

MATERIALS LICENSE

Amendment No. 18

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		In accordance with letter dated July 9, 1996	
1. Indiana University School of Medicine Northwest Center for Medical Education		3. License Number 13-18384-01 is amended in its entirety to read as follows:	
2. 3400 Broadway Gary, IN 46408		4. Expiration Date April 30, 2001	
		5. Docket or Reference No. 030-14970	
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. Carbon-14	A. Any	A. 40 millicuries	
B. Hydrogen-3	B. Any	B. 140 millicuries	
C. Phosphorus-32	C. Any	C. 80 millicuries	
D. Sulfur-35	D. Any	D. 50 millicuries	
E. Iodine-125	E. Any	E. 100 millicuries	
F. Iodine-131	F. Any	F. 20 millicuries	
G. Chlorine-36	G. Any	G. 2 millicuries	
H. Sodium-24	H. Any	H. 15 millicuries	
I. Sodium-22	I. Any	I. 25 millicuries	
J. Potassium-42	J. Any	J. 50 millicuries	
K. Calcium-45	K. Any	K. 2 millicuries	
L. Chromium-51	L. Any	L. 50 millicuries	
M. Technetium-99m	M. Any	M. 10 millicuries	
N. Rubidium-86	N. Any	N. 30 millicuries	
O. Magnesium-28	O. Any	O. 25 millicuries	

9. Authorized Use:

A. through O. Laboratory research, animal studies and student instruction.

190064

9612190299 961202
PDR ADOCK 03014970
C PDR

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-18384-01

Docket or Reference Number

630-14970

Amendment No. 18

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at the Northwest Center for Medical Education, 3400 Broadway, Gary, Indiana.
11. The Radiation Protection Officer for the activities authorized by this license is William Baldwin, Ph.D.
12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Dr. Norman Hudson	Carbon-14, Hydrogen-3, Iodine-125 Phosphorus-32, Iodine-131 and Sulfur-35
Dr. William Baldwin	All
Dr. William Marshall Anderson	All
Dr. Virgil Hoftiezer	Hydrogen-3
Dr. Panayotis G. Iatridis	Carbon-14,, Hydrogen-3 and Iodine-125
Dr. Roman Dziarski	All
Dr. Brian Kennedy	All
Dr. Subbiah Sivan	All
Dr. Niko Sakellaridis	Hydrogen-3, Carbon-14, Phosphorus-32, Rubidium-86 and Iodine-125
Dr. Tim Stabler	Hydrogen-3, Carbon-14, and Phosphorus-32
Dr. Stephen Echtenkamp	Iodine-125 and Hydrogen-3
Dr. Dipika Gupta-Roy	Hydrogen-3, Carbon-14, Sulfur-35, Phosphorus-32, Iodine-125, Calcium-45, and Chromium-51
13. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
14. The licensee shall maintain records of information important to safe and effective decommissioning at 3400 Broadway, Gary, Indiana per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE
SUPPLEMENTARY SHEETLicense Number
13-18384-01Docket or Reference Number
030-14970

Amendment No. 18

15. 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 May 21, 1985 (except Item 3 of Appendix E); and
- B. Letters dated October 29, 1985 (with attachments), July 21, 1986, November 11, 1986, January 18, 1988, February 1, 1989, October 18, 1990, April 30, 1991, and July 9, 1996 (except Item 1, "Survey Procedures").

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

December 2, 1996

By

Patricia J. Peene

Nuclear Materials Licensing Branch, Region III

DEC 09 1996

Roman Dziarski, Ph.D., Chairman
Radiation Safety Committee
Indiana University School of Medicine
Northwest Center for Medical Education
3400 Broadway
Gary, IN 46408

Dear Dr. Dziarski:

Enclosed is Amendment No. 18 to your NRC Material License No. 13-18384-01 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 note in particular that we have not approved the survey procedures proposed in your July 9, 1996 letter. Based on the procedures you provided, it appears that authorized users **may perform** area surveys at least once a week or at the completion of an experiment (if less than one week in duration). In addition, the authorized users record the results of these surveys once a month and provide copies to the Radiation Safety Officer (RSO) on a quarterly basis. Based on the size and scope of your program, the alternative you proposed is not adequate to insure that you satisfy the requirements of 10 CFR Part 20, Section 20.1501(a). In order to approve the alternative survey procedures, it will be necessary for you to modify the procedures to include independent, periodic surveys by the RSO. These random independent surveys should be performed on a monthly basis and the results recorded. As an alternative, the users may continue to perform the surveys at the frequencies proposed in your procedures; however, the results of these surveys must be recorded at the completion of each survey, not monthly, as specified in your July 9, 1996 letter.

Information submitted in response to this letter should be referenced as additional information to Previous Control Number 01584.

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:

301584

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).
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
Patricia J. Pelke
Nuclear Materials Licensing Branch

License No.: 13-18384-01
Docket No.: 030-14970

Enclosures: As stated

DOCUMENT NAME: M:\03014970.CL6

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								
NAME	PPELKE:jaw								
DATE	12/1/96								

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

July 19, 1996

William Baldwin
Radiation Safety Officer
Indiana University School Medicine
Northwest Center for Medical Education
3400 Broadway
Gary, IN 46408

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(☒ Letter ☐ Application ☐ Dated July 9, 1996)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License ☒ Amendment ☐ Renewal
☐ Termination ☐ Auth User (Amendment not required) ☐ QMP Revision
☐ Other _____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

It appears that your request is routine (see 1-3 below, as applicable) and complete.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (708) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301584
License No. 13-18384-01

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: EX 3M
EXP. DATE: 20010430
FEE COMMENTS: 170.11(A)(4)
DECOM FIN ASSUR REQD: N

RL

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: INDIANA UNIVERSITY SCHOOL MEDICINE
RECEIVED DATE: 960711
DOCKET NO: 3014970
CONTROL NO.: 301584
LICENSE NO.: 13-18384-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: 0
CHECK NO.: 0

3. COMMENTS

SIGNED
DATE

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE IS ENTERED) ☒

1. FEE CATEGORY AND AMOUNT: EX 3M FEE EXEMPT 170.11(A)(4)

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

3. OTHER

SIGNED
DATE

RECEIVED
JUL 29 1996
REGION 1.1

Log	<u>Jul 14 11</u>
Remitter	<u>[Signature]</u>
Check No.	<u>[Signature]</u>
FEE Category	<u>EX 3M</u>
Type of Fee	<u>EXEMPT</u>
Date Check Rec'd	<u>7/25/96</u>
Date Completed	<u>7/25/96</u>
By:	<u>Sc</u>

INDIANA UNIVERSITY



July 9, 1996

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

RE: Amendment to License No. 13-18384-01

Dear Sir/Madam:

I would like to request that our License No. 13-18384-01 be amended as follows:

1. Replace the existing "Survey Procedures" with amended "Survey Procedures" described in the attached "Appendix C".

The main change in this amended "Survey Procedures" is simplified record keeping for the weekly contamination surveys. While the radionuclide users will continue to perform surveys at least once a week or at the end of the experiment (if less than one week in duration), the users will be required to make permanent records of these surveys once a month (on the last working day of the month). To keep these records the radionuclide users will fill out the Radioactive Contamination Survey Form (attached in Appendix C). To assure the compliance with these surveys and to assure that the permanent records of the surveys are kept, the Radiation Safety Officer will collect the filled out Radioactive Contamination Survey Forms from all users of the radioactive materials at the end of each quarter. These forms will be kept in the Center's Radiation Safety Files.

2. Replace the existing "Procedures for Opening Packages Containing Radioactive Material" with amended "Procedures for Opening Packages Containing Radioactive Material" described in the attached "Appendix G".

The main change in the amended "Procedures for Opening Packages Containing Radioactive Material" is the simplified record keeping procedure for recording the results of the package survey. We have eliminated a separate form for recording the results of the package survey. Instead, the results of the package survey will be recorded on a self-adhesive sticker that will be placed on the order form in the possession records folder. This record keeping procedure will be easier, because the person who receives the package and checks it for contamination uses this order form to verify the contents of the package against the order that was placed. The order forms are checked quarterly by the Radiation Safety Officer, who reports quarterly to the Radiation Safety Committee on all the radioactive shipments received. At the same time (quarterly) these order forms will be checked for the record of contamination surveys.

Both of these proposed amended procedures have been accepted by NRC and are currently used at the Indiana University Bloomington campus.

We thank you for your cooperation and attention to this matter. If you need any additional information, please feel free to contact me at your convenience.

Sincerely yours,

Roman Dziarski

Roman Dziarski, Ph.D.
Chairman, Radiation Safety Committee, Phone: (219) 980-6535

Enclosures: APPENDIX C: Survey Procedures and Radioactive Contamination Survey Form
APPENDIX G: Procedures for Opening Packages Containing Radioactive Material

cc: P. G. Iatridis, M.D., D.Sc., Assistant Dean and Director

RECEIVED

JUL 11 1996

REGION III

301584

JUL 11 1996

THE NORTHWEST CENTER
FOR MEDICAL EDUCATION

3400 Broadway
Gary, Indiana
46408-1197

219-980-6550

Fax: 219-980-6566

170-11(A)(4)
FEE EXEMPT

pm: 7-9-96

APPENDIX C

Survey Procedures

A. Each Responsible Investigator must ensure that areas of use within their laboratory are surveyed routinely. If concentrated solutions of highly active radioisotopes are used, the area should be surveyed at the end of each day of use. All areas of use must be surveyed at least once a week or at the end of the experiment (if less than one week in duration). The surveys do not have to be performed if radioisotopes have not been used in the laboratory since the last survey.

B. The survey will consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr, if only high energy beta or gamma emitting radionuclides (^{32}P , ^{125}I , ^{131}I , ^{36}Cl , ^{22}Na , ^{24}Na , ^{42}K , ^{51}Cr , $^{99\text{m}}\text{Tc}$, ^{86}Rb , ^{28}Mg) have been used. To perform the survey, the probe must be moved slowly in close proximity (1 cm) to the surface being checked. Any surface whose count rate exceeds three times the background count rate of the meter will be considered contaminated.

OR:

2. A series of wipe tests sufficiently sensitive to detect 100 dpm. Wipe tests must be used if low to medium energy beta emitting radionuclides (^3H , ^{14}C , ^{35}S , ^{45}Ca) have been used. Wipe tests may also be used to survey for the high energy beta or gamma emitting radionuclides. To perform the survey, a 100 cm^2 area should be swabbed with an absorbent pad with a suitable solvent (e.g. alcohol prep), and the radioactivity of the pad should be analyzed in a scintillation counter. Any area or item whose counts are greater than $\text{Background (cpm)} + 3 \times \text{Background (cpm)}$ will be considered contaminated.

C. All areas and equipment designated for the use of radioactivity (including portable equipment, such as pipettors), refrigerator handles, door knobs, and selected areas not designated for the use of radioactive materials in the laboratory must be surveyed.

D. All contaminated areas must be decontaminated. If the contamination is greater than 22,000 dpm (cpm/efficiency) per 100 cm^2 , or the radiation level is greater than 10 mR/hr at 3 feet, notify the Radiation Safety Officer immediately. If the contamination level is lower than 22,000 dpm (cpm/efficiency) per 100 cm^2 , or the radiation level is lower than 10 mR/hr at 3 feet, decontaminate the area using the following procedure:

1. Put on protective apparel (lab coat and gloves).
2. Define the extent of contamination with a survey instrument or wipe tests and mark the perimeters of the contaminated area.
3. Scrub the area from the borders to the center with disposable cleaning supplies (e.g., paper towels and cleaning solution), cleaning small areas at a

time. Place all contaminated cleaning materials and gloves in a plastic bag and label as radioactive waste.

4. Monitor the effectiveness of decontamination with wipe tests or instrument surveys.

E. A permanent record of the contamination survey must be made on the last working day of each month. The record should include the date of the survey, the names of the responsible investigator and individual performing the survey, the room surveyed, the type of the survey (direct meter or wipe test), the areas surveyed, and the results (use the Radioactive Contamination Survey Form, see next page). The original signed survey forms should be submitted to the Radiation Safety Officer at the end of each quarter (end of March, June, September, and December).

RADIOACTIVE CONTAMINATION SURVEY FORM

Responsible Investigator: _____ Room: _____ Date: _____

Nuclide(s) used since last survey: _____

Survey method

_____ **Direct measure** (meter)

Survey meter type: _____ Model number: _____

Background count rate: _____

_____ All areas surveyed **not** contaminated (count rate lower than three times the background count rate)

_____ Areas contaminated indicated on the diagram below (count rate higher than three times the background count rate) (**indicate count rates**); all other areas surveyed not contaminated (count rate lower than three times the background count rate)

_____ **Wipe survey** (required for ^3H , ^{14}C , ^{35}S , ^{45}Ca)

Background cpm: _____ Efficiency: _____

_____ All areas surveyed **not** contaminated (cpm lower than background cpm + 3 x background cpm)

_____ Areas contaminated indicated on the diagram below (cpm higher than background cpm + 3 x background cpm) (**attach results**); all other areas surveyed not contaminated (cpm lower than background cpm + 3 x background cpm)

Corrective actions (indicate count rates or attach results of wipe tests after decontamination):

Surveyed by: _____

Area diagram

APPENDIX G

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Once a package containing radioactive material is received it should be opened as soon as possible (within 3 hrs of receipt) in accordance with the following procedure:

1. Put on labcoat and disposable gloves.
2. Place the package on an absorbent paper.
3. Turn radiation survey meter on, check it for proper operation, and place it near the package.
4. Remove the packing slip and verify if the type and the amount of the radioactive material agrees with the type and amount ordered.
5. Open the package and check the labels on the inner container and source vial to ensure that they agree with the contents listed on the packing slip.
6. Inspect the inner container, source vial, and packing materials for evidence of damage or leakage.
7. If the package contains high energy beta or gamma emitting radionuclides (^{32}P , ^{125}I , ^{131}I , ^{36}Cl , ^{22}Na , ^{24}Na , ^{42}K , ^{51}Cr , $^{99}\text{Tc}^m$, ^{86}Rb , ^{28}Mg), survey the package, packing material, and the container for contamination using a survey meter sufficiently sensitive to detect 0.1 mR/hr. To perform the survey, the probe must be moved slowly in close proximity (1 cm) to the surface being checked. If the count rate exceeds three times the background count rate of the meter, the package is considered contaminated. If the contamination is greater than 200 mR/hr, notify the Radiation Safety Officer immediately.
8. If the package contains low to medium energy beta emitting radionuclides (^3H , ^{14}C , ^{35}S , ^{45}Ca), survey the package for contamination using the wipe tests. Wipe tests may also be used to survey for the high energy beta or gamma emitting radionuclides. To perform the survey, wipe the external surfaces of the inner container and the source vial with wet absorbent pads with a suitable solvent (e.g. alcohol prep). Then, analyze the radioactivity of the pads in a scintillation counter. If the counts are greater than Background (cpm) + 3 x Background (cpm), the package is considered contaminated. If the contamination is greater than 22,000 dpm (cpm/efficiency), notify the Radiation Safety Officer immediately.
9. If the package is free of contamination, place the container with the source vial of radioactive material in a designated storage location.
10. **Record** that the shipment was received, the date and time, and the results of the package survey on the self-adhesive receiving label (shown below), and place the label on the order form in the possession records folder.
11. Deface radioactive labels on the outer package and place the empty package and any other packing materials shown to be free of contamination in normal trash. The styrofoam containers are usually recycled. Place the return label on the styrofoam container, make sure that the container does not have any radioactive labels, and return it to the vendor.

Radioisotope receiving label:

Received:
Date _____ Time _____
Package survey OK:
Yes NO
Signature _____