



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

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JUL 26 2002

E. Lynn McGuire, Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, Arkansas 72114

Dear Mr. McGuire:

Enclosed is Amendment No. 65 to NRC Material License No. 22-01859-01 in accordance with your request. Please note that the changes made to the license are printed in bold font.

A couple of conditions of your license have been modified pertaining specifically to your possession and use of the Novoste A1000 series intravascular brachytherapy (IVB) devices. Please review these conditions carefully to assure that you understand the terms and requirements contained therein. Also, note the following point of clarification regarding the use of the Novoste A1000 series IVB devices, the routine medical use of these devices requires a Premarket Approval (PMA) from the Food and Drug Administration (FDA) and the source(s)/device(s) must be registered by either the NRC or an Agreement State. Refer to the device registration (copy enclosed) for the current models of the A1000 series which have received PMA's and are authorized for routine medical use. If you wish to use a device that has not received a PMA, that use would be considered research (not routine medical use) and would be conducted under Subitem A. of Items 6.,7.,8., and 9. of your current license. I have enclosed a copy of an NRC Information Notice 2000-19 dated December 5, 2000, "Implementation of Human Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials" which you may find helpful regarding this matter.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact me at (630) 829-9868 so that I can provide appropriate corrections and answers.

Sincerely,

Patricia J. Pelke
Health Physicist
Materials Licensing Branch

License No. 22-01859-01
Docket No. 030-02205

Enclosures: Amendment No. 65

NRC Information Notice 2000-19 dated December 5, 2000, "Implementation of Human Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials"; and

Novoste A1000 Source and Device Registration No. GA-1115-D-101-S dated April 8, 2002

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions 2
FOIA- 2005-0293

H/6

MATERIALS LICENSE

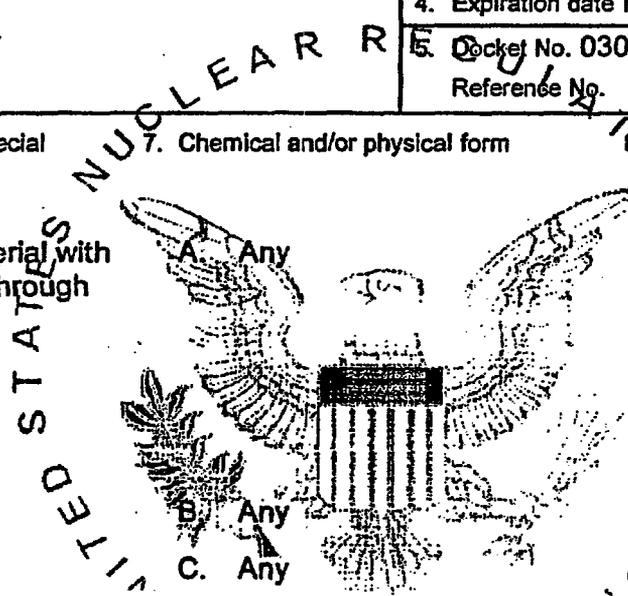
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

PC 02110

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<p>Licensee</p> <p>1. V.A. Medical Center</p> <p>2. One Veterans Drive Minneapolis, MN 55417</p>	<p>In accordance with letter dated July 9, 2002,</p> <p>3. License number 22-01859-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date November 30, 2011</p> <p>5. Docket No. 030-02205 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 3 through 83</p> <p>B. Sulfur-35</p> <p>C. Hydrogen-3</p> <p>D.</p> <p>E. Technetium-99m</p> <p>F. Iodine-131</p> <p>G. Iridium-192</p> <p>H. Cesium-137</p> <p>I. Nickel-63</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Sealed sources</p> <p>H. Sealed sources</p> <p>I. Any foil source registered pursuant to 10 CFR 32.210 or has been approved by an Agreement State.</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 50 millicuries of each radionuclide with a total possession limit of 1 curie; except as listed below:</p> <p>Phosphorus-32 100 millicuries Cesium-137 110 millicuries</p> <p>B. 100 millicuries</p> <p>C. 400 millicuries</p> <p>E. 20 curies</p> <p>F. 500 millicuries</p> <p>G. 50 millicuries each total of 400 millicuries</p> <p>H. 50 millicuries each total of 400 millicuries</p> <p>I. 2 sources not to exceed 15 millicuries each</p>
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Ex 2

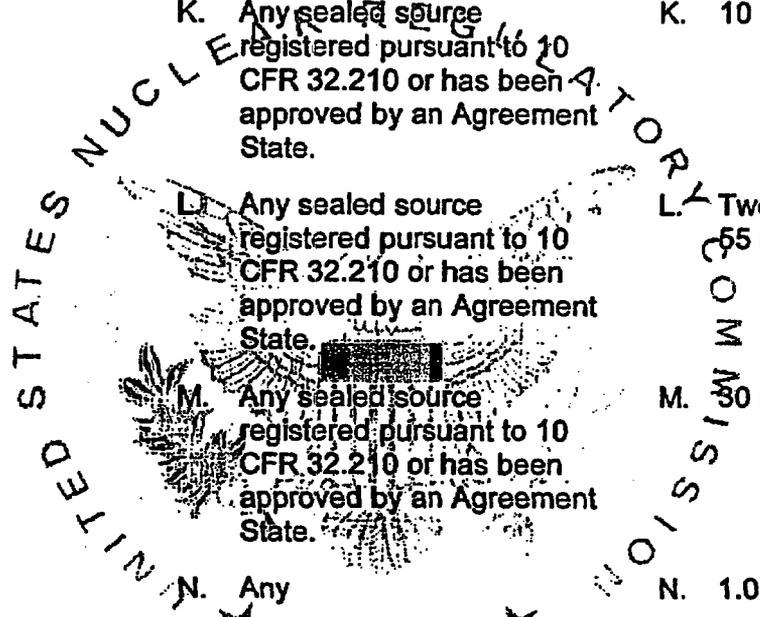
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
7 J. Cesium-137	J. Any sealed source registered pursuant to 10 CFR 32.210 or has been approved by an Agreement State.	J. 250 millicuries
K. Cobalt-60	K. Any sealed source registered pursuant to 10 CFR 32.210 or has been approved by an Agreement State.	K. 10 millicuries
L. Strontium-90	L. Any sealed source registered pursuant to 10 CFR 32.210 or has been approved by an Agreement State.	L. Two sources not to exceed 55 millicuries each
M. Americium-241	M. Any sealed source registered pursuant to 10 CFR 32.210 or has been approved by an Agreement State.	M. 30 millicuries
N. Samarium-153	N. Any	N. 1.0 curie
O. Palladium-103	O. Sealed sources identified in 10 CFR 35.400	O. 650 millicuries
P. Iodine-125	P. Sealed sources identified in 10 CFR 35.400	P. 150 millicuries
Q. Strontium-90	Q. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)	Q. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries.



9. Authorized Use:

A. through H. Medical diagnosis, therapy and research in humans, Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies, Instrument calibration (In house only).

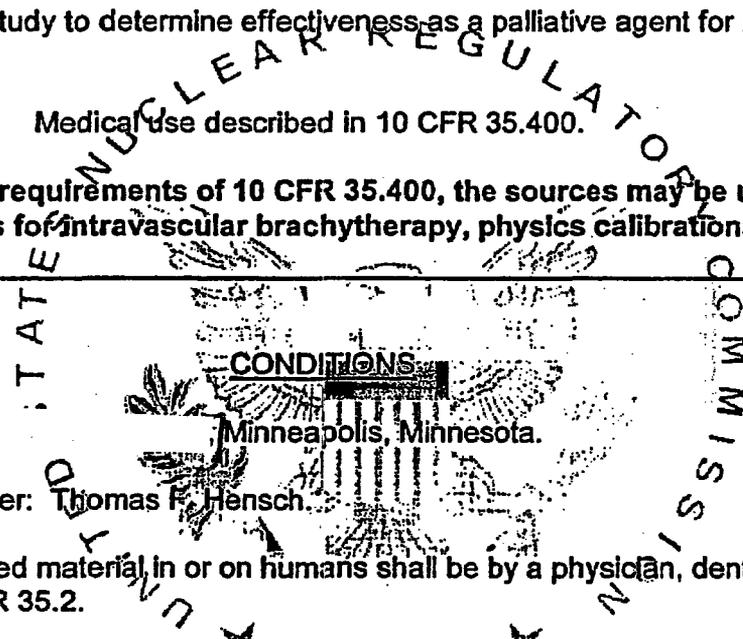
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- I. Gas Chromatograph.
- J. and K. Instrument Calibration (In house only).
- L. One source for use in Ophthalmic eye applicator for treatment of superficial eye conditions. One source for storage only as described in letter dated July 26, 1993.
- M. For use as anatomical materials and instrument calibration.
- N. To be used in a study to determine effectiveness as a palliative agent for patients with bone metastases.
- O. and P. Medical use described in 10 CFR 35.400.
- Q. Notwithstanding the requirements of 10 CFR 35.400, the sources may be used in devices for intravascular brachytherapy, physics calibrations and quality assurance testing.



- CONDITIONS**
- 10. Location of Use: Minneapolis, Minnesota.
 - 11. Radiation Safety Officer: Thomas F. Hensch.
 - 12. A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
 - B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee.
 - C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee, Bert Larson, M.D., Chairperson.
 - 13. Licensed material listed in Subitem Q. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user that meets the training and experience criteria specified in 10 CFR Part 35, Section 35.940, designated as an authorized user in accordance with Condition 12.B.; and used in the physical presence of an authorized user designated in accordance with Condition No. 12.B or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user designated in accordance with Condition No. 12.B. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.

Ex2

Ex2

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14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material to quantities less than 10^5 times the applicable limits in Appendix C of 10 CFR 20, as specified in 10 CFR 30.35(d).
15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only krypton-85; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting materials; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test result shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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- G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
16. Pursuant to 10 CFR 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
17. The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every six months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).
18. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1) of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without regard to color requirement.
19. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR 35 except Sections 35.49(a) and (b), 35.100, 35.200, and 35.300.
20. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, the licensee may use for medical use any byproduct material. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other section of 10 CFR 35. This does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) and other Federal and State requirements.
21. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
22. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
23. The licensee is authorized to hold Scandium-46, and Sulfur-36 for decay-in-storage before disposal by incineration as ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed using appropriate instrumentation to determine that its radioactivity cannot be distinguished from background.

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24. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of carbon-14 and hydrogen-3 by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table 2, Column 1, 10 CFR Part 20.
25. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing carbon-14 and hydrogen-3 provided the concentration expressed in μCi per gram of ash, at the time of disposal does not exceed 10 percent of the numerical values listed in Appendix B, Table 2, Column 2, 10 CFR Part 20.
26. The licensee shall not perform iodination with Iodine-131 or Iodine-125 using quantities in excess of 50 millicuries of Iodine-131 or Iodine-125 without specific written authorization from the Nuclear Regulatory Commission.
27. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
28. This license does not authorize distribution to persons licensed pursuant to Section 35.11 of 10 CFR Part 35.
29. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:
- Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each Novoste A1000 series intravascular brachytherapy treatment.
 - Promptly make a survey of the area of use to confirm that no sources have been misplaced.
 - Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr ($\mu\text{Sieverts/hr}$), time, date and name of the individual making the survey.
 - Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).
30. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

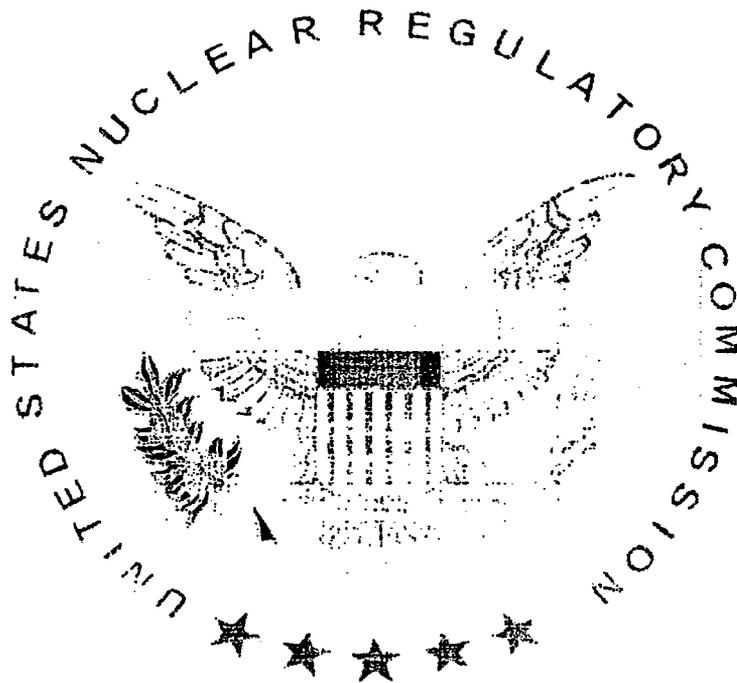
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- A. Application dated June 8, 2001, (Excluding the Quality Management Program); and
- B. Letters dated January 10, 2002 and March 15, 2002.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUL 26 2002

By *Patricia J. Pelke*
 Patricia J. Pelke
 Materials Licensing Branch
 Region III