Yale University

Office of Environmental Health & Safety
135 College Street, 1st Floor
New Haven, Connecticut 06510-2411

Telephone: 203 785-3550
Fax: 203 785-7588

April 15, 2005

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

Re: Report of a damaged ionizer source [Ni-63]

To whom it may concern:

In accordance with 10 CFR 30.50(c)(2), and subsequent to my conversation with Elizabeth Ullrich of the US Nuclear Regulatory Commission, this letter is to report damage to an electroplated Ni-63 beta ionization ring source. The model NER 004 source is 10 mCi of Ni-63, and was supplied by Isotope Products Laboratory of Valencia, CA. It was used for ionization experiments in the Yale Mechanical Engineering Department at Mason Laboratory.

The source had not been in active use, but remained stored in place inside the equipment. The damage to the source was identified on March 22, 2005 subsequent to routine, semi annual leak testing. Subsequent survey of the laboratory failed to identify any contamination, other than within the equipment where the Ni-63 source rested. Using tweezers, the source was removed from the equipment, briefly examined, and immediately taken out of service. This removal from service is permanent. That is, the source will be disposed of via a licensed radioactive waste broker.

The cause of the damage to the source appears to have been compression within the equipment when a flared, thin wall tube holding the source in place was tightened beyond the design point. The compression slightly deformed one end of the very thin ring, creating a depressed edge. There is not evidence to indicate source failure or source malfunction.

We have discussed the source with Isotope Products Laboratory staff. Do note that the levels of Ni-63 identified on wipe tests are below the 0.5 uCi listed in the vendor's Registry of Radioactive Sealed Sources and Devices documents. [Attachments 1-3] Levels of contamination of the equipment were found to range from approximately 0.03 to 0.18 uCi. Decontamination of the portion of the equipment housing the source has been completed.

There were no occupational exposures. There is no evidence of personnel or laboratory contamination. The source has been removed from service, and will be disposed via a licensed broker. Internal contamination of the equipment housing the source has been successfully decontaminated.

Should you have any questions or require additional information, please contact me at the Office of Environmental Health and Safety at (203) 737-2142.

Sincerely,
Agnes Barlow

Agnes Barlow, CHP
Radiation Safety Officer

cc: US NRC, Region 1 Elizabeth Ullrich
Dr. Stephanie Spangler, Deputy Provost for Biomedical and Health Affairs

IL MS501

Subject: Ni-63 rings
Date: Thu, 24 Mar 2005 11:11:40 -0800
From: Cary Renquist <crenquist@isotopeproducts.com>
To: "'agnes.barlow@yale.edu'" <agnes.barlow@yale.edu>

Aggie:

Here are copies of the SSDRs for Ni-63 sources:
0406S214S -- This is your ring's "cousin", the NER-004
0406S215S -- This is your ring, the NER-004R (it references the NER-004 SSD).
The 214 SSD states more explicity that the active surface wipe limit is 0.5 uCi.

Are the rings "sealed sources"?: yes, the regulatory body who reviewed the SSD deemed that it is a sealed source subject to the limitations and considerations of use cited in the SSD.

Feel free to contact me via one of the numbers below or just send an email.

Best regards,
Cary

Cary Renquist
Radiation Safety Officer
Manager, Health Physics
Isotope Products Laboratories
661-309-1010 x343 (voice)
818-558-4087 (fax)
661-510-7015 (cell)

ssdr_04060214.pdf	**Name:** ssdr_04060214.pdf **Type:** Acrobat (application/pdf) **Encoding:** BASE64 **Download Status:** Not downloaded with message

ssdr_04060215.pdf	**Name:** ssdr_04060215.pdf **Type:** Acrobat (application/pdf) **Encoding:** BASE64 **Download Status:** Not downloaded with message

Attachment 1

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

NO.: CA-0406-S-214-S (Supercedes MA-0476-S-131-S) DATE: September 28, 2001 PAGE: 1 OF 6

SOURCE TYPE: Beta Ionizing Source

MODEL: NER-004, NER-004P

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
Phone (818) 843-7000
FAX (818) 843-6168

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

50 millicuries (1.85 GBq)

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(S) Foil Source

CUSTOM SOURCE:

____ YES _X_ NO

Attachment 2

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

SOURCE TYPE: Beta Ionizing Source

DESCRIPTION:

The sources consist of radioactive Ni-63 electroless plated or electroplated onto components fabricated from the approved materials in the following table:

MODEL	APPROVED BASE MATERIALS
NER-004	Gold, platinum, copper, or monel (copper-nickel alloy)
NER-004P	Gold, platinum, copper, monel, or stainless steel

The NER-004 indicates a foil configuration of IPL's design and manufacture. The NER-004P allows plating onto components of other manufacturer's design and manufacture. All sources must meet the following constraints:

Maximum Activity: 50 mCi (1.85 GBq)
Minimum Specific Activity: 5 mCi/mg (0.185 GBq/mg)
Radiopurity of Ni-63: > 99.9%.

LABELING:

The Model NER-004 foils are serialized by scribing or laser engraving on the non-radioactive side. A self-adhesive label is affixed to the primary container for the source foil. The label states the model number, activity, date, and serial number; and has the words "Caution Radioactive Material" along with the manufacturer's name and address.

The Model NER-004P sources are permanently marked on a non-radioactive surface of the component with the radiation symbol, serial number and model number (i.e. "NER-004P"). If space permits, the sources will also be labeled with the isotope, activity, and the words "Caution, Radioactive Material".

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

SOURCE TYPE: Beta Ionizing Source

DIAGRAM:

Attachment 1: NER-004 Dose Rate Report
Attachment 2 NER-004 Source Foil Diagram

CONDITIONS OF NORMAL USE:

The Models NER-004 and NER-004P are beta ionizing sources and are routinely used in gas chromatography systems, gas detection equipment, and aerosol neutralizing applications. The source shall not be subjected to temperatures which exceed 752°F (400°C).

PROTOTYPE TESTING:

The manufacturer tested prototype models NER-004 and NER-004P sealed sources to the ANSI N542-1977 77C32211 requirements. In addition, the prototypes were subjected to 752°F (400°C) in air for 2 hours. Wipes of the inactive side of the sources after the test revealed no removable contamination above 0.005 microcurie (185 Bq).

EXTERNAL RADIATION LEVELS:

The manufacturer reports the maximum external levels as follows:

Model	Location	Dose Rate (deep/shallow) mRem/hr/mCi	Dose Rate (deep/shallow) mSv/hr/GBq
NER-004	On contact with active side inactive side	 0.15/12.3 1.1/1.1	 0.04/3.32 0.30/0.30
NER-004P	At mouth of cavity*	0.11/6.7	0.03/1.81

See Attachment 1 for diagrams of dose rate locations.

SOURCE TYPE: Beta Ionizing Source

* The electroplating is typically within a cavity of the component and this is the typical radiation dose when installed in the cavity.

QUALITY ASSURANCE AND CONTROL:

The sources are manufactured and distributed under the guidelines of Isotope Products Laboratories' quality assurance and control program. The California Department of Health Services has deemed the program acceptable for licensing purposes. A copy of the program is on file with the California Department of Health Services.

REVIEWERS NOTE: The Models NER-004 and NER-004P sources are being manufactured and distributed by Isotope Products Laboratories from two locations in California. However, only one address is listed on PAGE 1 OF 6, since mail service is no longer available to the second location. The second address that is not listed is:

Isotope Products Laboratories
1800 North Keystone Street
Burbank, CA 91504

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The maximum activity concentration shall be 15 millicurie (0.555 GBq) per square centimeter.
- The sources shall only be distributed to persons specifically licensed by the NRC, an Agreement State, or Licensing State.
- The sources shall not be exposed to environments which exceed their ANSI Classification.
- The sources shall not be subjected to temperatures which exceed 752°F (400°C).

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

SOURCE TYPE: Beta Ionizing Source

- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination. Removable contamination from the inactive side not exceed 0.005 microcurie and the active side shall not exceed 0.5 microcurie (185 kBq).
- The models NER-004 and NER-004P sources shall only be used in devices which are registered with the NRC or Agreement State.
- Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.
- This registration certificate and the information contained within the reference shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

Based on our acceptance of a previous NRC review of the information and test data cited below, we continue to conclude that the IPL models NER-004 and NER-004P sealed sources are acceptable for registration purposes.

Furthermore, we conclude that the sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents are hereby incorporated by reference and are made a part of this registry document:

- NEN Products letter dated October 1, 1984, with enclosures thereto.
- DuPont Pharmaceuticals Company letters dated December 9, 1991, May 15, 1992, June 11, 1992, July 31, 1992, and May 4, 1993, with enclosures thereto.

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

NO.: CA-0406-S-214-S DATE: September 28, 2001 PAGE: 6 OF 6
(Supercedes MA-0476-S-131-S)

SOURCE TYPE: Beta Ionizing Source

- DuPont Pharmaceutics Company letter dated May 2, 2000, with enclosures thereto.
- Isotope Products Laboratories' letter dated July 26, 2000, with attachments thereto.

ISSUING AGENCY: California Department of Health Services

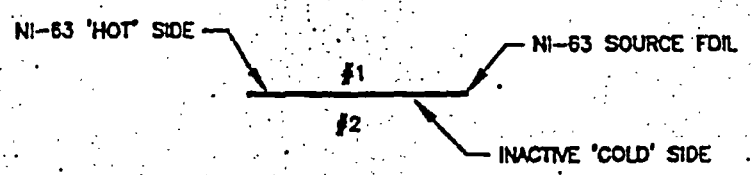
DATE: September 28, 2001 REVIEWED BY: _____
John Rexroth

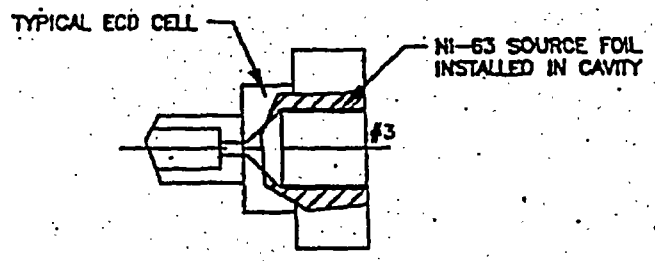
DATE: September 28, 2001 CONCURRED BY: _____
Xiaosong Yin

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

NO.: CA-0406-S-214-S DATE: September 28, 2001 ATTACHMENT: 1
(Supercedes MA-0476-S-131-S)

NER-004 DOSE RATE REPORT





LOCATION NO.	DOSE RATE mREM/HR/MCI DEEP / SHALLOW
#1	0.15 / 12.3
#2	1.1 / 1.1
#3	0.11 / 6.7

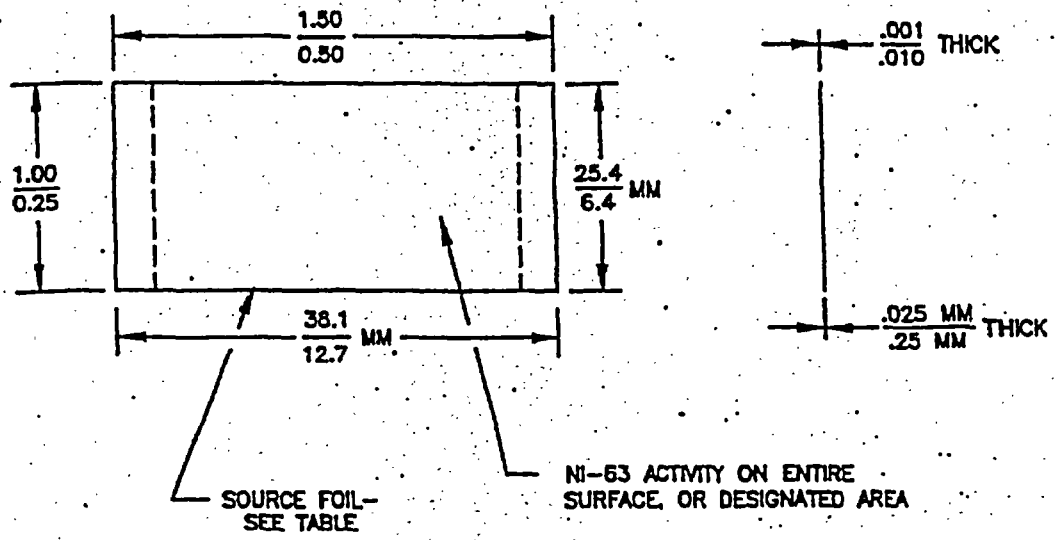
NOTES

1. THE 'LANDAUER' DOSE REPORT IS THE DOSIMETRY DATA FOR THE DURATION OF THE SURVEY (6 HOURS) USING A 15 MCI NI-63 SOURCE FOIL.
2. TLD BADGES ARE 'LANDAUER' TYPE K.

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

NO.: CA-0406-S-214-S (Supercedes MA-0476-S-131-S) DATE: September 28, 2001 ATTACHMENT: 2

NER–004 SOURCE FOIL DIAGRAM



FOIL THICKNESS	FOIL MATERIAL
0.001 – 0.010 IN. (.025 – .25 MM)	COMMERCIAL PURE GOLD, 24K
	COMMERCIAL PURE PLATINUM
	COMMERCIAL PURE NICKEL
	COMMERCIAL PURE COPPER
	NICKEL ALLOY: NICKEL 50 – 100% COPPER 0 – 50% OTHERS 10% MAX.

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

NO.: CA0406S215S (Supercedes MA0476S151S) DATE: May 3, 2001 PAGE: 1 of 6

SEALED SOURCE TYPE: Beta Ionization Ring Source

MODEL: NER-004R, NER-004R-Rh

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories, Inc.
1800 North Keystone Blvd.
Burbank, CA 91504
Phone (818) 843-7000
FAX (818) 843-6168

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.555 GBq)

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(N) Ionization Generator

CUSTOM SOURCE:

_____ YES __X__ NO

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

(Supercedes MA0476S151S)

SEALED SOURCE TYPE: Beta Ionization Ring Source

DESCRIPTION:

Model NER-004R design is similar in methodology of construction to the model NER-004. The only exception to this is that the NER-004R is electroplated on both the inner and external surfaces of the brass ring. That is to say the radioactive Nickel-63 is electroplated onto the entire surface of the brass cylindrical ring. The brass cylinder consists of 70% copper and 30% zinc. The cylinder has a length of 7.70 millimeters, a diameter of 7.0 millimeters, and a wall thickness of 0.15 millimeters. For more information on the source model NER-004, reference SS&D Registry Sheet MA-0476-S-131-S or CA-0406-S-214-S. **Model NER-004R-Rh is essentially the same as NER-004R, but has a non-radioactive rhodium overcoat. The rhodium overcoat is applied as a finished coat after the Ni-63 has been electroplated on to the brass ring. The rhodium is applied by a proprietary chemical deposition process to a thickness of approximately 50 microns.**

LABELING:

The manufacturer reports that it is impractical to label the brass ring. Therefore, information as to the loading, the testing that was done on the source, and the handling procedures are provided as a separate attachment to the shipping papers.

DIAGRAM:

See Attachment 1 for diagram of source size.

CONDITIONS OF NORMAL USE:

The manufacturer reports that the ring sources are intended for use in an air ionization source in a portable chemical agent monitor. The sources are secured in the instrument probe assembly. The intended operational temperature range of the ring sources are -55°C to 70°C. Also the sources are to be used at ambient pressures and be exposed to air with varying degrees of humidity. Other applications of a research and development nature are acceptable provided the

SEALED SOURCE TYPE: Beta Ionization Ring Source

sources are not subjected to environmental conditions which exceed those listed in the following prototype testing section. **Conditions of use for the NER-004R-Rh are the same as established for the NER-004R.**

PROTOTYPE TESTING:

The manufacturer reports that prototype ring sources were subjected to four environmental tests which meet or exceed the recommended operation and conditions of the source/instrument assembly.

- Methanol leach test – The source rings were individually placed in a 10 milliliter methanol solution for a period of 24 hours. The amounts of activity found in the solution by a liquid scintillation counting measurement were less than 5 microcuries.

- Water leach test – Source rings were then individually placed in a 10 milliliter water solution for a period of 24 hours. The amounts of activity found in the solutions by liquid scintillation counting measurements were less than 5 microcuries.

- Heat test – The source rings were placed in a Pyrex tube and heated to 250°C for 4 hours in air. The rings were removed from the oven and allowed to reach ambient temperature. The rings were viewed under 30X magnification and slight oxidation to the ring was observed. The smear test results of the rings each yielded less than 0.1 microcurie. Both pre and post heating conditions were tested.

- Cold test – The ring sources were individually placed in a dry ice bath for a period of 2 hours. The rings were removed from the bath and allowed to reach ambient temperature. The rings were viewed under 30X magnification and no damage to the rings was observed. The smear test results of the rings each yielded less than 0.5 microcurie after the test.

The above source testing criteria are very similar to the model NER-004 which has been in use for several years with no reported problems.

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

SEALED SOURCE TYPE: Beta Ionization Ring Source

EXTERNAL RADIATION LEVELS:

The following are measured dose rates submitted by the manufacturer for the Model NER-004R ring source at various distances. **The radiation profiles established with tests conducted on the NER-004R are adopted as conservative estimates for the NER-004R-Rh.**

On contact with the source surface – 25 R/hr beta

5 centimeters from source surface – 10 R/hr beta

30 centimeters from source surface - Background

QUALITY ASSURANCE AND CONTROL:

The sources are manufactured and distributed under the guidelines of Isotope Products Laboratories' quality assurance and control program. The California Department of Health Services has deemed the program acceptable for licensing purposes. A copy of the program is on file with the California Department of Health Services.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall only be distributed to persons specifically licensed by the NRC or an Agreement State.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.5 microcuries (185 KBq) of removable contamination.
- Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.

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

SEALED SOURCE TYPE: Beta Ionization Ring Source

- This registration certificate and the information contained within the reference shall not be changed without the written consent of the California Department of Health Services.
- The model NER-004R and NER-004R-Rh shall only be used in devices which are registered with the NRC or an Agreement State.
- The sources shall not be exposed to environments or other conditions of use which exceed the prototype test criteria specified in this document.

SAFETY ANALYSIS SUMMARY:

Based on our acceptance of a previous NRC review of the information and test data cited below, we continue to conclude that the model NER-004R and NER-004Rh sealed sources are acceptable for registration purposes.

Furthermore, we conclude that the sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents are hereby incorporated by reference and are made a part of this registry document.

- NEN Products letter dated October 1, 1984, with enclosures thereto.
- DuPont Pharmaceuticals Company letter dated May 2, 2000, with enclosures thereto.
- DuPont Pharmaceuticals Company letter dated August 17, 2000 with enclosures thereto
- IPL's letter dated July 26, 2000, with attachments thereto.

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

NO.: CA0406S215S (Supercedes MA0476S151S) DATE: May 3, 2001 PAGE: 6 of 6

SEALED SOURCE TYPE: Beta Ionization Ring Source

- **IPL's letter dated April 30, 2001.**
- **IPL's letter dated May 18, 2001.**

DATE: May 3, 2001 REVIEWED BY: John Rexroth

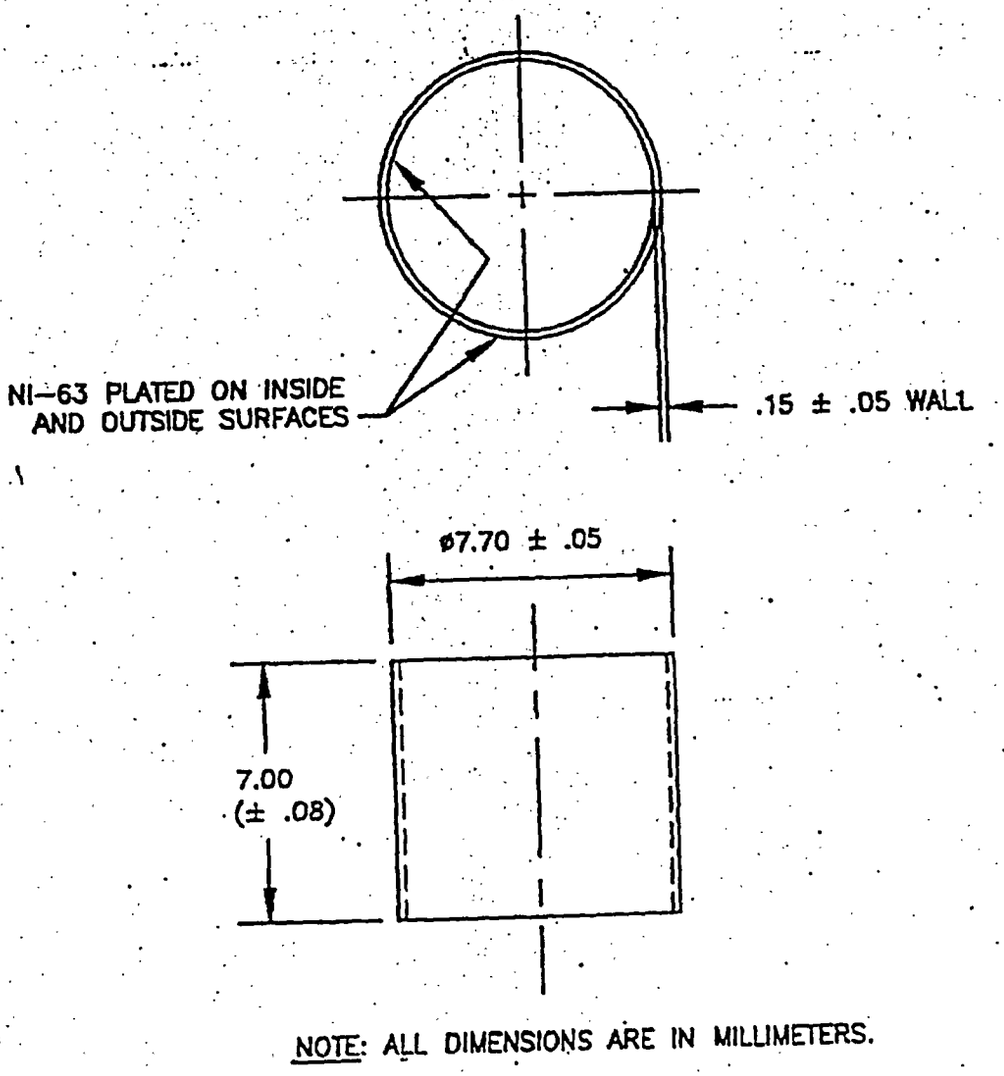
DATE: May 3, 2001 CONCURRED BY: Xiaosong Yin

ISSUING AGENCY: California Department of Health Services

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

NO.: CA0406S215S (Supercedes MA0476S151S) DATE: May 3, 2001 ATTACHEMENT: 1

NER-004R RING SOURCE DIAGRAM



NOTE: ALL DIMENSIONS ARE IN MILLIMETERS.

STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY GRAY DAVIS, Governor

DEPARTMENT OF HEALTH SERVICES
RADIOLOGIC HEALTH BRANCH
P.O. BOX 942732, MS-178
SACRAMENTO, CA 94234-7320
(916) 445-0931

May 3, 2001

Dr. Thomas L. Morgan
Isotope Products Laboratories
1800 North Keystone Street
Burbank, CA 91504

Please send to Tibbitts
24937 Avenue Tibbitts
Santa Clarita CA 91355

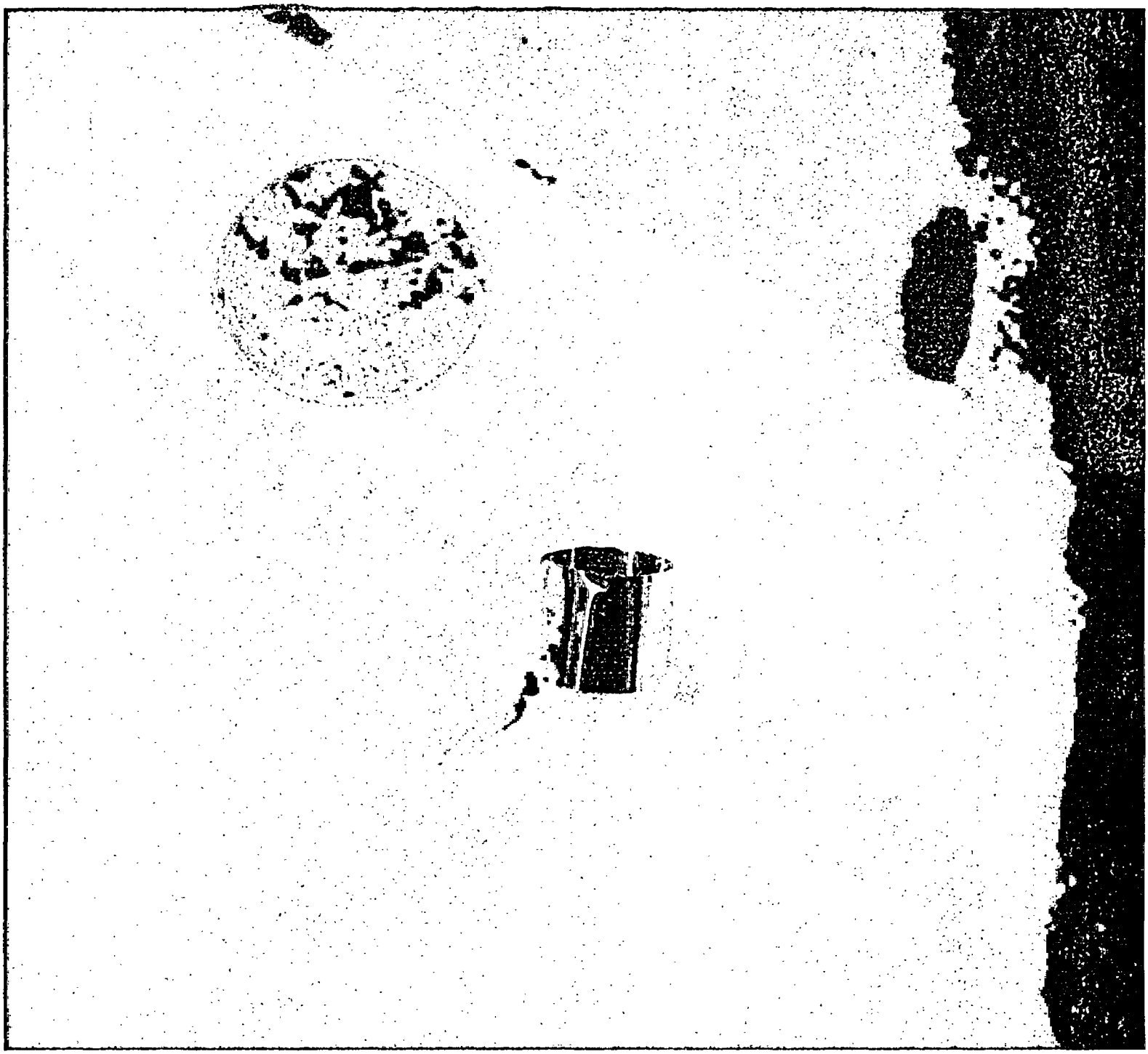
Dear Dr. Morgan:

Enclosed is Sealed Source and Device registry certificate, CA0406S215S. Please review it for errors or omissions as it will be distributed nationwide to all NRC regional offices, Agreement States, and Licensing States, and will be used for determination of licensing requirements.

If you have any questions or comments please call me directly at (916) 445-7125.

Sincerely,

John M. Rexroth
Health Physicist
Licensing Projects Unit



Attachment 4