test performance data, etc.

Adverse environments could affect the appearance and integrity of a source. It is the user's responsibility to regularly inspect and test the source in order to assess at what point during the "recommended working life" the source should be replaced.

ANSI Classification

American National Standards Institute has proposed a system of classification of sealed radioactive sources based on safety requirements for typical uses (See ANSI N542—1977).

"This system provides a manufacturer of sealed radioactive sources with a set of tests to evaluate the safety of his products under working conditions. It also assists a user of such sealed sources to select types which suit the application he has in mind, especially where protection against the release of radioactive material is concerned."

The tests to which specimen sources are subjected are listed in Table 1.

Each test can be applied in several degrees of severity.

Test results are expressed as a five figure code to indicate the severity of the tests.

These figures are preceded by the letter C or E to show whether the source activity is less than or greater than certain limits. These limits depend upon the toxicity, solubility and reactivity of the active component of the source.

C indicates that the activity level of the source does not exceed the prescribed limit and
E that the limit is exceeded.

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 hr)	−40 °C (20 min) +180 °C (1 hr)	−40 °C (20 min) +400 °C (1 hr) and thermal shock 400 °C to 20 °C	−40 °C (20 min) +600 °C (1 hr) and thermal shock 600 °C	−40 °C (20 min) +800 °C (1 hr) thermal shock 800 °C to 20 °C	Special Test
External pressure	No Test	25 kN/m² abs. (3.6 lb/in²) to atmosphere	25 kN/m² abs. to 2 MN/m² (290 lb/in²) abs.	25 kN/m² abs. to 7 MN/m² (1 015 lb/in²) abs.	25 kN/m² abs. to 70 MN/m² (10 153 lb/in²) abs.	25 kN/m² abs. to 70 MN/m² (24 656 lb/in²) abs.	Special Test
Impact	No Test	50 g (1.8 oz) from 1 m (3.28 ft) and free drop ten times to a steel surface from 1.5 m (4.92 ft)	200 g (7 oz) from 1 m	2 kg (4.4 lb) from 1 m	5 kg (11 lb) from 1 m	20 kg (44 lb) from 1 m	Special Test
Vibration	No Test	30 min 25 to 500 Hz at 5 g peak amp.	30 min 25 to 50 Hz at 5 g peak amp. and 50 to 90 Hz at 0.635 mm amp. peak to peak and 90 to 500 Hz at 10 g	90 min 25 to 80 Hz at 1.5 mm amp. peak to peak and 80 to 2000 Hz at 20 g	Not Used	Not Used	Special Test
Puncture	No Test	1 g (15.4 gr) from 1 m (3.28 ft)	10 g (154 gr) from 1 m	50 g (1.76 oz) from 1 m	300 g (10.8 oz) from 1 m	1 kg (2.2 lb) from 1 m	Special Test

Notes to Table 1.

1. Details of the testing procedures are given in ANSI N 542. A further class X can be used where a special test procedure has been adopted.
2. External pressure
   100 kN/m² = 1 atmosphere (approx.)
3. Impact test
   The source, positioned on a steel anvil, is struck by a steel hammer of the required weight, the hammer has a flat striking surface, 25 mm diam. with the edges rounded.
4. Puncture test
   The source, positioned on a hardened steel anvil, is struck by a hardened pin, 6 mm long, 3 mm diam., with hemispherical end, fixed to a hammer of the required weight.

Performance requirements for typical uses

Typical applications in which sealed radioactive sources may be used, with minimum performance requirements are also given in ANSI N542. (see Table 2 below). These recommendations take into account normal usage and reasonable accidental risks, but do not include exposure to the risk of fire, explosion or corrosion.

Table 2. Sealed source performance requirements for typical uses.

Sealed source use		Sealed source test and class: Temperature	Pressure	Impact	Vibration	Puncture
Industrial radiography	Unprotected source	4	3	5	1	5
	Source in device	4	3	3	1	3
Gamma gauges (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 X-ray fluorescence analysis (excluding gas-filled sources)		3	3	2	2	2
Oil well logging		5	6	5	2	2
Portable moisture and density gauges (including hand held or 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 1.11 MBq, 30 μCi		2	2	2	1	2
Gamma irradiation sources	Unprotected source	4	3	4	2	4
	Source in device	4	3	3	2	3
Ion generators (source-device combination may be tested)	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors	3	2	2	2	2
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
	Beta teletherapy	5	3	3	2	2
	Interstitial and intracavitary appliances*	5	3	2	1	1
	Surface applicators	4	3	3	1	2

*Sources of this nature may be subject to severe deformation in use. Manufacturers and users may wish to formulate additional or special test procedures.

If the sealed source has a 'C' classification,
Table 2 can be used directly to assess the suitability of the source for the proposed application provided that there is no significant fire, explosion or corrosion hazard.

If such a hazard does exist, the user and the manufacturer have to consider the following factors to determine whether additional testing is required:

1. consequences of loss of activity,
2. quantity of active material contained in the source,
3. radiotoxicity,
4. chemical and physical form of the material and the geometrical shape,
5. environment in which it is to be used,
6. protection afforded to the source or source-device combination.

If the sealed source has an 'E' classification,
Table 2 cannot be used directly.

To determine whether any additional testing is necessary, an evaluation of the fire, explosion and corrosion hazards must first be made and a separate evaluation of the use and design of the source.

Some of our source designs exceed the recommendations of Table 2 and may therefore be acceptable for the applications listed despite the 'E' classification.

Laboratory applications

The ANSI classification system does not refer explicitly to sources designed for research laboratory usage because of the wide variety of applications and environments in which such sources might be used.

Special applications

No test program can cover all possible combinations of environments to which a source may be exposed.

Users should therefore consult our technical staff before using sources in potentially adverse environments.