NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 13

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.

Licensee	
1. The University of Oklahoma Health Sciences Center	In accordance with letters dated August 6, 1996, and September 4, 1996
2. P.O. Box 26901 Oklahoma City, Oklahoma 73190	3. License number 35-03176-04MD is amended in its entirety to read as follows:
	4. Expiration date January 31, 1995
	5. Docket or Reference No 030-12750

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 Section 35.100 of 10 CFR Part 35	A. Any form identified in Section 35.100 of 10 CFR 35	A. 50 curies
B. Any byproduct material identified in Section 35.200 of 10 CFR Part 35	B. Any form identified in Section 35.200 of 10 CFR 35, including Mo99/Tc99m generators	B. 300 curies
C. Any byproduct material identified in Section 35.300 of 10 CFR Part 35	C. Any form identified in Section 35.300 of 10 CFR 35	C. 10 curies Total possession of I-131 not to exceed 3 curies
D. Any byproduct material identified in Section 35.500 of 10 CFR Part 35	D. Any form identified in Section 35.500 of 10 CFR 35	D. 10 curies

0/1

OFFICIAL RECORD COPY

ML40

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
35-03176-04MD

Docket or Reference Number
030-12750

Amendment No. 13

E. Any byproduct material authorized under Section 35.57(a) of 10 CFR Part 35	E. Any sealed source identified in Section 35.57(a) of 10 CFR Part 35 that has been 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	E. 10 curies
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged kits for in-vitro diagnostic testing	F. 200 millicuries
G. Uranium (Depleted in Uranium-235)	G. Metal	G. 400 kilograms

9. Authorized use:

A. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients, use of technetium-99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals, research and development as defined in 10 CFR 30.4, and academic instruction.

B. Dispensing and/or distribution of radioactive drugs (including Mo99/Tc99m generators) to authorized recipients, use of technetium-99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals, research and development as defined in 10 CFR 30.4, and academic instruction.

C. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients, research and development as defined in 10 CFR 30.4, and academic instruction.

D. Redistribution of sealed sources identified in Section 35.500 of 10 CFR Part 35 to specifically authorized recipients, research and development as defined in 10 CFR 30.4, and academic instruction.

E. Calibration of licensee's instruments, distribution of sources identified in 35.57(a) of 10 CFR Part 35 to specifically authorized recipients, research and development as defined in 10 CFR 30.4, and academic instruction.

F. Redistribution to specific licensees, research and development as defined in 10 CFR 30.4, and academic instruction.

G. As shielding for molybdenum-99/technetium-99m generators.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States, and to persons licensed pursuant to Sections 32.72 and 32.74 of 10 CFR Part 32.

CONDITIONS

10. Licensed material shall be used only at the College of Pharmacy, 1110 North Stonewall Avenue, Oklahoma City, Oklahoma.

11. A. Licensed material shall be used by, or under the supervision and in the physical presence of, Stanley L. Mills, Ph.D., R.Ph., or individuals designated by The University of Oklahoma Health Sciences Center Radiation Safety Committee, Chairperson as identified in License No. 35-03176-01.

B. At least one individual named in Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.

C. The Radiation Safety Officer for this license is Subhash M. Danak.

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 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 and detector cells 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. 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 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.

F. 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Radiation Safety and Safeguards. 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.

G. 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 conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

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. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in letter dated November 20, 1989, and August 6, 1996.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 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 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. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

    D. A record of each disposal permitted under this License Condition shall be retained for 3 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.

18. The licensee shall not store licensed material contained in waste for more than 2 years from the date the waste is put into storage. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage.

19. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.

20. Used molybdenum-99/technetium-99m generators shall not be redistributed.

21. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an Food and Drug Administration (FDA)-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND); or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND; and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

C. The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

22. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

23. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.

24. Any proposed changes in packaging, shielding, or labeling shall be submitted for review to U.S. Nuclear Regulatory Commission, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Radiation Safety and Safeguards. Approval of the changes shall be received by the licensee prior to implementing the changes.

25. Prepackaged <u>in vitro</u> diagnostic test kits that are distributed to a specific licensees shall contain labeling that conforms to the requirements of Sections 20.1901(a) and 20.1904 of 10 CFR Part 20.

26. A. The licensee shall perform a test to detect and quantify the activity of molybdenum-99 contamination in each elution of technetium-99m from a molybdenum-99/technetium-99m generator and in each extraction or separation of technetium-99m from molybdenum-99 not contained in a generator.

B. The licensee shall not distribute technetium-99m for human use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Subitem B. above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records describing Subitem E.1. above shall be maintained for 2 years following the performance of the tests and the training of personnel.

27. In addition to the possession limits in Condition 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
35-03176-04MD

Docket or Reference Number
030-12750

Amendment No. 13

28. 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 June 28, 1988
B. Letter dated August 16, 1989
C. Letter dated November 20, 1989
D. Letter dated November 2, 1990
E. Letter dated April 25, 1991
F. Letter dated June 14, 1991
G. Letter dated April 21, 1992
H. Letter dated October 29, 1992
I. Letter dated October 30, 1992
J. Letter dated November 24, 1992
K. Letter dated September 9, 1993
L. Letter dated March 4, 1994 and received November 14, 1994
M. Letter dated June 8, 1995
N. Letter dated June 30, 1995
O. Letter dated July 31, 1995
P. Letter dated August 6, 1996
Q. Letter dated September 4, 1996

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date DEC 31 1996

By Original Signed By
Jack E. Whitten

Jack E. Whitten
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

December 31, 1996

The University of Oklahoma
Health Sciences Center
ATTN: Subhash Danak, M.S.
Radiation Safety Officer
P.O. Box 26901
Oklahoma City, OK 73190

SUBJECT: LICENSE AMENDMENT

Please find enclosed License No. 35-003176-04MD. You should review this license carefully and be sure that you understand all conditions. Although its expiration date has not been changed by this amendment, your license remains in effect (that is, in timely renewal status) until further notice. If you have any questions, you may contact the reviewer who signed your license at (817) 860-8197.

Note, as requested in your September 4, 1996, letter that the Chairperson will only be identified on License No. 35-003176-01. This change will ensure that the Chairperson, once approved on License No. 35-003176-01, will automatically be reflected on this and other University of Oklahoma licenses. Additionally, this will reduce the licensing activities required to make future changes in Radiation Safety Committee Chairpersons and the need for duplicate amendments..

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public which can result from failure to comply with NRC requirements, 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: Inspection and Investigations," 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 (no fee required if the location of radioactive material remains the same).

5. Request and obtain written NRC consent before transferring your license or any right thereunder, either voluntarily or involuntarily, directly or indirectly, through transfer of

control of your license to any person or entity. A transfer of control of your license includes not only a total change of ownership, but also a change in the controlling interest in your company whether it is a corporation, partnership, or other entity. In addition, appropriate license amendments must be requested and obtained for any other planned changes in your facility or program that are contrary to your license or contrary to representations made in your license application, as well as supplemental correspondence thereto, which are incorporated into your license. A license fee may be charged for the amendments if you are not in a fee-exempt category.

6. Maintain in a single document decommissioning records that have been certified for completeness and accuracy listing all the following items applicable to the license:

   - Onsite areas designated or formerly designated as restricted areas as defined in 10 CFR 20.3(a)(14) or 20.1003.

   - Onsite areas, other than restricted areas, where radioactive materials in quantities greater than amounts listed in Appendix C to 10 CFR 20.1001-20.2401 have been used, possessed, or stored.

   - Onsite areas, other than restricted areas, where spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site have occurred that required reporting pursuant to 10 CFR 30.50(b)(1) or (b)(4), including areas where subsequent cleanup procedures have removed the contamination.

   - Specific locations and radionuclide contents of previous and current burial areas within the site, excluding radioactive material with half-lives of 10 days or less, depleted uranium used only for shielding or as penetrators in unused munitions, or sealed sources authorized for use at temporary job sites.

   - Location and description of all contaminated equipment involved in licensed operations that is to remain onsite after license termination.

7. 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.

8. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

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; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and

Procedure for NRC Enforcement Actions" (Enforcement Policy), 60 FR 34381, June 30, 1995.

Thank you for your cooperation.

Sincerely,

Jack E. Whitten
Senior Health Physicisit
Nuclear Materials Licensing Branch

Docket: 030-12750
License: 35-003176-04MD
Control: 466145

Enclosures: As stated

DOCUMENT NAME: P:\ltr\uohsc4md.wpd
To receive copy of document, indicate in box: "C" = Copy without enclosures **"E"** = Copy with enclosures **"N"** = No copy

RIV:NMLB	N	RIV:					
JEWhitten							
12/31/96							

OFFICIAL RECORD COPY

From: Jackie Whitten
To: INTERNET:cclink.net.uokhsc.edu:Subhash:Danak
Date: 12/24/96 12:33pm
Subject: Chairman of the Radiation Safety Committee

Subhash//

As you will recall, we discussed amending the UOHSC licenses to require that only one license, instead of two, need be change for any change in the RSC Chair. We decided that we would amend the Type A Broad Scope (35-21035-01) license and by reference, we would address all others to this licenses. We agreed we would something like ...or under the supervision of, the University of Oklahoma Health Sciences Center, Radiation Safety Committee, and its respective chairperson ad identified in 35-21035-01.

This way we would only have to amend one license, limit the amount of material that the NRC and UOHSC must maintain in our respective files. To accomplish this, please address the chairman change by requesting the above process. I will then implement this procedure and we both will win!

Thx//JackW

PS: Have a Merry Christmas and Happy New Year. I will be in the office on Thursday and Friday.

The University of Oklahoma

Health Sciences Center

RADIATION SAFETY OFFICE

December 12, 1996

Mr. Jack Whitten
Senior Health Physicist
Nuclear Material Licensing Section
U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Re: Amendment to NRC License #35-03176-04MD dated August 6, 1996

Dear Mr. Whitten:

Please inform us as to the status of the above referenced amendment for the Nuclear Pharmacy license. I appreciate your assistance in this matter.

Sincerely,

Subhash M. Danak, M.S., D.A.B.R.
Radiation Safety Officer

/lsv

Re attached Email reply.

DEC 24 1996

From: <Subhash.Danak@cclink.net.uokhsc.edu>
To: Jackie Whitten <JEW1@nrc.gov>
Date: 8/30/96 9:19am
Subject: Re: AMENDMENT TO LICENSE NO. 35-03176-04MD

Jack,

I have begun working with the director, nuclear pharmacy to complete
the requested items. Should be done soon.

Have a nice long weekend. Thanks.

_____Subhash_____ Reply Separator

Subject: AMENDMENT TO LICENSE NO. 35-03176-04MD
Author: Jackie Whitten <JEW1@nrc.gov> at cclink
Date: 8/29/96 4:13 PM

University of Oklahoma Health Sciences Center
Subhash Danak, R.S.O.
1000 Stanton L. Young Blvd.
Oklahoma City, OK 73190

SUBJECT: AMENDMENT REQUEST (LICENSE NO. 35-03176-04MD)

Gentlemen:

Letter dated August 6, 1996, included an overview diagram of a section of the Nuclear Pharmacy. To better understand you plans for using Room 144, it will be necessary to provide a detailed diagram of Room 140 and a diagram of Room 144. This diagram should be complete and indicated the location of locks, shielding, counter tops, sinks, fume hoods, radiation monitors, etc.

Is Room 140 to be returned to unrestricted use, and if so what plans have been made for close out and return it to unrestricted use?

Per our discussion today, you should modify this request to address the Radiation Safety Committee Chairman modification. As we discussed, the ability to refer to License No. 35-03176-01 may be the best approach.

If you have any questions please feel free to contact me at (817) 860-8197 or E-mail me at JEW1@NRC.GOV.

Sincerely,

Jack E. Whitten
Senior Health Physicist

Received: from igate.nrc.gov by irm12 (5.x/TMD1.7)
id AA16618; Fri, 30 Aug 1996 09:22:36 -0400
Received: from uokhsc.edu by igate.nrc.gov (8.7.5/8.7.5) with SMTP id JAA11491 for <JEW1@nrc.gov>; Fri, 30 Aug 1996 09:22:41 -0400 (EDT)
From: Subhash.Danak@cclink.net.uokhsc.edu
Received: from cclink.uokhsc.edu by uokhsc.edu (SMI-8.6/UOKHSC-1.19)
id IAA08009; Fri, 30 Aug 1996 08:22:23 -0500
Received: from ccMail by cclink.uokhsc.edu (SMTPLINK V2.10.08)
id AA841420126; Fri, 30 Aug 96 08:19:45 CST
Date: Fri, 30 Aug 96 08:19:45 CST
Message-Id: <9607308414.AA841420126@cclink.uokhsc.edu>
To: Jackie Whitten <JEW1@nrc.gov>
Return-Receipt-To: Subhash.Danak@cclink.net.uokhsc.edu
Subject: Re: AMENDMENT TO LICENSE NO. 35-03176-04MD

From: Jackie Whitten
To: INTERNET:"Subhash.Danak@cclink.net.uokhsc.edu"
Date: 8/29/96 3:46pm
Subject: AMENDMENT TO LICENSE NO. 35-03176-04MD

University of Oklahoma
Health Sciences Center
Subhash Danak, R.S.O.
1000 Stanton L. Young Blvd.
Oklahoma City, OK 73190

SUBJECT: AMENDMENT REQUEST (LICENSE NO. 35-03176-04MD)

Gentlemen:

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If you have any questions please feel free to contact me at (817) 860-8197 or E-mail me at JEW1@NRC.GOV.

Sincerely,

Jack E. Whitten
Senior Health Physicist

Mail Envelope Inf(32226018D.25D : 21 : 9680)

Subject: AMENDMENT TO LICENSE NO. 35-03176-04MD
Creation Date: 8/29/96 3:46pm
From: Jackie Whitten

Created By: ARD1.ARP1:JEW1

Recipients	Action	Date & Time
Post Office INTERNET	Transferred	08/29/96 03:46p
No More Status		08/29/96 03:46p
"Subhash.Danak@cclink.net.uokhsc.edu"		

Domain.Post Office	Delivered	Route
INTERNET		INTERNET

Files	Size	Date & Time
MESSAGE	1083	08/29/96 03:46pm
View	3422	08/29/96 10:46am

Options
Auto Delete: No
Expiration Date: None
Notify Recipients: Yes
Priority: Normal
Reply Requested: No
Return Notification:
Send Receipt/Notify when Opened

Concealed Subject: No
Security: Normal

To Be Delivered: Immediate
Status Tracking: Delivered & Opened

The University of Oklahoma

Health Sciences Center

RADIATION SAFETY OFFICE

September 12, 1996

Ms. Billie Gruszynski
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

RE: License #35-03176-05, Control #466146
#35-03176-04MD, Control #466145
#35-21035-01, Control #466148

See 35-03176-01 for backup info. Jag

Dear Ms. Gruszynski:

Pursuant to the previous letter we sent you dated August 6, 1996, please be advised that the Interim Chairman of the Radiation Safety Committee, George N. Chacko, M.D., has decided to continue his interim chairmanship through December 1996. The new Chairman of the Radiation Safety Committee will be Kenneth E. Blick, Ph.D., Associate Professor of Pathology and Director of RIA Endocrinology, of The University Hospital. He will assume the responsibilities of the position in January of 1997.

Rebecca Blackstock, Ph.D., Associate Professor Microbiology, of the Oklahoma Health Sciences Center will become the Vice-Chairman also effective January 1997.

Please find enclosed the Curriculum Vitaes for both Dr. Blick and Dr. Blackstock.

I appreciate your assistance in this matter.

Sincerely,

Subhash Danak

Subhash M. Danak, M.S., D.A.B.R.
Radiation Safety Officer

SMD/cl

Enclosures

466145

1000 Stanton L. Young Boulevard • Library 176 • Oklahoma City, Oklahoma 73190 • (405) 271-6121

The University of Oklahoma

Health Sciences Center

RADIATION SAFETY OFFICE

September 4, 1996

Mr. Jack Whitten
Senior Health Physicist
Nuclear Material Licensing Section
U.S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Re: Amendment to NRC License #35-03176-04MD dated August 6, 1996

Dear Mr. Whitten:

Attached is the overview diagram you requested for room 143 and the current room 140. Room 140 receiving area will be wipe tested and surveyed as part of the decommissioning of this room by the Radiation Safety Office and reviewed by the Radiation Safety Officer prior to returning this space to unrestricted use. Please indicate in the license that the Radiation Safety Committee Chairperson will be the same Radiation Safety Committee Chairperson as in License #35-03176-01 in the future.

Following your approval of the amendment request, room 140 will not be released to unrestricted use and 143 activated as the receiving area for the Nuclear Pharmacy until such time as the Radiation Safety Officer reviews and approves the area for use.

Please note the typographical error in the diagram submitted with the original amendment dated August 6, 1996. The receiving room was noted as 144 instead of 143. The correction has been made in the new diagrams.

Please do not hesitate to contact me should you have any questions.

Sincerely,

Subhash Danak

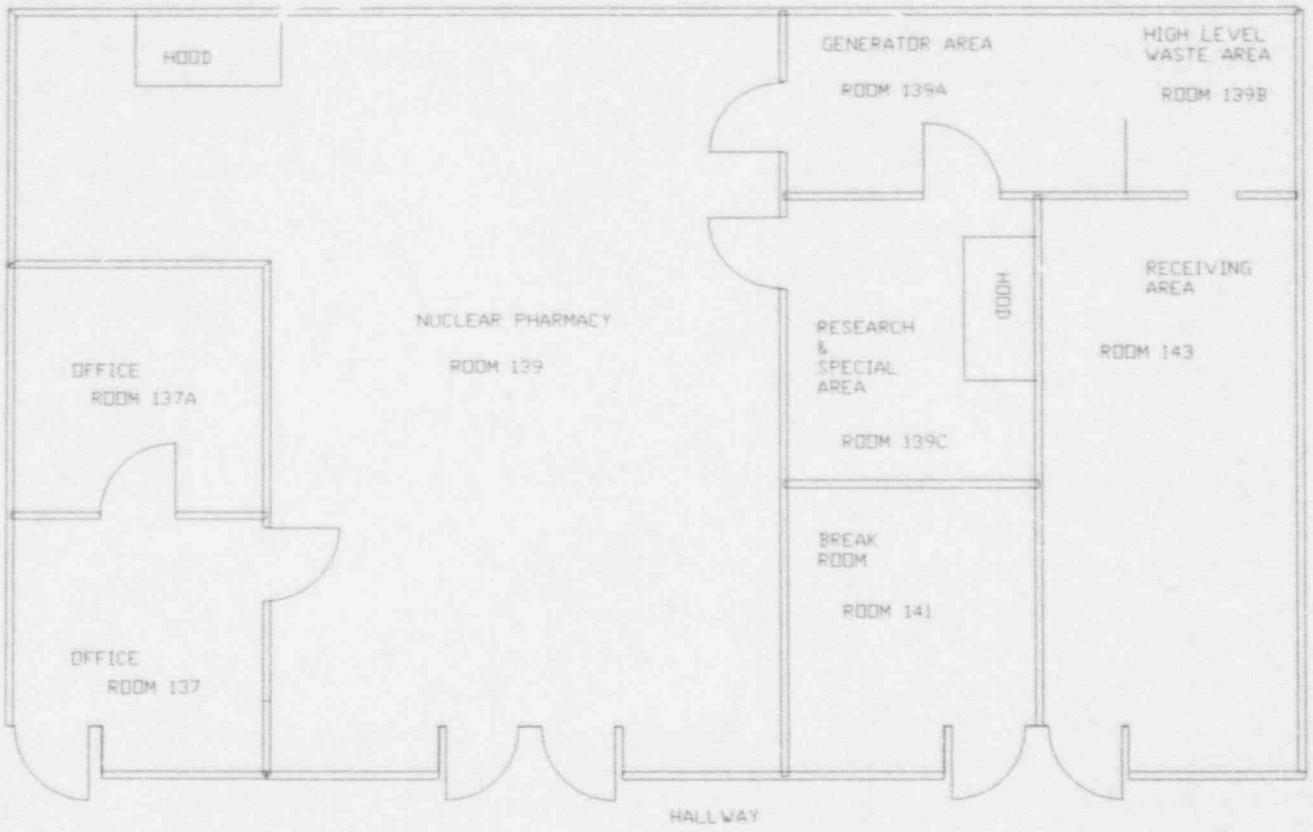
Subhash M. Danak, M.S., D.A.B.R.
Radiation Safety Officer

/lsv

Attachments

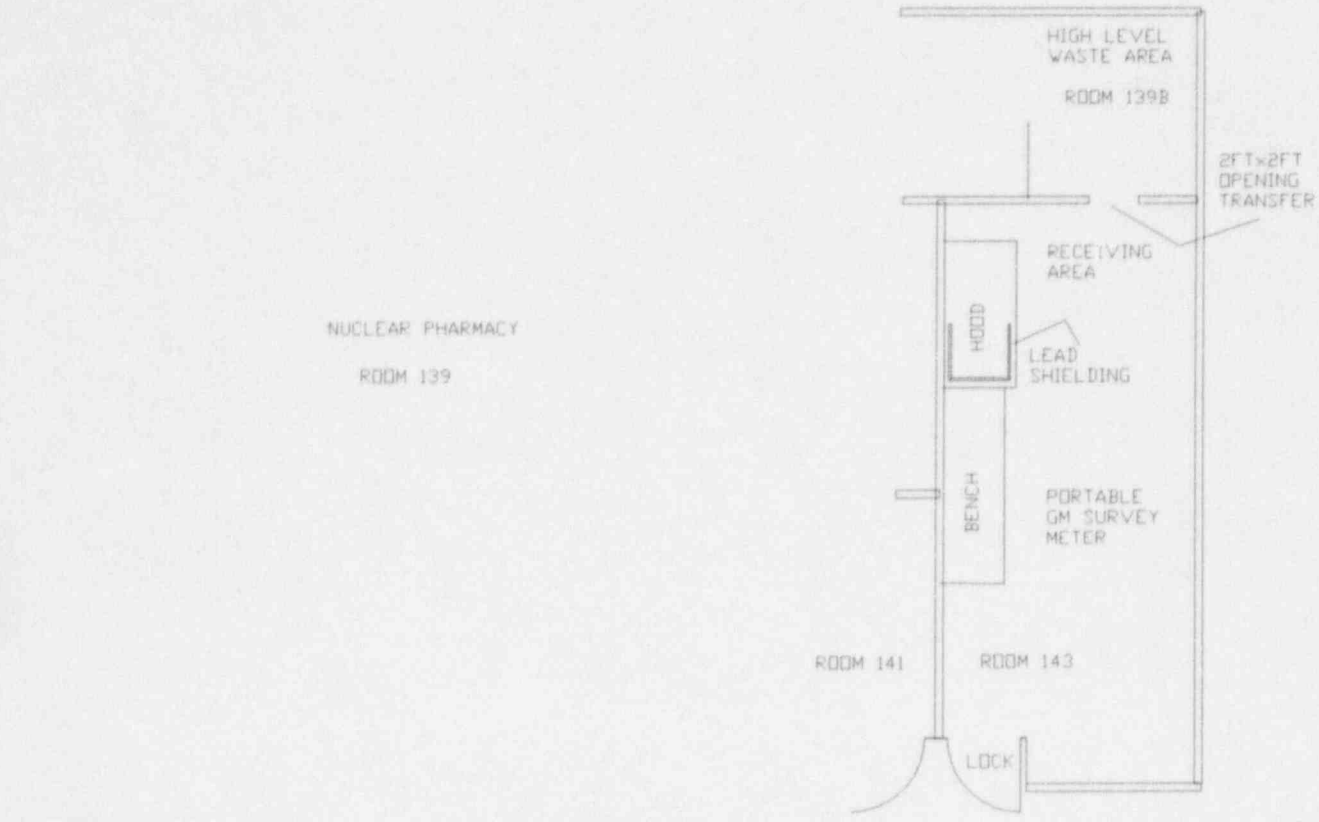
1000 Stanton L. Young Boulevard • Library 176 • Oklahoma City, Oklahoma 73190 • (405) 271-6121

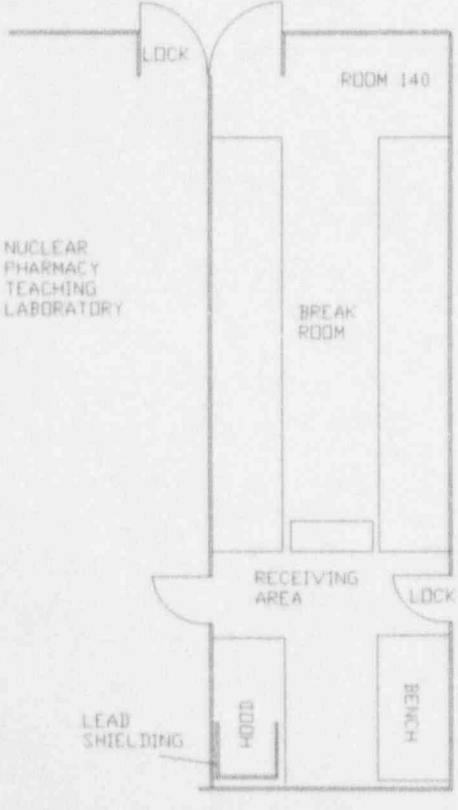
NUCL R PHARMACY COLLEGE OF PHARMACY OUHSC



SCALE 1"=1/8"

NUCLEAR PHARMACY COLLEGE OF PHARMACY OUHSC





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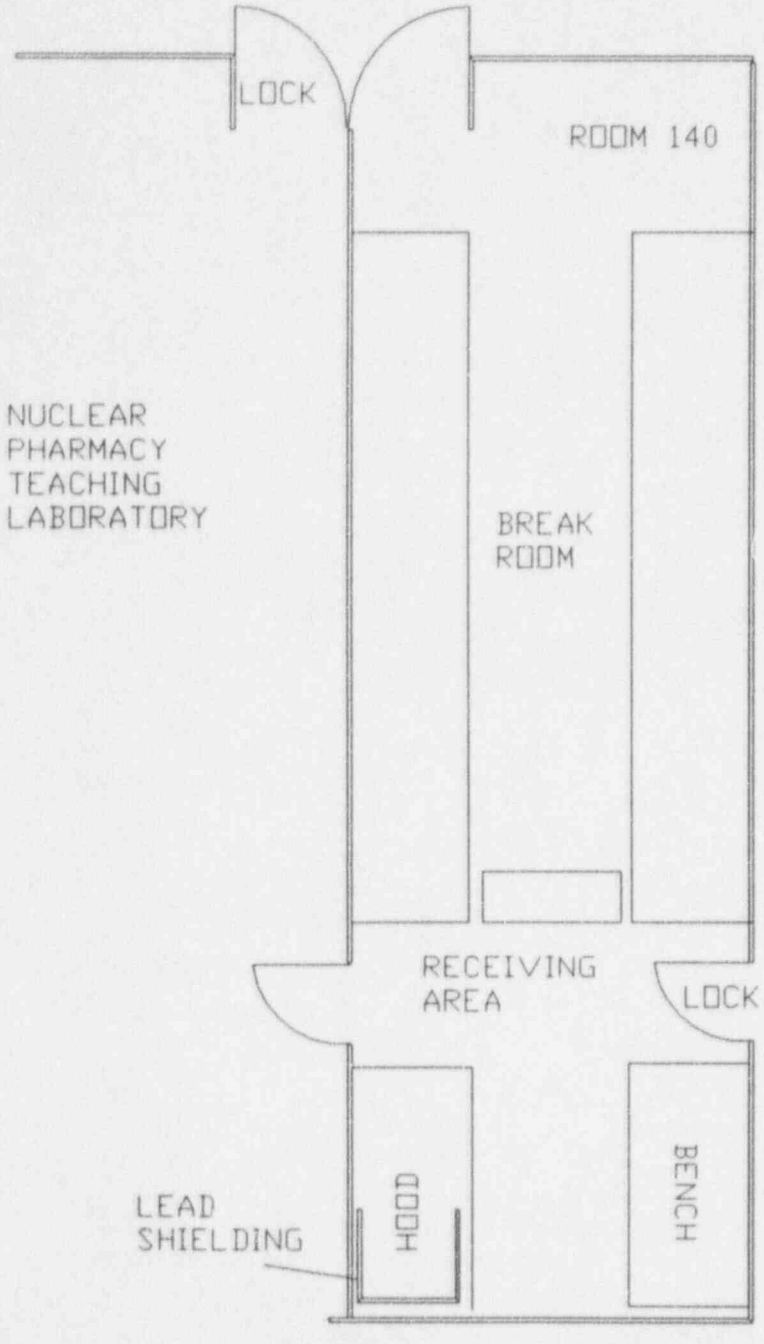
LOCK
ROOM 140
NUCLEAR
PHARMACY
TEACHING
LABORATORY
BREAK
ROOM
RECEIVING
AREA
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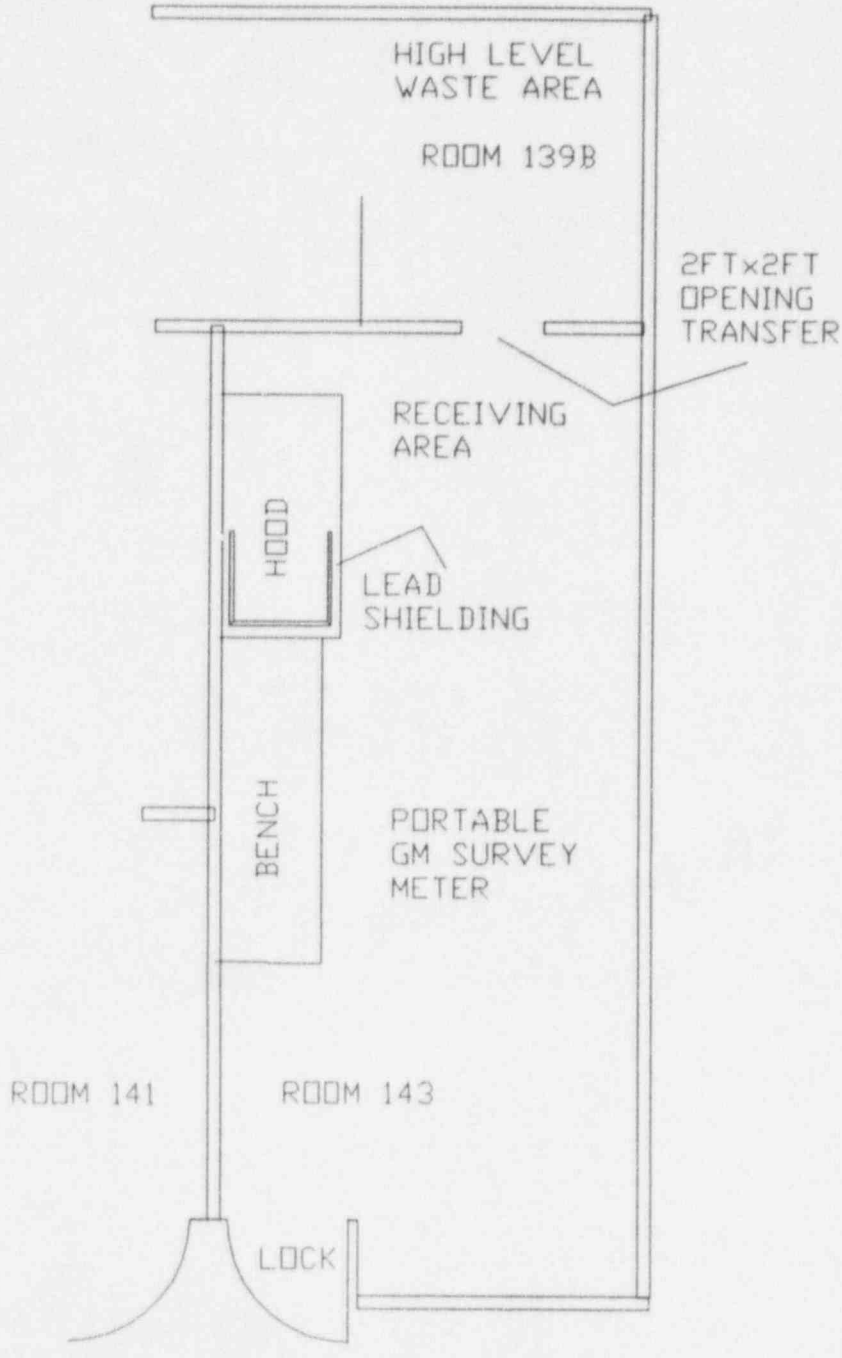
BENCH
LEAD
SHIELDING

SCALE 1'=1/8"

COLLEGE OF PHARMACY OUHSC



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SCALE 1"=1/8"

The University of Oklahoma

Health Sciences Center

RADIATION SAFETY OFFICE

August 6, 1996

Mr. Jack Whitten
Senior Health Physicist
Nuclear Material Licensing Section
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Re: Amendment to NRC License # 35-03176-04MD

Dear Mr. Whitten:

We respectfully request two changes to U.S. Nuclear Regulatory Commission license number 35-03176-04MD.

I. The first change is requested because no provision was made in the original application for excepted packages that conformed to 10 CFR 173.421. The change is to item 10.9 PROCEDURES FOR RETRIEVING WASTE FROM CUSTOMERS in the license application to read:

The OUHSC Nuclear Pharmacy will receive only those items (e.g., syringes, vials, etc.) that contain or are contaminated with radioactive materials that the Nuclear Pharmacy supplied. We will provide detailed instructions to customers that will package radioactive waste for return to the Nuclear Pharmacy pursuant to 10 CFR 173.421 (see attached).

II. The second change is to allow receiving of radioactive packages from suppliers in room 143 College of Pharmacy Building, 1110 N. Stonewall Ave, OKC, OK. This change in receiving location should reduce the radiation exposure to personnel and the public in transporting the material across the hallway from room 140 College of Pharmacy Building, 1110 N. Stonewall Ave, OKC, OK. The room will be maintained under negative pressure to the hallway (see attached diagram).

1000 Stanton L. Young Boulevard • Library 176 • Oklahoma City, Oklahoma 73190 • (405) 271-6121

Please process this amendment as soon as possible. If you have any further questions, or if I can be of further assistance to you, please contact me at (405) 271-6121.

Sincerely,

Subhash M. Danak, M.S., D.A.B.R.
Radiation Safety Officer

/lsv

Attachments

SHIPPING PROCEDURE FOR EXCEPTED PACKAGES-LIMITED QUANTITY RETURNS

HOSPITAL AND CLINIC PERSONNEL

I. The radiopharmaceuticals to be shipped must not exceed the limits specified in the excepted package limits tables attached for any given shipping container. If multiple radioisotopes (Tc-99m and Tl-201) are to be shipped in a single container use the lowest radioactivity limit for the group.

II. Make sure the radiation level at any point on the external surface of the package does not exceed 0.5 mrem per hour using a calibrated GM survey meter.

III. Make sure the nonfixed removable radioactive surface contamination on the external surface of the package does not exceed 6,600 dpm/ 300 cm^2.

IV. Make sure the package bears the notice:

University of Oklahoma Health Science Center
Regional Nuclear Pharmacy
"This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910.

And

The Biohazard symbol

VIII. If shipment fails to meet the above requirements hold the container for decay or NOTIFY THE OUHSC Regional Nuclear Pharmacy for assistance.

IV. If the package activity, survey and wipe test are within limits, place in the designated return area.

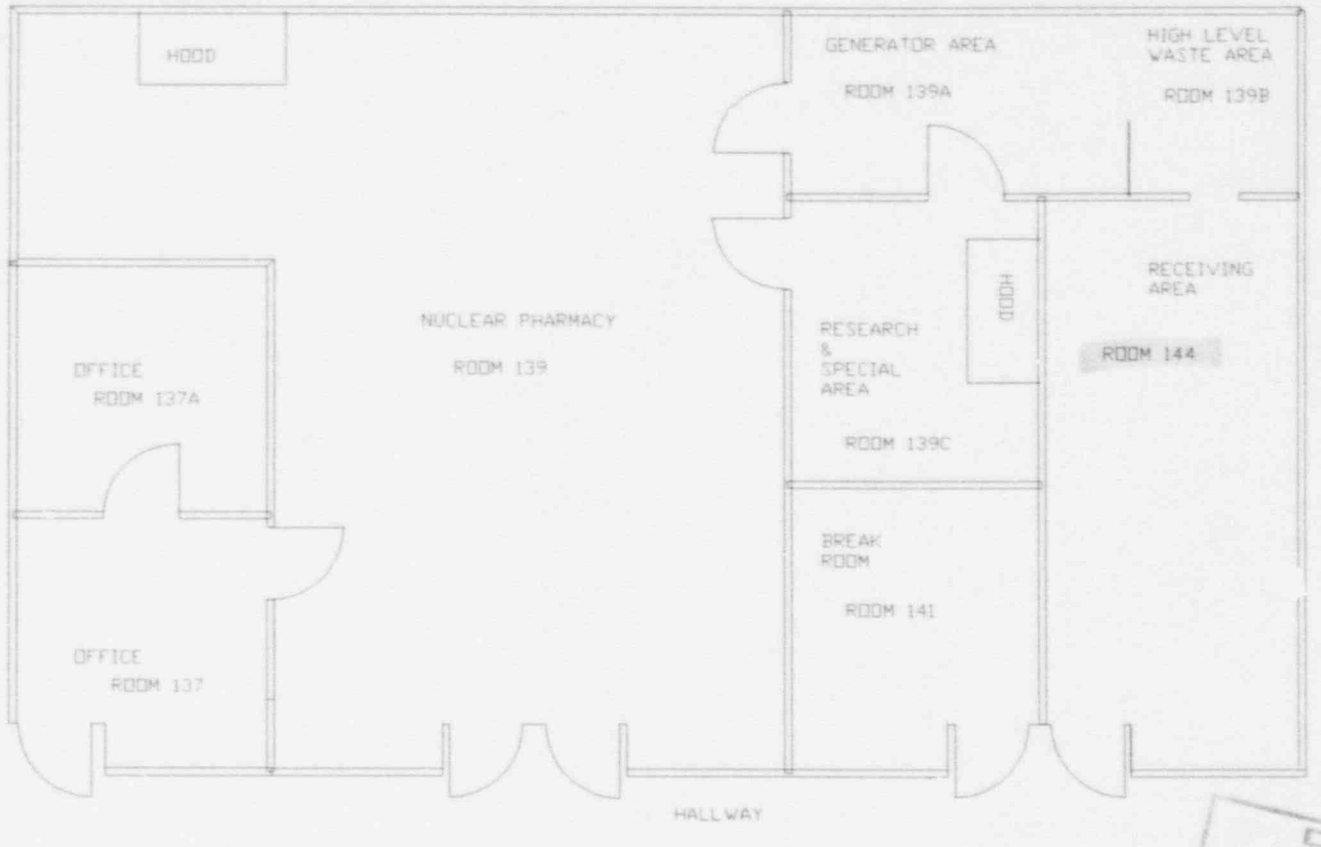
The United States Department of Transportation requires you tne shipper of hazardous materials to insure the limits for excepted package-limited quantity are in compliance. The appropriate regulations should be maintained on site: 49 CFR, parts 171-177 and 10 CFR, part 71.

EXCEPTED PACKAGE LIMIT

	RADIOISOTOPE	EXCEPTED mCi	TOTAL ACTIVITY IN BOX
	P-32	0.81	0.81
	Sr-89	1.35	1.35
	I-131	1.35	1.35
	In-111	5.41	5.41
	I-125	5.41	5.41
	Ga-67	16.20	16.20
	I-123 solid	162.00	162.00
	Tc-99m	21.60	21.60
	Co-57	21.60	21.60
	Tl-201	27.00	27.00
	Xe-133 gas	541.00	541.00
	Cr-51	81.10	81.10

C:\QPW\EXCEPTED.WB1

NUCLEAR PHARMACY COLLEGE OF PHARMACY OUHSC



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4661145

Room 140

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

RECEIVED
JUL 30 1995

UNIVERSITY OF OKLAHOMA
HEALTH SCIENCES CENTER
ATTN: SUBHASH M. DANAK, M.S., D.A.B.R.
RADIATION SAFETY OFFICER
1000 STANTON L. YOUNG BOULEVARD
LIBRARY 176
OKLAHOMA CITY, OK 73190

NUCLEAR PHARMACY
Rec'd
Dept #
Date
Rec'd

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 7-15-96

LICENSE NUMBER: 35-03176-04MD 35-03176-05 35-21035-01

CONTROL NUMBER: 466145, 466146, 466148 ATN: RITA MESSIER

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3C	$	$	$ 520.00
~~4B~~	$	$	$ ~~410.00~~
~~7B~~	$	$	$ ~~880.00~~
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE $ ~~1,810.00~~
PAYMENT RECEIVED $
AMOUNT DUE $ ~~1,810.00~~

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

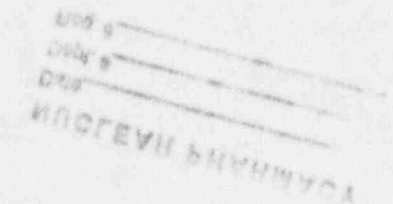
IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	(LEAVE BLANK)	DATE
Rita Messier RITA MESSIER		7-25-96



Did not find Fee sheet in package.

bg

The University of Oklahoma

Health Sciences Center

RADIATION SAFETY OFFICE

July 15, 1996

Mr. Jack Whitten
Senior Health Physicist
Nuclear Materials Licensing Section
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Lic 35-03176-01
for backup info
per JE Whitten.

RE: **LETTER OF INFORMATION** Regarding Licenses:

#35-03176-01
#35-03176-05
#35-03176-06
#35-03176-04MD
#35-21035-01

Dear Mr. Whitten:

For your information, A.M. Chandler, Ph.D., completed his term as Chairman of the University of Oklahoma Health Sciences Center Radiation Safety Committee on June 30, 1996. George N. Chacko, M.D. has accepted the Chairmanship of the Radiation Safety Committee effective July 1, 1996, on a temporary basis until a new chairperson can be appointed.

I will notify you immediately upon this appointment. A copy of Dr. Chacko's curriculum vitae is enclosed for your files.

Please contact me if you have any questions.

Sincerely,

Subhash M. Danak, M.S., D.A.B.R.
Radiation Safety Officer

/lsv

Enclosure
NRC71596.ltr