NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 56

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, 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 October 7, 1992
2. Hines, IL 60141	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

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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
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

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

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.

9. (Continued)

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.

CONDITIONS

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

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Mark A. Boles, 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.

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.

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12. (Continued)

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.

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, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, 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.

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

17. 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.

18. 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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19. 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.

20. 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.

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

22. 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 and November 26, 1991; and

    C. Application dated February 25, 1992.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/26/92

By John R. Macle
Materials Licensing Section, Region III

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BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: EX 7B
EXP. DATE: 19951231
FEE COMMENTS:
DECOM FIN ASSUR REQDT ?

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: V. A. EDWARD HINES JR., MEDICAL CTR
RECEIVED DATE: 921008
DOCKET NO: 3001391
CONTROL NO.: 394124
LICENSE NO.: 12-01087-07
ACTION TYPE: AMENDMENT

fee exempt
EX 7B

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: 0

3. COMMENTS

SIGNED Deborah Hersey
DATE 10-7-93

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: _____

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____
_____

SIGNED _____
DATE _____

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

In Reply Refer To 001A-S

October 7, 1992

Chief, Material Licensing Section
U.S.N.R.C. Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Sir or Madam,

This is a request to amend and increase our possessions limit for Sulphur-35 on our U.S.N.R.C. Broad-Medical License 12-01087-07.

In the past hydrogen-3 and carbon-14 were the major nuclides used in research, but with the advent of molecular biology research we find that we have an inadequate possession limit for Sulphur-35 (50 millicuries).

We are requesting that you expand our possession limit for Sulphur-35 to allow us to possess a maximum at any given time of 500 millicuries.

We thank you for your cooperation in this matter, should you have any questions please feel free to contact Lawrence Case Hospital Radiation Safety Officer (HRSO) at (708) 343-7200, extension 1955.

Sincerely,

for Joan E. Cummings

Joan E. Cummings, M.D.
Director

OCT 2 7 1992

V.A. Edward Hines, Jr.,
Medical Center
ATTN: Joan E. Cummings, M.D.
Director
Hines, IL 60141

Dear Dr. Cummings:

Enclosed is Amendment No. 56 to your NRC License No. 12-01087-07 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

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You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (708) 790-5625.

Sincerely,

Original Signed By
John R. Madera
Materials Licensing Section

Enclosure: Amendment No. 56

RIII
Madera/dg
10/26/92