

**DEPARTMENT OF HEALTH SERVICES****RADIOLOGIC HEALTH BRANCH**

P.O. BOX 942732, MS-178

SACRAMENTO, CA 94234-7320

(916) 445-0931



December 19, 2001

David F. Belden  
North American Scientific, Inc  
20200 Sunburst Street  
Chatsworth, CA 91311

Dear Mr. Belden:

Enclosed you will find a new (or amended) sealed source and device registry certificate, number CA0510S120S. Please look it over carefully for errors and/or omissions as it will be distributed nationwide to all NRC Regional Offices and Agreement States, and used for determination of licensing requirements.

If you have any questions, please call me at (916) 327-6214.

Sincerely,

A handwritten signature in black ink, appearing to read 'Xiaosong Yin'.

Xiaosong Yin  
Associate Health Physicist  
Radiologic Health Branch



Do your part to help California save energy. To learn more about saving energy, visit the following web site:  
[www.consumerenergycenter.org/flex/index.html](http://www.consumerenergycenter.org/flex/index.html)

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

NO: CA0510S120S

DATE: December 19, 2001

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SEALED SOURCE TYPE: FLOOD SOURCE

MODEL: MED3700 – MED3749

MANUFACTURER/DISTRIBUTOR:

North American Scientific, Inc  
7435 Greenbush Ave.  
North Hollywood, CA 91605

ISOTOPE:

Co-57

MAXIMUM ACTIVITY:

25 mCi

LEAK TEST FREQUENCY: 6 months

PRINCIPLE USE: Medical Reference Sources (X)

CUSTOM SOURCE: \_\_\_\_\_ YES \_\_\_\_\_ X \_\_\_\_\_ NO

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SEALED SOURCE TYPE: FLOOD SOURCE

DESCRIPTION:

This source series represents a range of source configurations to match the detector size requirements for a particular nuclear medicine gamma imaging camera system. Sources are circular or rectangular in shape. Circular configurations range from 13" to 26" in diameter. Rectangular configurations range from 9" x 9" to 18" x 26". The active matrix consists of Co-57 uniformly dispersed in an epoxy resin which is then cut into the desired shape approximately 0.150" thick. **Or, the active matrix consists of Co-57 chemically bonded to a thin substrate heat sealed between polyester laminate, which is then cut into the desired shape.** In either case, the active element is then placed between two halves of an outer plastic housing (polyethylene, delrin, or nylon) of accommodating shape and size. **A foam insert may also be included for spacing purposes.** Minimum thickness of the outer plastic shall be 0.06" and the active element shall be contained utilizing an epoxy seal, heat seal, or ultrasonic weld to complete containment. No portion of the active element is exposed once containment is complete. The outer housing shall provide at minimum of 0.75" inactive region around the active portion of the source to minimize exposure during handling. All sources shall be supplied in shielded containers for transport and storage.

LABELING:

Each source is labeled with a company-identifying label along with the activity level, serial number, isotope, and reference date. Each source is also labeled with the radiation symbol and the words, "Caution Radioactive Material."

DIAGRAM:

See attachment 1.

CONDITIONS OF NORMAL USE:

These sources are designed for use under controlled laboratory conditions primarily in clinical surroundings. They should be handled by qualified individuals and should not be subjected to extreme temperatures.

PROTOTYPE TESTING:

Two representative samples containing approximately 5 millicuries of Co-57 **in an epoxy resin matrix** were tested and shown to pass a level of ANSI 77C23313, which exceeds the required level of ANSI 77C22212 **for calibration sources.** **No testing was performed on**

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**polyester laminate samples since the dimensions and construction of the outer plastic housing is the same and this active element is more robust than the samples tested.**

EXTERNAL RADIATION LEVEL:

Radiation levels were measured at the distances defined below on the 5 millicurie prototype samples using an Eberline RO-2 portable ion chamber with the thin window exposed to allow for low energy contribution. Radiation levels for the maximum loading of 25 mCi were calculated and are shown below. The distance was measured from the face of the source to the center-line of the ion chamber.

	<u>5 cm</u>	<u>10 cm</u>	<u>30 cm</u>
5 mCi	40 mR/hr	24 mR/hr	8 mR/hr
25 mCi	200 mR/hr	120 mR/hr	40 mR/hr

QUALITY ASSURANCE AND CONTROL:

**The sources are manufactured and distributed under the guidelines of North American Scientific's 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:

1. License requirements: These sources shall be distributed to licensees of the NRC, Agreement States, **or a Licensing State.**
2. Leak Testing: These sources shall be tested for leakage at time intervals not to exceed 6 months **using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.**
3. Environmental Limitations: These sources are designed for use in controlled laboratory conditions. They should not be subjected to extreme temperatures or conditions, which exceed the testing specifications to which they have been tested and registered.

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4. Handling: In keeping with the ALARA philosophy these sources should be handled utilizing the inactive border region of the source. If possible remote handling and localized shielding may be used as needed.
5. Storage: These sources should be stored in the shielded container provided. When not in used they should be kept in a controlled area.
6. Use: These sources are designed for instrument calibration under controlled laboratory conditions and at no time should they be subjected to conditions, which exceed the limits to which they have been tested. They should be used by qualified individuals as noted in the specific NRC, Agreement State, **or a Licensing State** license.
7. Transfer and Disposal: Transfer and disposal shall be in accordance with the specific license issued by the NRC, Agreement State, **or a Licensing State**.
8. Cleaning: Water and a mild detergent may be used, with remote handling as necessary.
9. Activity Level: Activity levels of each source manufactured shall be kept to within +/- 15% of the stated value.
10. Radiopurity: Isotopes used for manufacturing shall have a radiopurity of 97% or better with respect to other nuclides (associated daughters not included) as determined by gamma spectroscopy of the batch materials used prior to production.
11. This registration sheet and the information contained within the references shall not be changed without written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

**Based on review of the Models MED-3700-MED3749 sealed sources, its ANSI classification, and the information and test data cited below, we continue to conclude that the sources are acceptable for licensing purposes.**

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

REFERENCES:

The following supporting documents for Models MED3700 – MED3749 sealed sources are hereby incorporated by references and made part of this registry document.

1. North American Scientific, Inc. letters dated April 1, 1991 and associated attachments (QC document and procedures) and April 18, 1991 and associated attachments.
2. Letter dated December 22, 1993 signed by L. Michael Cutrer.
3. Letter dated March 16, 1993 signed by L. Michael Cutrer.
4. NBS Handbook No. 126, ANSI N.542, Classification of sealed Radioactive Source, 1997.
5. North American Scientific letter dated November 5, 2001.

ISSUING AGENCY: California Department of Health Services

DATE: December 19, 2001

REVIEWED BY:

  
Xiaosong Yin

DATE: December 19, 2001

CONCURRENCE:

  
Ronald Rogus, Ph.D.

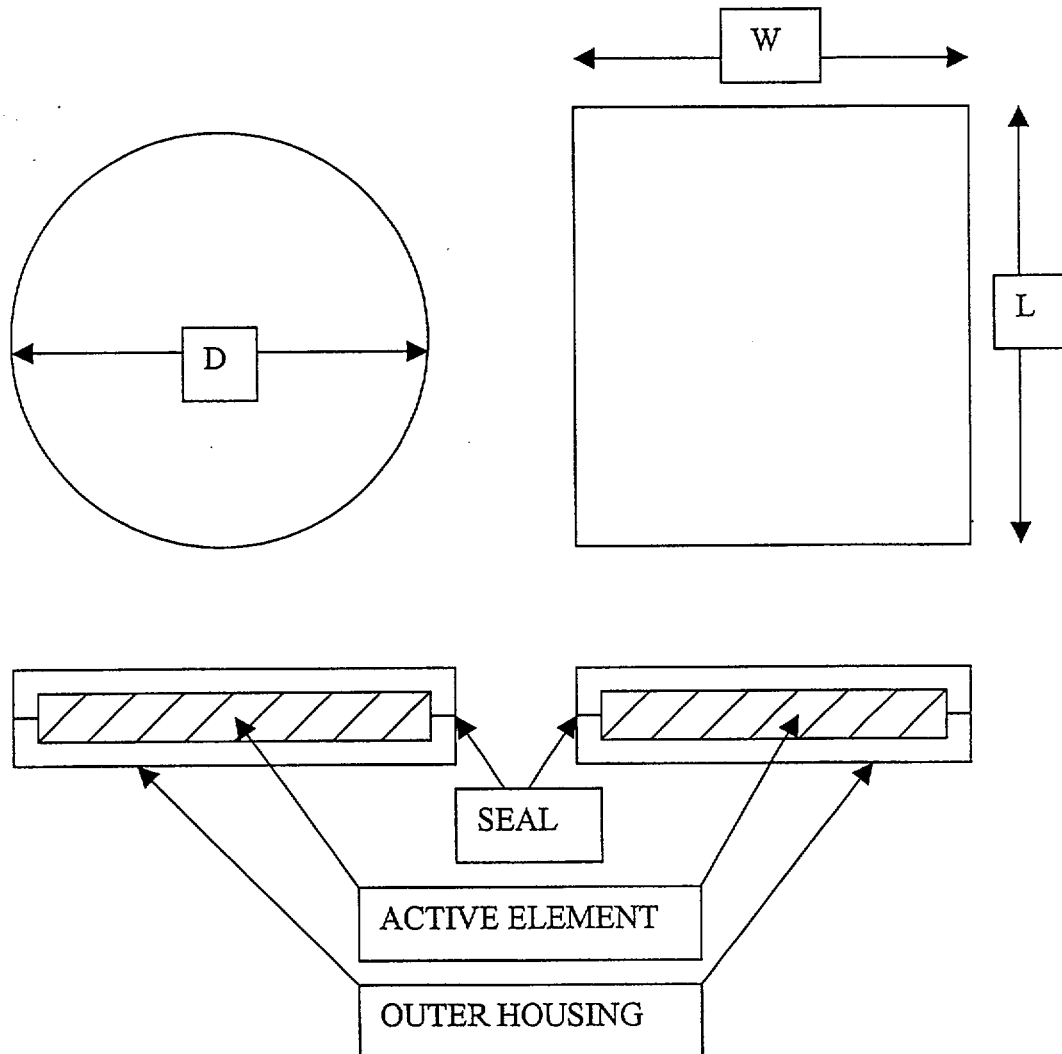
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ATTACHMENT 1

$D_{\text{maximum}}$	26"	$L_{\text{maximum}}$	26"	$W_{\text{maximum}}$	18"
$D_{\text{minumim}}$	16"	$L_{\text{minumim}}$	9"	$W_{\text{minumim}}$	9"



DEPARTMENT OF HEALTH SERVICES  
RADIOLOGIC HEALTH BRANCH  
601 NORTH 17TH STREET MS 178  
PO BOX 942732  
SACRAMENTO CA 94234-7320

ELAS



Mr. Frederick Sturz, Section Leader  
Source Containment and Devices Branch  
Office of Nuclear Material Safety  
and Safeguards  
U.S. Nuclear Regulatory Commission  
PI-37  
Washington, D.C. 20555