PUBLIC

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Iron Mountain MI 49801

In Reply Refer To:

October 24, 1996

Nuclear Regulatory Commission
Region III
Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

SUBJ: Additional Authorized Users to Materials License #21-12916-01

1. Please add the following authorized users to our radioactive materials license:

Parvez H. Shirazi, M.D.
Leo Ackerman, M.D.
Nicholas C. Friedman, M.D.

2. These authorized users have been approved to use any byproduct material identified in 10 CFR 35.100, 35.200 and 35.300.

3. Please reference the attached letter from Lawrence Case at the VA Hospital in Hines, Illinois for authorizing them to use materials at their facility.

Glen W. Grippen
Medical Center Director

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DEPARTMENT OF VETERANS AFFAIRS
Edward Hines, Jr. Hospital
Hines IL 60141

In Reply Refer To: 578/115/138S

August 28, 1996

Christina Casey, CNMT
Nuclear Medicine Department
Iron Mountain, Michigan 49801

Dear Ms. Casey:

This letter is to confirm that the following physicians are authorized users for uptake, dilution, excretion, imaging, and therapeutic uses of radionuclides under our type A Broad Scope Medical License; US Nuclear Regulatory Commission License number 12-01087-07.

Parvez H. Shirazi, M.D.
Leo Ackerman, M.D.
Nicholas C. Friedman, M.D.

Each of the above is a Board Certified Nuclear Medicine Physician and has been authorized by the VA Hines Hospital Radiation Safety Committee.

If you need any further information in regard to amending your license, please feel free to contact me at (708) 343-7200 extension 1955.

Sincerely,

Lawrence F. Case

Lawrence F. Case
Hospital Radiation Safety Officer

Amendment No. 65

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.

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Licensee	
1. V.A. Edward Hines, Jr., Medical Center	In accordance with letter dated April 14, 1995
2. Hines, IL 60141-5000	3. License Number 12-01087-07 is amended in its entirety to read as follows:
	4. Expiration Date December 31, 1995
	5. Docket or Reference No. 030-01391

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
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 12-01087-07
Docket or Reference number: 030-01391
Amendment No. 65

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
E. Any byproduct material between Atomic Nos. 1 and 83, inclusive	E. Any	E. 50 millicuries of each byproduct material, except as noted below: Hydrogen-3 750 millicuries, Carbon-14 750 millicuries, Cobalt-60 100 millicuries, Iodine-125 750 millicuries, Phosphorus-32 200 millicuries, Sulfur-35 500 millicuries
F. Iridium-192	F. Sealed sources (Isotopen-Technik Dr. Sauerwein in GmbH Dwg. No. GM 252.20-001 (Byk Mallinckrodt CIL B.V. 1775 ZG, Petten, Holland)) or (Model 722 RTS Technology Inc. NR-555-D-104-S)	F. 20 curies (2 sources not to exceed 10 curies each)
G. Uranium (depleted in U-238)	G. Plated metal	G. 6 millicuries
H. Cesium-137	H. Sealed sources (Amersham Corporation Model CDCK)	H. Not to exceed 1.0 curie in the MicroSelectron storage safe and 3.0 curies within the 45 channel source train assemblies. Total possession not to exceed 4.0 curies

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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
I. Iridium-192	I. Seeds encased in nylon ribbon (Manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations)	I. Not to exceed 3.0 curies total
J. Cesium-137	J. Sealed sources (J. L. Shepherd & Associates Model 6810)	J. 600 curies per source. Not to exceed 1200 curies total
K. Americium-241	K. Sealed sources (Amersham Model AMC.D3 or CTC.D2)	K. Two sources not to exceed 30 millicuries each.
L. Cesium-137	L. Sealed sources (AECL Model C-161)	L. 8400 curies (4200 curies in the unit, 4200 curies in storage of time of sources replacement)

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

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C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. To be used for medical research, animal studies, radioimmunoassay and student instruction.

F. To be used in Isotopen-Technik Dr. Sauerwein GmbH Model GammaMed II-i remote afterloading device for interstitial and intercavitary treatment of cancer.

G. To be used as shielding in Isotopen-Technik Dr. Sauerwein GmbH Model GammaMed II-i remote afterloading device.

H. and I. To be used in a Nucletron Corporation MicroSelectron-LDR Model SEL 4000 remote afterloading brachytherapy unit for intracavitary and interstitial treatment of cancer.

J. To be used in a J. L. Shepherd & Associates Model 143-45A Gamma Irradiator for the irradiation of human blood products.

K. For use in a Renalyzer PRX-90 Model 615-00-00 X-Ray florescence analyzer to determine glomerular filtration rate.

L. To be used in an AECL Model Gammacell 40 irradiator for the irradiation of biological samples.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at Edward Hines, Jr., Medical Center, Hines, Illinois.

B. Licensed material listed in Subitem L. shall be used only at the licensee's facilities located at Room B314, Building 1, Hines, Illinois.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Parvez Shirazi, M.D. Chairman.

B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.2 of 10 CFR Part 35.

C. The Radiation Protection Officer for the activities authorized by this license is Lawrence F. Case.

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12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicting that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A 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, describing the equipment involved, the test results, and the corrective action taken.

13. 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 a color requirement.

14. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

15. Experimental animals administered licensed materials or their products shall not be used for human consumption.

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

17. Licensed material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this license.

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18. A. Access to the rooms housing the Nucletron Corporation and the Gamma Med II-i afterloading brachytherapy units shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

19. Prior to initiation of a treatment program, and subsequent to each source exchange for the afterloading brachytherapy units listed in Subitems F., H., and I; radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgens per hour.

(2) All areas adjacent to the treatment room with source in the "irradiation" position. The survey shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation" (10 CFR 10).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b) 10 CFR 20.

B. Records of the survey results shall be maintained for inspection by the Commission.

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20. The following shall be performed only be persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of sources contained in the afterloading brachytherapy devices listed in Subitems F., H., and I.

B. Any maintenance or repair operations on the afterloading devices involving work on the source head, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and results in increased radiation levels.

21. The licensee shall maintain records of information important to safe and effective decommissioning at the location listed in Item 2. of the license per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

22. The licensee shall not perform repairs or alterations of the irradiators involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiators shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

23. For licensed material listed in Subitem L., the procedures contained in the AECL instruction manual for the Model Gammacell 40 device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

24. The license is based on the licensee's statements and representations listed below:

A. Letter, with enclosed application, dated June 15, 1984, and application received August 29, 1990 (with attachments); and

B. Letters dated September 10, 1985, July 29, 1987 (with attached application), May 24, 1988 (with attachments), December 30, 1988, February 16, 1989, June 11, 1990, August 8, 1991, November 26, 1991, October 23, 1992, November 24, 1992, April 30, 1993, July 23, 1993, June 28, 1993, August 5, 1993, November 5, 1993, November 22, 1993, June 15, 1994, November 10, 1994, February 28, 1995, March 31, 1995 and April 14, 1995; and

C. Applications dated February 25, 1992 and June 24, 1993 and May 16, 1994.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUL 24 1995

By Loren J. Hunter
Materials Licensing Section, Region III

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DATE: 11-6-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: BJ HOLT

LICENSEE: V.A. - IRON MOUNTAIN, MI

LICENSE NUMBER: 21-12916-01

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not started.

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.

Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☑ Licensee is adding authorized users.

A check is included _____. No check is included ✓.

Amendment is necessary _____. Amendment is not necessary ✓.
(This is a Notification)

☐ Process in as a new licensing action:

A. Amendment _____
B. Renewal _____
C. New License Application _____

☐ Other: _____

Thank You For Your Help!!! 10/16/96