

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

NM5512

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PAGE: 2 of 6

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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

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PAGE: 3 of 6

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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.

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PAGE: 4 of 6

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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.

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PAGE: 5 of 6

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- 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.

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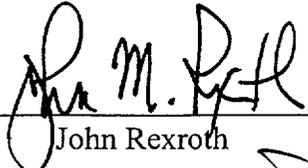
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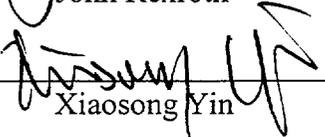
PAGE: 6 of 6

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

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FIRST
CLASS



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