NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 34

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.

Licensee	
1. Department of Health & Human Services National Institutes of Health	In accordance with the letter dated May 1, 1997,
2. 31 Center Drive, MSC 2260 Bethesda, Maryland 20892-2260	3. License Number 19-00296-17 is amended in its entirety to read as follows:
	4. Expiration Date July 31, 2003
	5. Docket or Reference No. 030-08478

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. Cesium 137	A. Sealed source (ORNL-50-RAMCO)	A. Not to exceed 2,400 curies per irradiator and 4,800 curies total
B. Cesium 137	B. Sealed source (AECL Model C-161, Type 8 or C-440)	B. Not to exceed 4,200 curies per irradiator and 21,000 curies total
C. Cesium 137	C. Sealed source (ORNL SK-342-B or JLS-6810)	C. 1,555 curies total
D. Cesium 137	D. Sealed source (ORNL SK-342-B or JLS-6810)	D. 6,600 curies total
E. Cesium 137	E. Sealed source (Nordion C-3000 or C-3001)	E. 3,264 curies total
F. Cesium 137	F. Sealed source (ORNL-50-RAMCO or ISO-1000)	F. 1,440 curies total
G. Cesium 137	G. Sealed sources (JLS-6810)	G. 6,600 curies total
H. Cesium 137	H. Sealed source (CSL-15)	H. 6,120 curies total
I. Cesium 137	I. Sealed sources (Nordion C-3000 or C-3001)	I. 3,048 curies total
J. Cesium 137	J. Sealed sources (Nordion C-440)	J. 4,000 curies total
K. Cesium 137	K. Sealed source (ORNL-50-RAMCO)	K. 3,264 curies total

9. Authorized use

A. For use in Isomedix Gammator Model M (Series M38) self-contained irradiators for irradiation of biological specimens.

B. For use in AECL Gammacell 40 self-contained irradiator for irradiation of biological

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C. For use in J. L. Shepherd Model 143-45 self-contained irradiator for irradiation of biological specimens.
D. For use in J. L. Shepherd Model 68 self-contained irradiator for irradiation of biological specimens.
E. For use in a Nordion International, Inc. Gammacell 1000 Elite-Type II self-contained irradiator for irradiation of biological specimens or blood.
F. For use in an AECL Gammacell 1000 Model B self-contained irradiator for irradiation of biological specimens.
G. For use in J. L. Shepherd Model 68-A-1 self-contained irradiator for irradiation of biological specimens.
H. For use in CIS-US, Inc., Model IBL 437C self-contained irradiator for irradiation of biological specimens.
I. For use in a Nordion International, Inc. Gammacell 3000 Elan-Type II self-contained irradiator for irradiation of biological specimens or blood.
J. For use in Nordion Model Gammacell 40 self-contained irradiator for irradiation of biological specimens.
K. For use in AECL Gammacell 1000 self-contained irradiator for irradiation of biological specimens or blood.

CONDITIONS

10. Licensed material in item 9.A., 9.B., 9.C, 9.D., 9.F., 9.H., 9.I., and 9.K shall be used only at the Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. Licensed material in item 9.A. shall also be used at 5 Research Court, Rockville, Maryland. Licensed material in item 9.B. and 9.E. shall also be used at the Center for Biologics Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Maryland. Licensed material in item 9.G. shall be used only at the licensee's facility at the Department of Health and Human Services, 12441 Parklawn Drive, Rockville, Maryland. Licensed material in item 9.J. shall be used only at the Department of Health and Human Services, Gerontology Research Center, 4940 Eastern Avenue, Baltimore, Maryland.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the last use of licensed material by the individual.

B. The Radiation Safety Officer for this license is Robert A. Zoon.

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

13. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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 three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, 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 and detector cells 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 transfer 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 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken. Records of leak 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.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. 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 persons specifically licensed by the Commission or an Agreement State to perform such services.

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

16. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license. Records of inventories shall be maintained for five years from the date of each inventory, and shall include the quantities and kinds of byproduct material, manufacturer name and model numbers, location of sources and/or devices, and the date of the inventory.

17. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:

A. permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

B. permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

C. have room monitors installed that will:

(i) operate at all times when the irradiator is in use; and

(ii) activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and

(iii) detect any radiation leaking from the irradiator door; and

(iv) be visible to the irradiator user when he is next to the irradiator; or

D. if a room monito is not installed, have available a calibrated and operable survey meter which will be used to:

(i) determine the radiation level at the irradiation door when the door is closed; and

(ii) check for any increase in radiation levels each time the irradiator door is opened.

E. immediately stop the use of the irradiator and notify the Commission by telephone as described in 10 CFR 20.2202(d) if abnormal levels of radiation or any malfunction of the irradiator is detected;

F. not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

18. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license shall be followed and copies of these manuals shall be made available to each person using or having responsibility for the use of the device.

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License number: 19-00296-17

Docket or Reference number: 030-08478

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19. 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. 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 dated August 26, 1992
B. Letter dated November 16, 1994
C. Letter dated November 20, 1996
D. Letter received February 14, 1997
E. Letter dated May 1, 1997

Date MAY 30 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By John R. McGrath

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

MAY 30 1997

Robert W. McKinney, Ph.D
Director, Division of Safety
Department of Health and Human Services
National Institutes of Health
31 Center Drive MSC 2260
Bethesda, Maryland 20892-2260

Dear Dr. McKinney:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
John R. McGrath

John R. McGrath
Senior Health Physicist
Division of Nuclear Materials Safety

License No. 19-00296-17
Docket No. 030-08478
Control No. 124548

Enclosure:
Amendment No. 34
DOCUMENT NAME: R:\WPS\MLTR\L1900196.17
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	McGrath JRM							
DATE	05/27/97		05/ /97		05/ /97		05/ /97	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

030-08478

MAY -1 1997

U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
Region I
475 Allendale Road
King of Prussia, PA 19406

Ref: License #19-00296-17

Dear Sir;

The purpose of this letter is to request an amendment of the above referenced license to allow the NIH to relocate one of the five irradiators in section 6B. The NIH plans to move the Nordion International, Inc. Gammacell 40 self-contained irradiator from 9000 Rockville Pike, Bethesda, Maryland to the Center for Biologics Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Maryland.

The irradiator will be operated according to the conditions of License #19-00296-17.

If you have any questions concerning this amendment, please contact me at 301-496-2254.

Robert A. Zoon, M.E., M.S.
Radiation Safety Officer, NIH

cc: Dr. Lance Liotta, Chairman, NIH Radiation Safety Committee
Dr. Robert McKinney, Director, Division of Safety

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MAY - 7 1997

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03510
Status Code: 0
Fee Category: EX 3E
Exp. Date: 20030731
Fee Comments: V
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: HEALTH & HUMAN SERVICES, DEPT. OF
   Received Date: 970507
   Docket No: 3008478
   Control No.: 124548
   License No.: 19-00296-17
   Action Type: Amendment

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

3. COMMENTS

Signed M. A. Perkins
Date 5/9/97

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 _____