



State of Louisiana
Department of Environmental Quality



M.J. "MIKE" FOSTER, JR.
GOVERNOR

J. DALE GIVENS
SECRETARY

April 3, 2000

United States Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, DC 20555-0001

RE: Sealed Source: LA-0760-S-107-S

Dear Sirs:

Enclosed you will find sealed source registry LA-0760-S-107-S. Please add this sealed source in the registry.

Thank you for your assistance in this matter. If you have any questions, please contact me at (225) 765-0140.

Sincerely,

Soumaya Ghosn
Louisiana Department of Environmental Quality
Office of Environmental Services
Permits Division
Radiation Licensing

enc.

*NM5502
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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

No. LA-0760-S-107-S

DATE: March 27, 2000

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SEALED SOURCE TYPE: Brachytherapy Source

MODEL: VS2000 Source

MANUFACTURER/ DISTRIBUTOR: Alpha-Omega services, INC.
1282 Big woods and Starks Road
Edgerly, Louisiana 70668
(318) 589-5720
State of Louisiana Radioactive Material license
LA 10025-L01.

OTHER COMPANIES INVOLVED: Varian Oncology Systems
911 Hansen way
Palo Alto, CA 94304-1028
Device is manufactured and distributed for Varian Oncology

ISOTOPE: Iridium 192

MAXIMUM ACTIVITY: 10Curies (Loading Tolerance)
9-13 Curie at time of shipping

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: High dose rate radionuclide brachytherapy.

CUSTOM SOURCE: Yes No

DESCRIPTION:

The Model VS2000 Iridium 192 Sealed Sources are intended for medical use in Brachytherapy radiation treatment. It can only be used with the Varian VariSource High Dose Rate Remote Afterloader device, models 200 and 200t..

The source's specifications are similar, to the sealed sources SL-777 and SL -777V now in the registry of Radioactive sealed Sources, except for the shorter capsule length, and

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the heat treated distal end of the Nitinol wire for better ductility. The same manufacturing facility and equipment will be utilized with the same safety and control procedures.

The source is made of Nitinol Solid wire with an outer diameter approximately 0.0235" (0.60 mm). A hole is drilled through the center of the capsule to the depth of the Iridium 192 core. The Ir 192 cores, 2 each, are 0.0984" (2.5 mm) in length for a total length of 5 mm. The overall length of the finished wire assembly is approximately 101.9" (2588.3 mm). The Ir 192 seed is secured by welding the open end of the capsule. The material used is Nitinol (Nickel-Titanium) and the seal method is Laser/Tig welding.

The radioactive source cable will be shipped in a type "A" container. The shipping safe is the same for this source and the Omnitron model 777 sealed source that has already been in use for the same isotope and source strength.

LABELING:

Brachytherapy wires are not labeled, since there is insufficient space. A "Caution: Radioactive Material" tag with the radiation symbol is attached to the sheath via a string tie. It contains information about the isotope, activity, calibration date, and emergency telephone number. The shipping container has Type A DOT package designation. The used source cable will be returned after source exchange, in the same transport container with the "Caution radioactive Material" tags attached to it and all required Type a DOT required package labeling.

DIAGRAM:

See attachments 1

CONDITIONS OF NORMAL USE:

These sources are intended specifically and exclusively for use in a medical environment. They are intended for specific and exclusive use in Varian model VariSource 200 and 200t High Dose Rate Afterloaders.

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These sources should be used only by licensed health care professionals in facilities that are specifically licensed by the NRC or by an Agreement State.

Users will return the sources to the AOS laboratory in Edgar Louisiana.

PROTOTYPE TESTING:

Prototype testing was carried out in accordance with standards set forth in ISO 2919-1980 and US DOT special form radioactive Material.(the category, "Medical: Interstitial and Intracavitary Appliances" from Annex C, designation ISO/C53211.

Varian Medical Systems has established, for the mode VS2000, a special test procedure consisting exclusively of extensions through a 180° arc of turn of radius 17 mm, the minimum allowable bending radius for the sealed source.

The testing was carried on an Alpha-Omega capsule approximately 6 mm (0.236 inches) long and 0.6 mm (0.024 inches) in diameter and contains two 2.5 mm seeds of radioactive source of ¹⁹²Ir with an activity of approximately 127 millicuries. The material for the capsule is Nitinol. The capsules tested were similar to the capsule that will be used except for the activity.

In these tests the VS2000 source wires were used Labeled CD09-CD15. CD15 was heat-treated wire. For CD 09, a series of five (5) tests was devised to approximate a worst case clinical situation. The series of tests begins by (1) running the source cable into a dead-end catheter 5 transfers to verify that the tip will not dislodge. (2) The cable is then driven for 40 transfers through a "minimum radius" "U" turn of 1.7 cm. (3) The cable is then driven for 200 transfers through a "small radius" "U" turn of 2.0 cm. (4) The cable is then driven 200 extensions through a 2.9cm radius "S" turn. (5) The wire is then driven through a 4.0 cm radius "U" turn followed directly by a 3.0 cm radius "U" t for 2 transfers.

CD10 through CD15 were tested as follows:

- 1) Running the source cable into a dead-end catheter 5 transfers to verify that the tip will not dislodge.

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- 2) The wire was driven extensions through a minimum radius of 1.7 cm until failure. The CD15 wire that represents the wires that will be used, since it was heat treated, sustained 40585 cycles in the R 1.7cm test.

Prototype sources successfully passed all tests required by the 49 CFR §173.469 and ISO 2919-1980 for a classification of ISO/C53211.

EXTERNAL RADIATION LEVELS:

The following are dose rates as reported by Alpha-Omega for a 10Curie source:

Distance (cm)	Dose Rate (Rem/hour)
1	46900
25	117
50	18.8
100	4.69

These figures shall not be used for planning patient dosimetry. The dosimetry of Iridium -192 wire is complex and is dealt with in a number of theoretical papers. The above numbers were calculated based on 10 curies ¹⁹²Ir source.

The levels for the shipping safe were measured, using a calibrated Keithly instrument, as 40-50 mR/hr on the surface and a maximum of 1.2 mR/hr at one meter.

QUALITY ASSURANCE AND CONTROL:

Alpha-Omega Services Inc. (AOS) maintains a quality assurance and control program (License number LA 10025-L01) which is deemed acceptable for licensing purposes by the State of Louisiana Department of Environmental Quality (LDEQ). When AOS is not the sole manufacturer, the requirements placed on the subcontractor for the Manufacturing Specification is to carry out all work in accordance with procedures that address the

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requirements of AOS Control system. If a case arises where such procedures are not in place, Varian medical Systems has procedures to assess suppliers and put in place other controls as appropriate.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The sources shall be distributed (in the United States) only to persons specifically licensed by the U.S. NRC or an Agreement State.
2. The source cable shall be distributed internationally to users with approval from local competent authorities.
3. The source shall be leak tested immediately following final construction and at the clinical site during the process of loading the wire in the afterloader. Also, a leak test shall be performed prior to disposition of the wire source.
4. Handling, storage, use, transfer and disposal: to be determined by the licensing authority. These sources should be handled only by experienced personnel, specifically licensed by the NRC or an Agreement State to perform such tasks, they should be using adequate equipment, shielding, and should follow procedures. Also they should be trained on the appropriate use of emergency procedures.
5. The licensee shall not cut, splice or alter the source wire in any manner.
6. The working life of the source shall be limited to one hundred and twenty (120) days or 1000 wire extensions, whichever occurs first.
7. To be used as an active source cable for the Varian Model Varisource HDR Afterloader models 200 and 200t at existing irradiation equipment installations. The licensee shall strictly abide by all requirements of the customer's license and applicable requirements of the USNRC, Agreement State, or International competent authorities in which the authorized work is performed.
8. The source wire shall not be subjected to environmental or operational conditions of use which exceed the ISO 2919-1980 Classification ISO/C53211.

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9. The source shall not be transported or stored in teflon-lined containers.
10. This registration sheet and the information contained within the references shall not be changed without the written consent of the Louisiana Department of Environmental Quality, Office of Environmental Services, Permits Division, Radiation Licensing.

REVIEWER'S NOTE:

1. In order to assure that the source is not used beyond its working life, records shall be kept of each (source) extension.
2. As listed on the first page, the source shall not be installed or used until it has decayed to 10 Curies. However, in order that it be 10 Curies when installed, Alpha-Omega Services Inc. is being allowed to ship the source at an activity level of up to 13 Curies.
3. Only heat-treated Nitinol wires will be used.

SAFETY ANALYSIS SUMMARY:

Based on a review of the information and test data contained within the references cited below, the Louisiana Department of Environmental Quality staff concludes that Model V2000-Ir 192 will maintain integrity under stresses likely to be encountered in normal use and, therefore, are acceptable for licensing purposes. This conclusion is also based on ISO 2919-1980 (E) with a classification of ISO/53211, with the addition of the cyclic fatigue test and modification of the Impact Test, as described under PROTOTYPE TESTING.

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REFERENCES:

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

Alpha-Omega Services Inc., Registration request letter of December 15, 1999, to Radiation Protection Division (DEQ).

Alpha-Omega Services Updated pages of January 11, 2000.

Alpha-Omega Services Inc Faxes from Delphi Consulting group (DCG) of March 7, 2000, from Harvey Knauss to Soumaya Ghosn, LDEQ, with copy of FDA approval.

ISSUING AGENCY:

State of Louisiana, Department of Environmental Quality, Office of Environmental Services, Permit Division, Radiation Licensing

Date: 3-30-00 Reviewed by: Soumaya A. Ghosn Soumaya Ghosn

Date: 3-30-00 Concurrence: Michael Henry Michael Henry

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Attachment 1
Drawings

No.

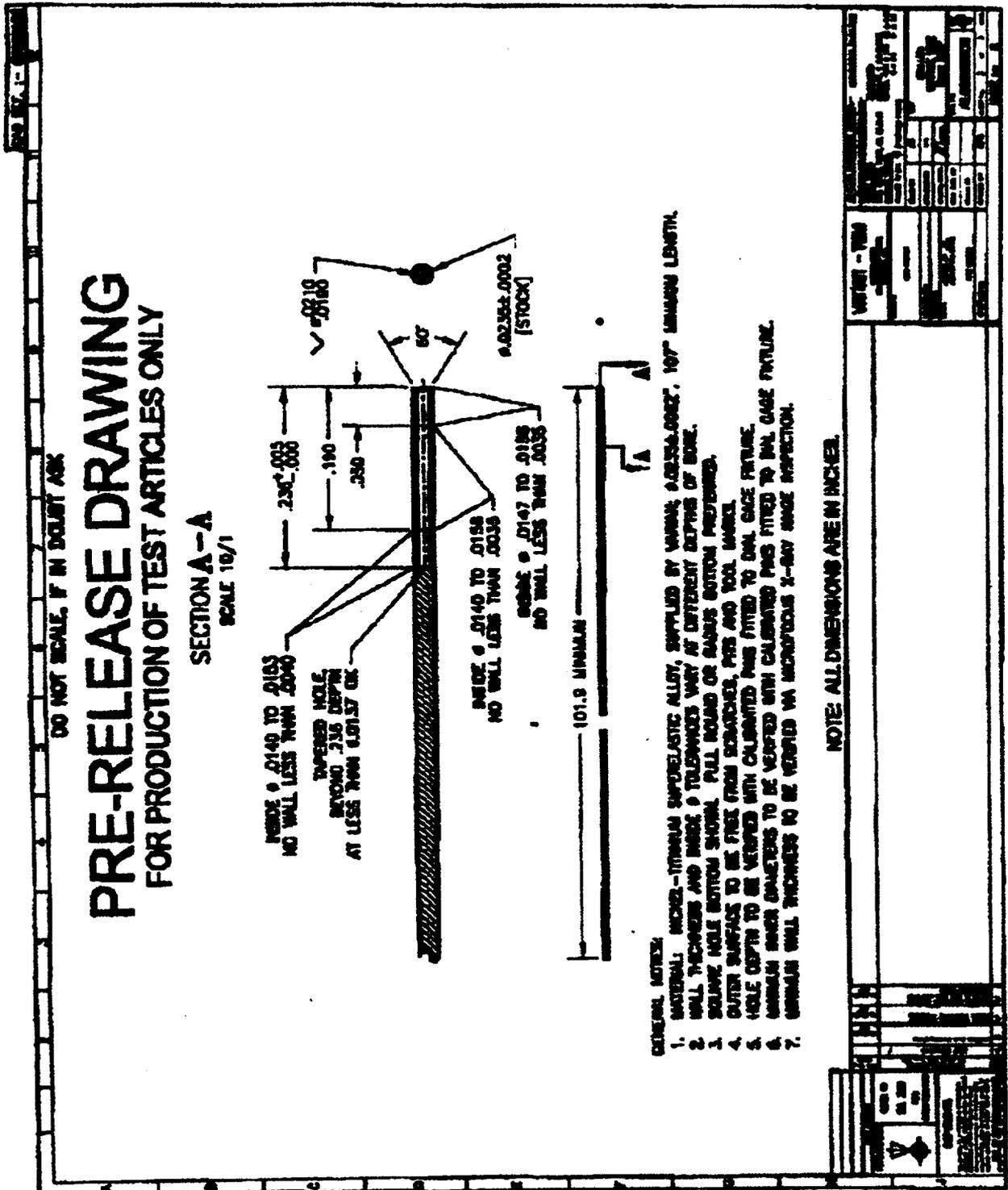


Figure 1, Details of wire cavity for seeds

No.

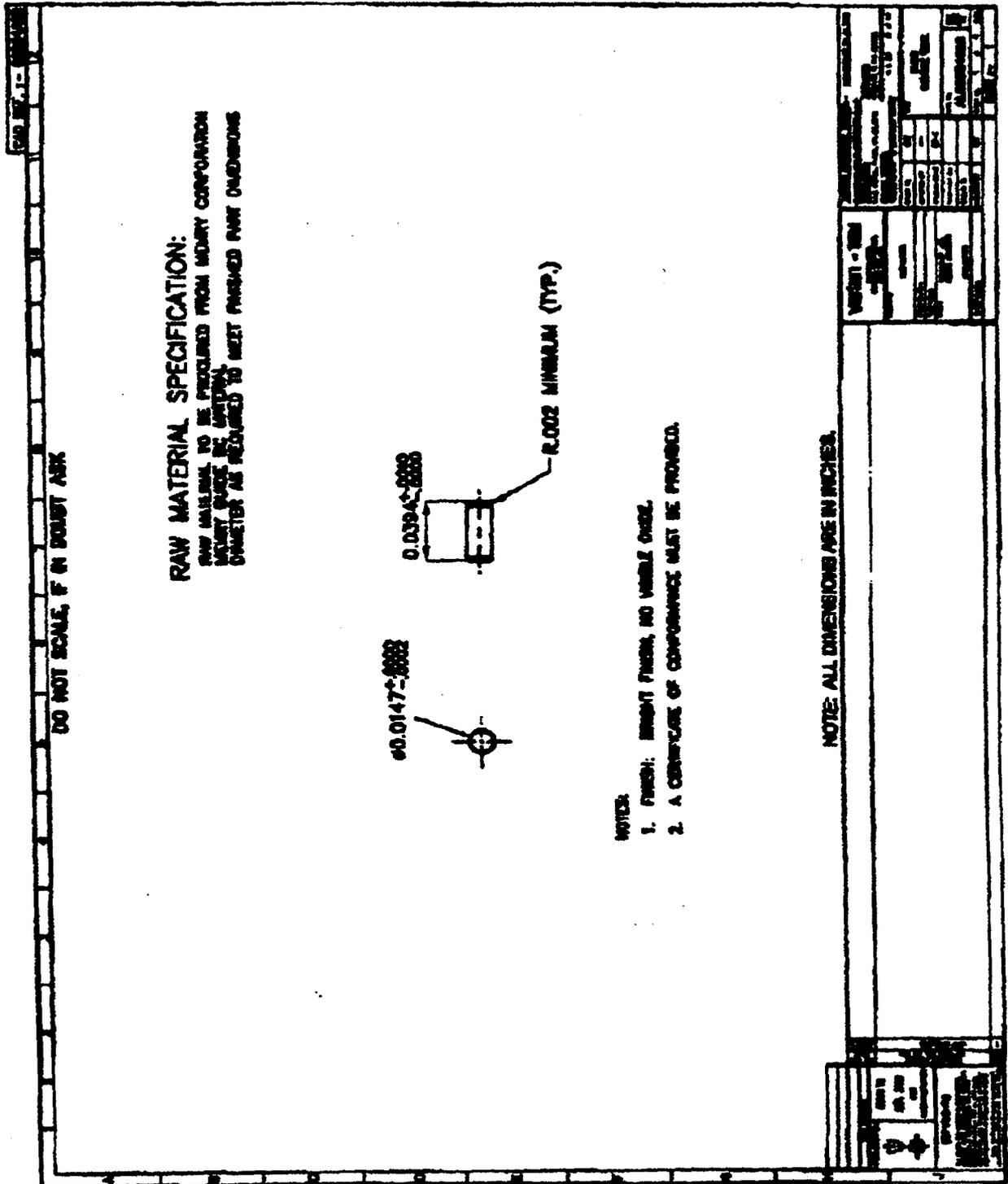


Figure 3, Details of end plug.

No.

CUT LINES - DO NOT PRINT

VariSource
Radionuclide Brachytherapy Source
RE-ORDER # AL09000001

QTY 1 **2585 mm**

Intended Use: High Dose Rate Brachytherapy

Source Wire S/N

CE **0086**

MANUFACTURED FOR
VARIAN MEDICAL SYSTEMS, GATWICK RD.
CRAWLEY, RH102RG U.K.

In case of Emergency, call: US & CAN. 1-800-424-9300
INTERNATIONAL 1-703-527-3987

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Figure 4, VariSource Identification Tag.

No.

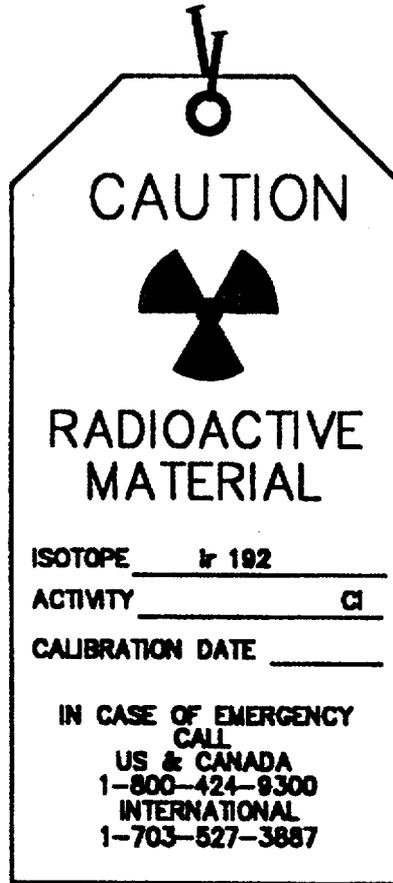


Figure 5, Radioactive Material Tag.