MAR 22 1996

MEMORANDUM TO: Steven L. Baggett, Chief
Sealed Source Safety Section
Source Containment & Devices Branch, NMSS

FROM: Paul H. Lohaus, Deputy Director
Office of State Programs

Original Signed By:
PAUL H. LOHAUS

SUBJECT: AGREEMENT STATE SEALED SOURCE AND DEVICE CERTIFICATES

Attached for your information and distribution are Agreement State sealed source and device certificates we have received directly from the States.

Attachments:
As stated

DISTRIBUTION:
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PDR YES__X__ NO____

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NAME	LBo'Hing		PLohaus		RBangart					
DATE	03/19/96		03/ /96		03/22/96					

OSP CODE: SP-0-9

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 22, 1996

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ATTACHMENT

1. IL-103-S-102-S AMENDED IN ENTIRETY 2/20/96
2. IL-136-S-348-S ISSUED 2/21/96
3. NJ-218-S-102-S ISSUED 3/8/96
4. IL-234-D-101-G ISSUED 2/15/96
5. IL-599-D-101-G AMENDED IN ENTIRETY 2/23/96

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE / DEVICE
(AMENDED IN ENTIRETY)

NO: IL-103-S-102-S DATE: February 20, 1996 PAGE: 1 of 7

SOURCE TYPE: Gamma Source

MODEL: Cs7.PO2, Cs7.PO2-A ("A" designates a source with adapter)

DISTRIBUTOR:

BEBIG Trade, Inc.
100 W. Monroe Street
Suite 1101
Chicago, IL 60603

MANUFACTURER:

BEBIG Isotopentechnik und
Umweltdiagnostik
GMBH
Robert-Rossle-Strasse 10
D-13125 Berlin
Germany

CESIO Ltd. (A BEBIG subsidiary)
RADIOVA 1
10227 Prague
Czech Republic

ISOTOPE:	MAXIMUM ACTIVITY:
Cs-137	18.5 GBq (500 mCi)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (D) Gamma Gauges

CUSTOM SOURCE: ___ YES _X_ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE / DEVICE
(AMENDED IN ENTIRETY)

SOURCE TYPE: Gamma Source

DESCRIPTION:

The ceramic, with dimensions of 3mm x 3mm, is saturated with the cesium nitrate solution, air dried and subsequently exposed to laser energy and heated to a temperature of 1300°C to create the glazed ceramic. The Cs-137 is thereby bonded to the ceramic and cannot be eluted.

After glazing, the ceramic activity is measured and is visually inspected. The ceramic is then placed into the primary capsule, plug inserted, and TIG welded. Following leak test of the primary capsule, it is placed in the outer capsule and TIG welded. The design feature of double stainless steel encapsulation and glazed ceramic provide the prime materials for source integrity. The outer capsule has a maximum length of 15.9 mm and a maximum width of 6.4 mm.

LABELING:

The following information will be engraved on the surface of the sources:

- BEBIG Logo "BB"
- Radionuclide
- Model "Cs7.PO2"
- Serial number/Year of manufacture "XXXX/XX"
- "Radioactive"

DIAGRAMS:

See attachments 1, 2 & 3.

SOURCE TYPE: Gamma Source

CONDITIONS OF NORMAL USE:

The Cs7.PO2 gamma industrial source is intended for rigorous industrial operations. The users of the source are manufacturers/operators of thickness, level, or density gauges. The manufacturer indicates a recommended working life of 15 years.

Other applications according to Principal Use Code D are acceptable provided that the environmental conditions do not exceed the stress limitations provided by the ISO 2919 (International Equivalent of ANSI N542-1977) classification of C66646.

Because of double encapsulation, theoretical analysis shows that the release of activity cannot occur up to a temperature of 1500°C. Due to the "non-leachable" nature and stability to high temperature of the ceramic, danger of release below 1500°C is estimated to be zero.

ISO (ANSI) classification categories are the ceilings to which test prototypes have been subjected. In no manner does the classification suggest long term operation under upper limit tolerances. If in doubt about operating conditions, the issuing agency should be contacted.

PROTOTYPE TESTING:

The prototypes passed the tests described in the ISO 2919 (ANSI N542-1977) performance classification and are classified as ISO C 66646.

Testing of prototypes was performed on 3 original dummy sources and 4 radioactive sources. The "dummy" sources were manufactured in exactly the same manner as production models. The only exception is that the ceramic was soaked in non-radioactive cesium. Hence, the chemical and physical properties are similar.

The dummy sources then under went vacuum bubble testing in accordance with ISO 9978, 6.2.1 (ANSI N542, A2.2.1) and passed.

SOURCE TYPE: Gamma Source

PROTOTYPE TESTING (cont'd):

The active sources were prototype tested and then successfully passed an immersion with boiling test in accordance with ISO 9978, 5.1.2 (ANSI N542, A2.1.3)

The Cs7.PO2 source has been special form certified by the IAEA German competent authority, Bundesanstalt Fur Forschung Material Und-Prufung (BAM).

EXTERNAL RADIATION LEVELS:

The following figures are calculated from the specific gamma ray constant for Cesium-137 τ_{20} and point source dose function for a 18.5 GBq source (τ_{20} from H. Reich, "Dosimetrie Ionisierender Strahlung," B.G. Teubuer, 1990).

Distance	Dose Rate
5 cm	650 mGy/h (65000 mrad/h)
30 cm	17.5 mGy/h (1750 mrad/h)
100 cm	1.5 mGy/h (150 mrad/h)

QUALITY ASSURANCE AND CONTROL:

BEBIG GmbH quality system is compatible with ISO 9001 and U.S. NRC Regulatory Guide 6.9, and a copy of the BEBIG GmbH Quality Manual is on file with the Department.

The following tests ensure that each finished sealed source meets the design specifications:

Visual Tests

a. Visual inspection for deformation and/or other irregularities of the weld.

SOURCE TYPE: Gamma Source

QUALITY ASSURANCE AND CONTROL (cont'd):

b. Visual inspection for deformation and/or other irregularities of the surface of the source.

Leakage Tests

a. Inner capsule - immersion test (boiling liquid)
Test specification conducted in accordance with ISO 9978, 5.1.2 (ANSI N542-1977 "Immersion with boiling test," A2.1.3).

b. Outer capsule - vacuum bubble test. Test specification conducted in accordance with ISO 9978 part 6.2.1 plus 1 additional minute of bubble observance (ANSI N542-1977 "Vacuum bubble test," A2.2.1).

Surface Contamination Test

a. Wet wipe test. Test specification conducted in accordance with ISO 9978, 5.3.1 (ANSI N542-1977 "Wipe (smear) test," A2.1.1).

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- This source may be distributed only to persons specifically licensed for manufacturing or distribution of sealed sources or devices by the Department, the Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State.

(Reviewer Note: Manufacturers and distributors authorized for this source must operate under a quality assurance program approved by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State which includes provisions for receipt and inspection of sources.)

- This source shall be leak tested at 6 month intervals using techniques capable of detecting 0.005 uCi of removable contamination.

SOURCE TYPE: Gamma Source

LIMITATIONS AND OTHER CONSIDERATIONS OF USE (cont'd):

- The Models Cs7.PO2 and Cs7.PO2-A shall not be subjected to environmental extremes or other conditions of use in excess of the ANSI classification of 77C66646.

- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. These services should be provided by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(Reviewer Note: BEBIG Trade, Inc. does not provide any vendor services for sources such as installation, disposal or leak testing. Licensees requesting use of these sources must provide evidence of adequate user support in these areas.)

- This registration sheet and the information contained within the references shall not be changed without the written consent of the Department.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data submitted by the BEBIG Trade, Inc. for source design Models Cs7.PO2 and Cs7.PO2-A, we conclude that the source design should maintain its integrity for normal conditions of use and accidental conditions which might occur.

SOURCE TYPE: Gamma Source

REFERENCES:

The following documents for the BEBIG Trade, Inc. Models Cs7.PO2 and Cs7.PO2-A are hereby incorporated by reference and are made a part of this registry document:

- Application dated October 19, 1994.
- Letters, with attachments, dated July 6, 1995, July 17, 1995, July 24, 1995, October 20, 1995, November 27, 1995, December 5, 1995, January 29, 1996 and February 12, 1996.
- BEBIG GmbH Quality Manual, QM-Dok.-Nr. Original, with Enclosure 2 of letter dated November 27, 1995 and Enclosure 1 of letter dated December 5, 1995.
- Telefacsimile dated February 19, 1996.

ISSUING AGENCY: Illinois Department of Nuclear Safety

DATE: 2/20/96 REVIEWED BY: Charles A. V[illegible]

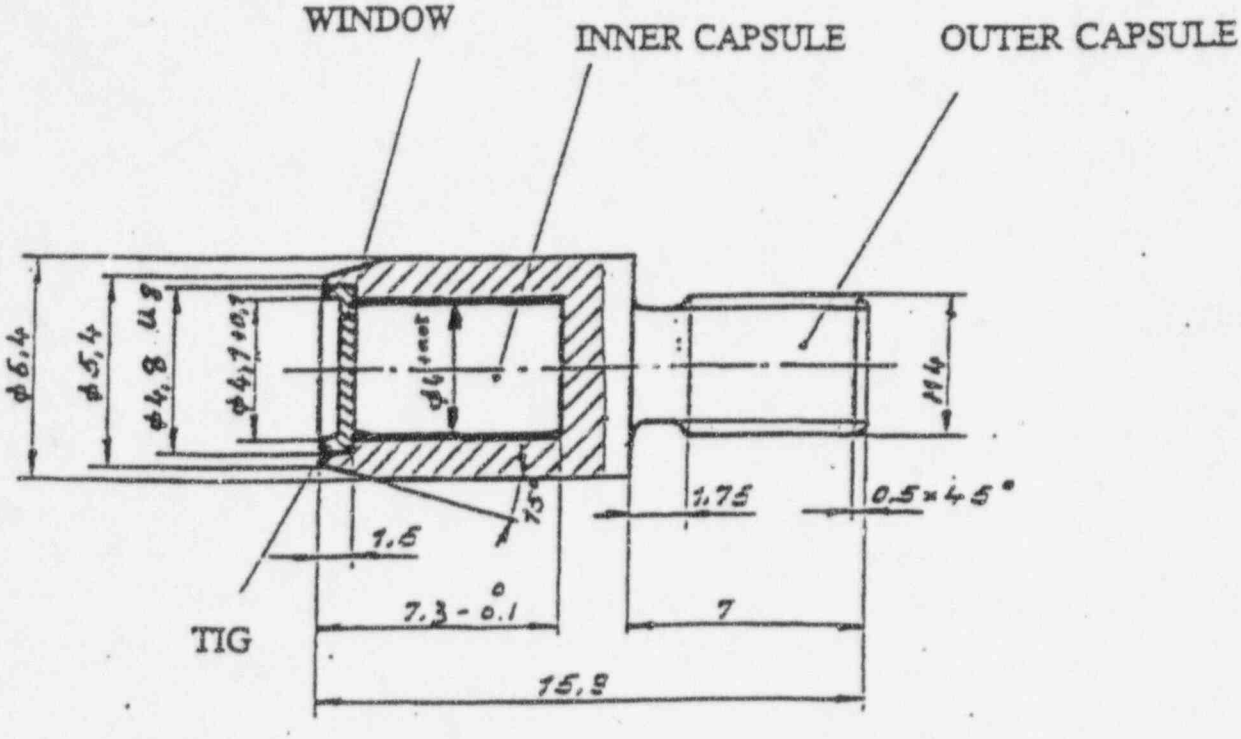
DATE: 2/20/96 CONCURRENCE: Joseph G. Klinger

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE / DEVICE
(AMENDED IN ENTIRETY)

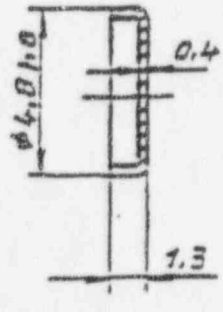
NO: IL-103-S-102-S DATE: February 20, 1996 ATTACHMENT 1

SOURCE TYPE: Gamma Source

Cs7.PO2 SOURCE



WINDOW



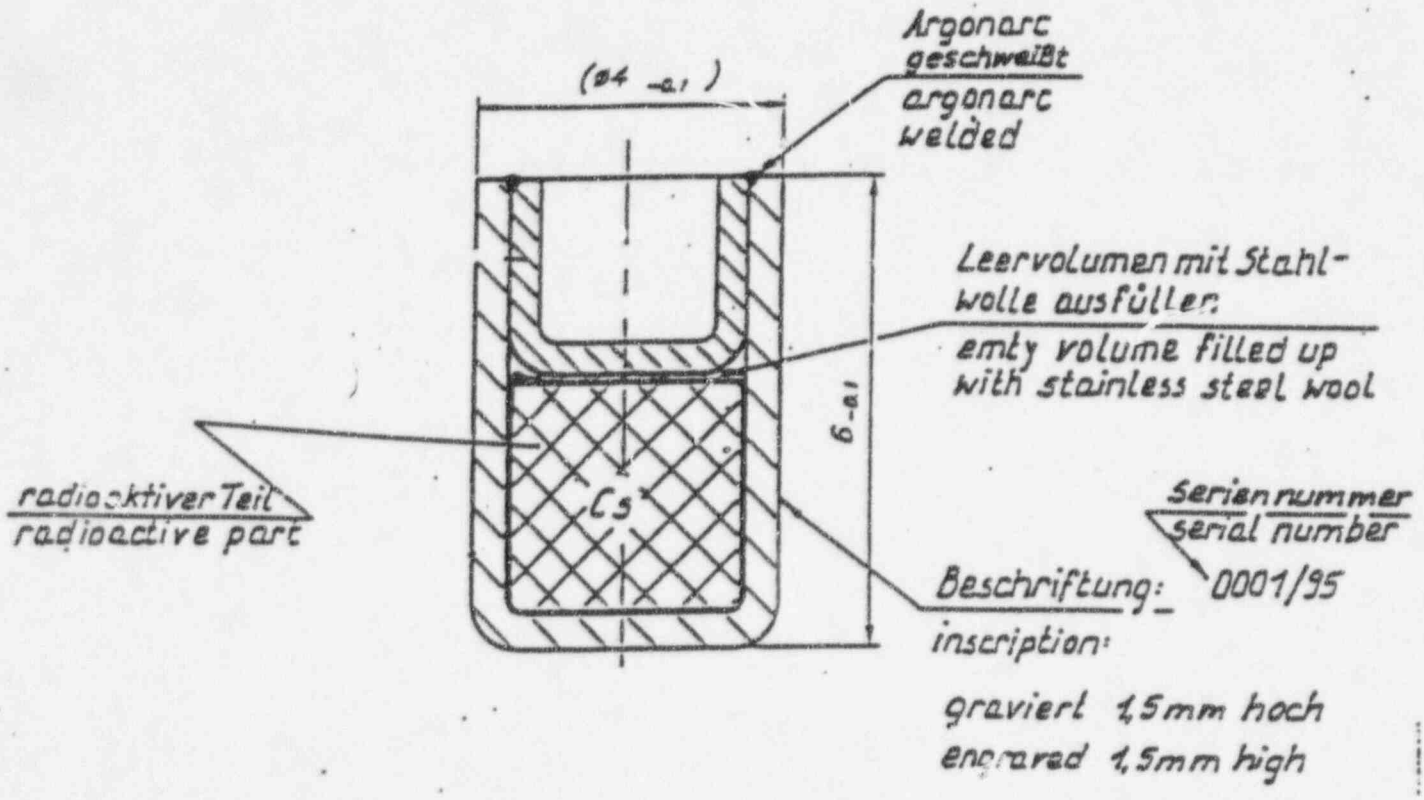
All dimensions in mm

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE / DEVICE
(AMENDED IN ENTIRETY)

NO: IL-103-S-102-S DATE: February 20, 1996 ATTACHMENT 2

SOURCE TYPE: Gamma Source

INNER CAPSULE Cs7.KO1
(Not to be authorized for use without Cs7.PO2)

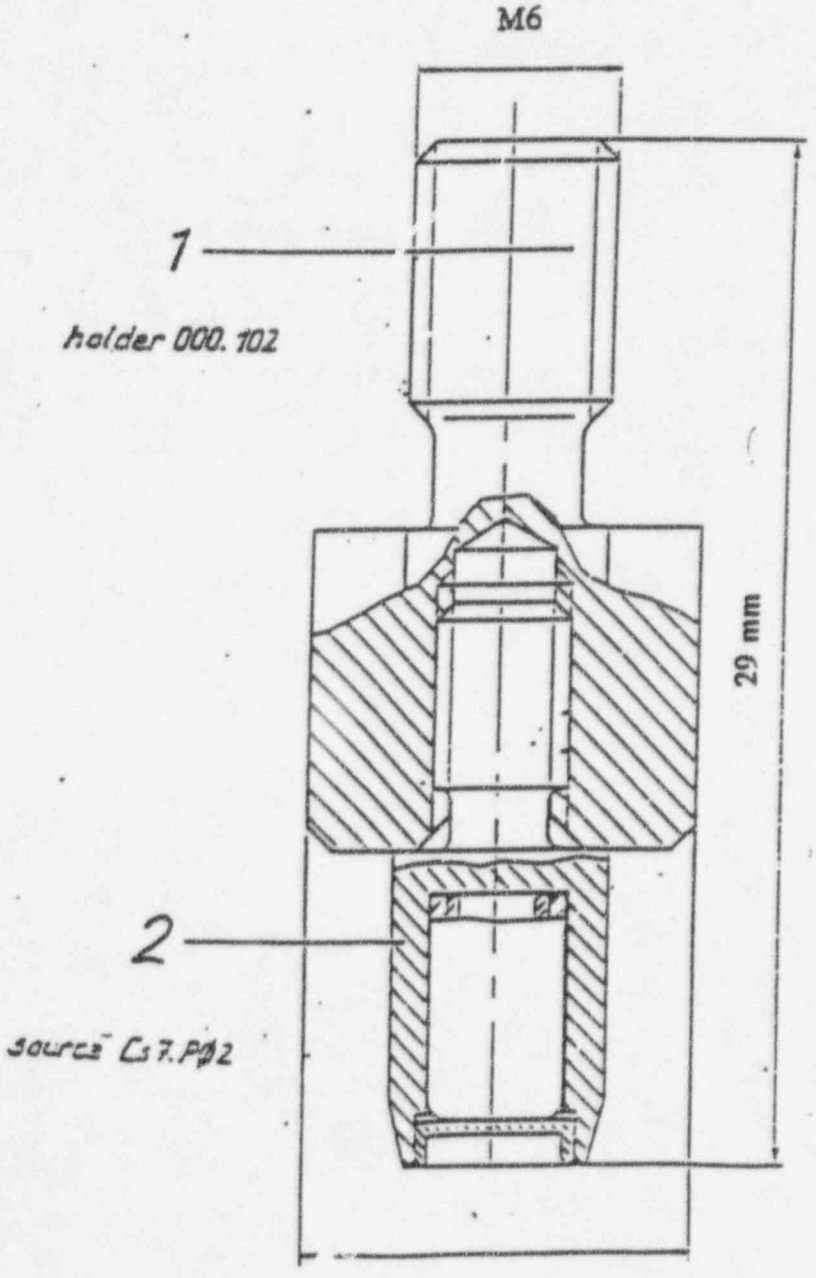


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE / DEVICE
(AMENDED IN ENTIRETY)

NO: IL-103-S-102-S DATE: February 20, 1996 ATTACHMENT 3

SOURCE TYPE: Gamma Source

Cs7.PO2-A HOLDER WITH Cs7.PO2 SOURCE



e = 11.5 Sechskant SW10
(Hexagon, edge to edge = 11.5mm; side to side 10mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: IL-136-S-348-S DATE: February 21, 1996 PAGE: 1 of 6

SOURCE TYPE: Low Energy Beta Source

MODEL: PHC.C2

DISTRIBUTOR:

Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, IL 60005-4692

MANUFACTURER:

Amersham Buchler GmbH & Co. KG
Gieselweg 1
D-3300 Braunschweig
Germany

ISOTOPE:

Promethium-147 (Pm-147)

MAXIMUM ACTIVITY:

2.5 Ci (92.5 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (E) Beta Gauging

CUSTOM SOURCE: ___ YES _X_ NO

SOURCE TYPE: Low Energy Beta Source

DESCRIPTION:

The manufacturer reports that the radionuclide is in the form of a ceramic insert, consisting of promethium-147 incorporated as an oxide into an aluminosilicate glass. The mixture of these ingredients is designed to give the ceramic its high melting point of 900°C and structural integrity. The enamel (melting point 900°C) containing promethium-147 is melted into a space 45 mm long (semi-circular ends), 9.5 mm wide and 1 mm deep in a steel insert 54.1 mm long x 16.5 mm wide x 5 mm deep. The enamel is protected by a 5 μm titanium foil. The ceramic technology is very similar to the ceramic technology used in current americium-241 and strontium-90 ceramic sources already licensed by the Nuclear Regulatory Commission (NRC). The VZ-1844 sources are sealed by gluing all components with a heat resistant glue (Gupalon 20).

LABELING:

The source is permanently engraved with the following information:

1. Isotope Pm-147
2. Unique Serial Number
3. Manufacturer Symbol, Flying A
4. Trefoil
5. Model Number

All other pertinent information such as activity, date of measurement, leakage, and contamination tests and ANSI rating will be included on a test report accompanying each source.

DIAGRAMS:

See Attachment 1.

SOURCE TYPE: Low Energy Beta Source

CONDITIONS OF NORMAL USE:

Sources will predominantly be used in the industrial environment in conjunction with a detector system to measure the thickness and density of very thin and light substrates such as in "Saran Wrap" and other types of plastic sheets. These sources will not be used under conditions that exceed the ANSI rating of C33222.

The sealed source will be mounted in a holder such that the shielded device containing the shutter mechanism will act as an automatic fail-safe mechanism when a source is not in use.

The radioactive component of this source is an enamel with melting point of 900°C and it is highly unlikely that there would be any significant dispersal of radioactive material if the source (or device) was involved in an accident or fire.

The recommended working life for this source is five years.

PROTOTYPE TESTING:

Testing was carried out by the manufacturer using four active sources containing up to 11 mCi promethium-147. According to the manufacturer the source achieved an ANSI N542 classification of 77C33222.

EXTERNAL RADIATION LEVELS:

Promethium-147 is a low energy beta emitter, with maximum energy at 225 KeV. There are no accompanying gamma rays except for low energy bremsstrahlung generated by the steel insert.

SOURCE TYPE: Low Energy Beta Source

The following dose rates at varying distances were reported by the manufacturer from a 2.5 Ci source.

DOSE RATES FOR THE PHC.C2 DWG. NO. VZ-1844

Active, window side

5 cm	4100 R/hr, 40 Sv/hr (calculated)
30 cm	1.4 R/hr, 14 mSv/hr (measured)
100 cm	<10 mR/hr, <0.1 mSv/hr (measured)

Inactive, rear side

5 cm	60 mR/hr, 0.6 mSv/hr (measured)
30 cm	<10 mR/hr, <0.1 mSv/hr (measured)
100 cm	<10 mR/hr, <0.1 mSv/hr (measured)

QUALITY ASSURANCE AND CONTROL:

These sources are manufactured according to the Quality Assurance Program described in Amersham-Buchler's Quality Assurance Manual, issued in October 1994, with revisions issued May 1995. A copy of the manual including revisions is on file with the Illinois Department of Nuclear Safety.

The following in-process tests are conducted during manufacture of the sources:

Before Source Assembly

Pressure test on source window
Measurement of emission and total activity from radioactive component

After Source Assembly

Measurement of emission and total activity
Low pressure test on window and glued lid
Visual inspection of window and glued lid

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

SOURCE TYPE: Low Energy Beta Source

The Final Quality Controls are:

Wipe test after assembly
Another wipe test one week later
Visual inspection before the source is packaged

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

- The source shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- The source shall be leak tested at six-month intervals using techniques capable of detecting 0.005 microcurie of removable contamination.
- The sources shall not be subjected to environmental or other conditions of use which exceed the ANSI N542 classification of 77C33222.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. These services should be provided only by persons specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform these services.
- When installed, the Model PHC.C2 sources should be protected from exposure to environmental factors such as highly corrosive chemicals, temperature extremes, impact, vibration, puncture, fire, or explosion as appropriate to the intended use.
- This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the Illinois Department of Nuclear Safety.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: IL-136-S-348-S DATE: February 21, 1996

SOURCE TYPE: Low Energy Beta Source

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data sited below, the claimed ANSI classification of the source, and that this source is similar in construction to a previously approved design, we continue to conclude that the source design Model PHC.C2 would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during the use specified in this certificate.

REFERENCES:

The following supporting documents for the Amersham Source Model PHC.C2 are hereby incorporated by reference and are made a part of this registry document.

- Amersham Corporation letter of application, with attachments, dated October 26, 1995.
- Amersham Corporation letters, with attachments, dated January 31, 1996.
- Amersham Corporation letter dated February 20, 1996.

ISSUING AGENCY: Illinois Department of Nuclear Safety

DATE: 2/21/96 REVIEWED BY: Charles G. Vinson

DATE: 2/21/96 CONCURRENCE: Joseph G. Klinger

REGISTRY OF RADIOACTI[illegible]ALED SOURCES AND DEVICES
SAFETY EVALUA[illegible]OF SEALED SOURCE

NO: IL-136-S-348-S DATE: February 21, 1996 ATTACHMENT 1

Sealed Source PHC.C2, DWG. VZ-1844