NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 54

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. Henry Ford Hospital	In accordance with letter dated August 26, 1996 3. License Number 21-04109-16 is amended in its entirety to read as follows:
2. 2799 West Grand Blvd. Detroit, MI 48202	4. Expiration Date December 31, 2004
	5. Docket or Reference No. 030-02043

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 sources identified in 10 CFR 35.400	D. 7 curies
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Any byproduct material with Atomic Nos. 2 through 83, inclusive	F. Any	F. 500 millicuries of each isotope, 10 curies total, except as noted below: Hydrogen-3 2 curies Phosphorus-32 2 curies Iodine-125 2 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
G. Iridium-192	G. Sealed source (Mallinckrodt Diagnostica B.V. Dwgs. Nos. GM 202.20-012, or GM 252.20-001, or RTS Technology, Inc. Model No. 722)	G. 20 curies total (2 sources not to exceed 10 curies each)
H. Cesium-137	H. Sealed sources (J. L. Shepherd Model 6810)	H. 6,000 curies
I. Any byproduct material identified in 10 CFR 31.11	I. Prepackaged Kits	I. As needed
J. Uranium depleted in uranium-235	J. Cadmium plated metal	J. 750 kilograms
K. Cesium-137	K. Sealed sources (Nordion Model C-3001)	K. 2 sources, not to exceed 3048 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. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

F. To be used for medical research and research and development as defined in 10 CFR Part 30, Section 30.5, including animal studies.

G. One source to be used in a Model Gamma Med II-i afterloading irradiation device, manufactured by Isotopen Technik Dr. Sauerwein Gmbh and distributed by Mick Radio-Nuclear Instruments for interstitial and intracavitary treatment of cancer. One source in its shipping container to be in the possession of the licensee as necessary for replacement of the source in the irradiation device.

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H. To be used in a J. L. Shepherd Model Mark I Series, Model 68 for irradiation of research samples excluding explosives or highly flammable materials.

I. In vitro studies.

J. Shielding in a linear accelerator, sealed source shielding, and shielding of technetium-99m generators.

K. To be used in a Nordion, Inc. GC 3000 Elan Model II irradiator for the irradiation of blood and blood products.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at Henry Ford Hospital, 2799 West Grand Blvd., Detroit, Michigan.

B. Licensed material listed in 10 CFR 35.100, 35.200 and 35.500 may also be used at the licensee's facilities located at Henry Ford Medical Center - West Bloomfield, 6777 West Maple Road, West Bloomfield, Michigan.

C. Licensed material listed in Subitem F. may be used at the licensee's facilities located at One Ford Place, "D" Wing, 4th and 5th Floors, Detroit, Michigan.

D. Licensed material listed in Subitem J. may be used at the licensee's facilities located at 23725 Northwestern Highway, Southfield, Michigan.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, Leonard Lutter, Ph.D., Chairperson.

B. The Radiation Protection Officer for the activities authorized by this license is Ralph P. Lieto.

C. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

D. 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. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

12. A. Sealed sources 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 leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; 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 material; 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.

E. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. 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 in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately 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, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

F. 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.

13. 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.

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14. The licensee shall conduct a physical inventory every 3 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 6 months for all other sources and/or devices.

15. 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."

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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

19. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

20. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

21. A. Access to the rooms housing the Gamma Med II-i afterloading brachytherapy device 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 each day of use.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position 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.

22. Prior to initiation of a treatment program, and subsequent to each source exchange using the Gamma Med II-i remote afterloading brachytherapy device, 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 milliroentgen per hour.

(2) All areas adjacent to the treatment room with the 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 10 CFR 20.1201.

(b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

23. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of the sealed source contained in the Gamma Med II-i afterloading brachytherapy device.

B. Any maintenance or repair operations on the remote afterloading brachytherapy unit listed in Item 9., Subitem G involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

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24. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

25. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

26. 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.

27. A. The procedures contained in the J. L. Shepherd instruction manual for the Model Mark I Series irradiator shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.

B. The procedures contained in the Nordion, Inc. instruction manual for the Model GC 3000 Elan Model II irradiator shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.

28. Notwithstanding Condition 24.A. of this license, Flavious Martin shall perform installation and replacement of sources contained in the Gamma Med II-i irradiation device, in accordance with procedures contained in letter dated April 12, 1989.

29. In addition to the possession limits in Condition 8, the licensee shall further restrict the possession of unsealed licensed material to quantities less than 10^4 times the application limits in Appendix C of 10 CFR Part 20, as specified in 10 CFR 30.35(d).

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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 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.

A. Application received June 6, 1994 (except Quality Management Program); and

B. Letters dated November 25, 1994, March 24, 1995, October 25, 1995 and January 12, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 17, 1996

By Colleen C. Casey
Nuclear Materials Licensing Branch, Region III

COPY

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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: 7B 3E 2B
Exp. Date: 20041231
Fee Comments: CODE 23
Decom Fin Assur Reqd: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: HENRY FORD HOSPITAL
   Received Date: 960903
   Docket No: 3002043
   Control No.: 301790
   License No.: 21-04109-16
   Action Type: Amendment

2. FEE ATTACHED
   Amount: ---X---
   Check No.: ---X---

* Addl Info 399351-S6

3. COMMENTS

Signed D. Hersey
Date 9-4-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /)

1. Fee Category and Amount: (7B) 3E 2B

FEE NOT REQUIRED

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal ---
   License ---

3. OTHER ---

Signed SC
Date 9/16/96

RECEIVED BY LFDCB
Date Sept. 12, 1996
Log Sep 3 III
By SC
Date Completed 9/16/96

SEP 19 1996

96 SEP 12 PM 3:59

Radiation Safety Office
2799 W. Grand Blvd.
Detroit, MI 48202
Voice: (313) 876-7042
Fax: (313) 876-9142

August 26, 1996

U.S. Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Branch
801 Warrenville Rd.
Lisle, IL 60532-4351

RE: Control Number 99351

Dear Sirs,

On July 17-18, 1996, Henry Ford Hospital (HFH) received and installed a Nordion Gammacell 3000 Elan Model II blood irradiator containing 2758 curies of Cs-137. This machine replaced a Gammacell 1000 Elite containing 800 curies of Cs-137, which was removed and shipped back to Nordion Inc. The installation of the Gammacell 3000 and the removal and shipment of the Gammacell 1000 were done by Nordion personnel and monitored by Henry Ford Radiation Safety Office personnel. Henry Ford Hospital received temporary authorization to possess both irradiators in Amendment No. 53 for NRC License No. 21-04109-21 on January 13, 1996. The replacement was completed July 18, 1996.

Leak testing of the received and returned Cs-137 sources was done independently by Nordion Inc. and the Henry Ford Radiation Safety Office. All results were less than 0.01 microcuries.

A radiation survey of the installed Gammacell 3000 machine was done by the Nordion representatives before the operator instruction on machine use was begun. The Radiation Safety Officer observed installation of the required secondary shielding. Surface measurements were repeated by the HFH Radiation Safety Office personnel on July 30. All surface measurements by Nordion and Henry Ford Hospital did not exceed 2 mR/hr. All survey and leak testing records will be kept on file for review by the NRC.

Accordingly, we request that Items 6.H, 7.H, 8.H, and 9.H and Condition 27A be updated to delete any reference to the Gammacell 1000 Elite in our NRC License No. 21-04109-16.

If you should have any questions, contact the Radiation Safety Office.

Sincerely,

Ralph P. Lieto, MSE

Ralph P. Lieto, M.S.E.
Radiation Safety Officer

Continuation of 39935

FEE NOT REQUIRED

RECEIVED
SEP 0 3 1996
REGION III

SEP 0 3 1996

pm: 8-27-96

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SEP 2 7 1996

Ralph P. Lieto, M.S.E.
Radiation Safety Officer
Henry Ford Hospital
2799 West Grand Blvd.
Detroit, MI 48202

Dear Mr. Lieto:

Enclosed is Amendment No. 54 to your NRC Material License No. 21-04109-16 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

A. Please note that, at this time, we changed the expiration date in item no. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.

B. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct 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. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

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3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Colleen C. Casey
Nuclear Materials Licensing Branch

License No.: 21-04109-16
Docket No.: 030-02043

Enclosures: 1. Amendment No. 54
2. 10 CFR Part 30

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To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII CCK	C							
NAME	CCASEY:jaw								
DATE	09/11/96								

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