

MATERIALS LICENSE

Amendment No. 12

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.

302358

Licensee		In accordance with letter dated January 28, 1997	
1. University of Cincinnati Radiation Safety Office		3. License Number 34-06903-11 is amended in its entirety to read as follows:	
2. P. O. Box 670591 231 Bethesda Avenue Cincinnati, OH 45267		4. Expiration Date September 30, 2003	
		5. Docket or Reference No. 030-18949	
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 sources (Isomedix Models RAMCO-50 or ISO-1000 or Nordion Models C-1000 or C-3000)	A. 1,650 curies	
B. Cesium-137	B. Sealed sources (Isomedix Models RAMCO-50 or ISO-1000 or Nordion Models C-1000, C-1001, C-3000, or C-3001)	B. 3,048 curies	
C. Cesium-137	C. Sealed sources (J.L. Shepherd & Associates Model 6810).	C. 2500 curies	

9. Authorized Use:

- A. To be used in Nordion International, Inc. (formally AECL, Ltd.), Gammacell 1000, Model B blood irradiator for irradiation of blood, blood products, bone marrow, bone marrow components, and peripheral blood and umbilical cord derived progenitor cells; excluding explosives and flammables.
- B. To be used in a Nordion International, Inc. (formally AECL, Ltd.) Gammacell 3000 Elan irradiator for irradiation of blood, blood products, bone marrow, bone marrow components, and peripheral blood and umbilical cord derived progenitor cells; excluding explosives and flammables.

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- C. To be used in a J.L. Shepherd & Associates Model Mark-1 Series (Sub Model 68) irradiator for clinical testing and for research and development, as defined in Part 30, Section 30.4 of 10 CFR, including irradiation of small animals, cells, and tissues; excluding explosives and flammables.

CONDITIONS

10. A. Licensed material listed in Item 6.A. shall be used only at the licensee's facilities located at 3231 Burnet Avenue, Cincinnati, Ohio. Licensed material may also be used in Room PB-4 Children's Hospital Medical Center (CHMC), Elland and Bethesda, Cincinnati, Ohio; or at CHMC Hospital Tower, Fourth Floor, Room 301, Cincinnati, Ohio.
- B. Licensed material listed in Item 6.B. shall be used only at the licensee's facilities located at 3231 Burnet Avenue, Cincinnati, Ohio. Licensed material may also be used in Room 5018 of the Hoxworth Blood Center on Highland and Goodman Streets.
11. Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Ronald Millard, Ph.D., Chairperson. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.
12. The Radiation Safety Officer for this license is Victoria Morris, M.S.
13. 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 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

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- (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. Records of leak test results 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 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, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source 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.
- 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.
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 a person specifically licensed by the Commission or an Agreement State to perform such services.
15. The procedures contained in device manufacturer's instruction manual for the Models Gammacell 1000-B and 3000 Elan devices and the J.L. Shepherd Model Mark-1 Series 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.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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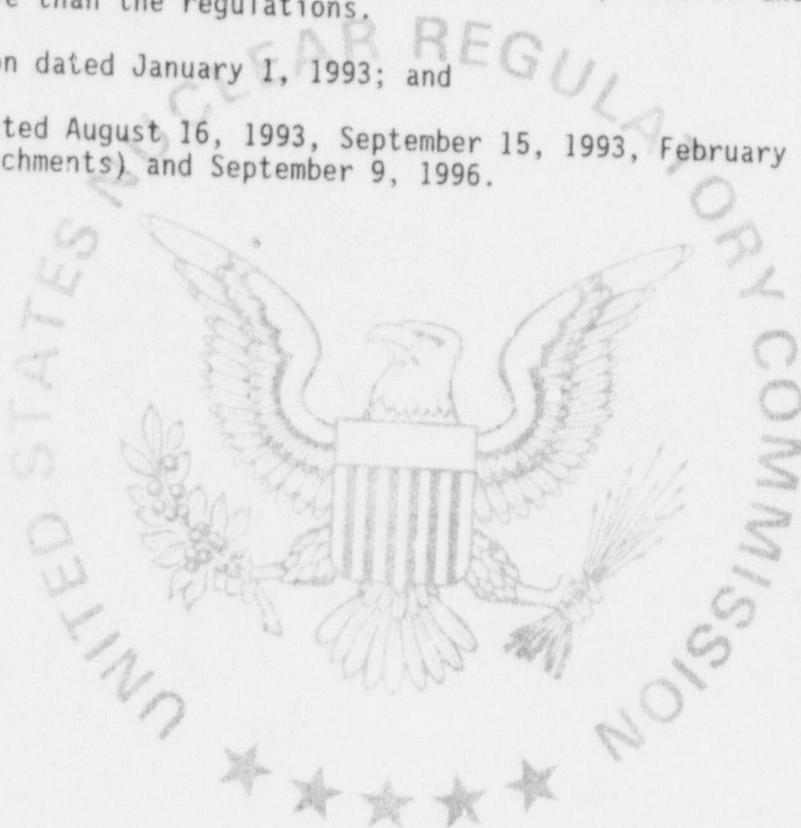
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17. Licensed material shall not be used in or on human beings.
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The 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.
- A. Application dated January 1, 1993; and
- B. Letters dated August 16, 1993, September 15, 1993, February 29, 1996 (with attachments) and September 9, 1996.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

3/21/97

By

Robert R. Matin

Nuclear Materials Licensing Branch, Region III

COPY

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: 20030930
Fee Comments: 170.11(A)(4)
Decom Fin Assur Req'd: N

1997 FEB 26

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: CINCINNATI, UNIVERSITY OF
Received Date: 970224
Docket No: 3018949
Control No.: 302358
License No.: 34-06903-11
Action Type: Amendment

2. FEE ATTACHED

Amount: -----
Check No.: -----

* mailing address
change

3. COMMENTS

Signed D. Hervey
Date 2-15-97

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

1. Fee Category and Amount: EX 3E **FEE NOT REQUIRED**

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal -----
License -----

3. OTHER

Signed SC
Date 2/26/97

MAR 06 1997

Log	Feb 14 1997
Remitter	
Check No.	
Amount	
Fee Category	EX 3E
Type of Fee	AMD
Date Check Rec'd	
Date Completed	2/26/97
By:	SC

University of Cincinnati



Radiation Safety Office
Radiation Safety Lab
University of Cincinnati
PO Box 670591
Cincinnati OH 45267-0591

Phone (513) 558-4110
Fax (513) 558-9905

January 28, 1997

United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Please change the address we have been receiving mailings to:

Victoria Morris/MS/RAD.SAF.OFC.
University of Cincinnati
Mail Location 0591
231 Bethesda Avenue
Cincinnati, OH 45267-0591

Thank you.

Linda Reagan
Secretary

Attachment

FEE NOT REQUIRED

PM: 1-30-97

An affirmative action/equal opportunity institution

RECEIVED

FEB 24 1997

REGION III

302358

FEB 24 1997

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

FIRST CLASS MAIL
POSTAGE AND FEES PAID
USNRC
PERMIT NO. G-67

*K50
Please
correct
address*

ATTN: VICTORIA MORRIS/MS/RAD.SAF.OFC
CINCINNATI, UNIVERSITY OF
MAIL LOCATION ~~569~~ *591*
234 GOODMAN STREET
CINCINNATI, OH 45267

34-06903-11

-05 also

070-539 also

MAR 21 1997

Victoria Morris
University of Cincinnati
Radiation Safety Office
P. O. Box 670591
231 Bethesda Avenue
Cincinnati, OH 45267

Dear Ms. Morris:

Enclosed is Amendment No. 12 to your NRC Material License No. 34-06903-11 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.

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,

V. Morris

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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
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No. 34-06903-11
Docket No. 030-18949

Enclosure: Amendment No. 12

DOCUMENT NAME: M:\03018949.CL7

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OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	ERMatson:brt <i>EM</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DATE	03/19/97	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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