MATERIALS LICENSE

Amendment No. 82

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.

30246

Licensee	
1. Oakwood Hospital and Medical Center 2. 18101 Oakwood Boulevard Dearborn, MI 48123-2500	In accordance with letter dated March 19, 1997 3. License Number 21-04515-01 is amended in its entirety to read as follows: 4. Expiration Date August 31, 2001 5. Docket or Reference No. 030-02051

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 1 curie of Iodine-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. As needed
F. Iridium-192 110086	F. Sealed sources (BYK Mallinckrodt Model CI LBV)	F. Two sources not to exceed 12 curies each
G. Cesium-137	G. Sealed sources (ORIS/CBI Model CSL-15)	G. Three sources not to exceed 1700 curies each

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-04515-01

Docket or Reference Number: 030-02051

Amendment No. 82

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. In vitro studies.

F. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, and bronchial radiotherapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

G. Three sources to be used in an International CIS self shielded blood irradiator, Model IBL-437C for the irradiation of biologic matter excluding materials that are flammable and/or explosive

CONDITIONS

10. Location of Use: 18101 Oakwood Boulevard, Dearborn, Michigan.

11. A. Radiation Safety Officer: David S. Yates, M.D.

B. The high dose rate afterloading brachytherapy physicist is Taljit S. Sandhu, Ph.D., Barbara G. Orton, M.S., and Lisa A. Langenstein, M.S.

12. A. Licensed material listed in Item 6. above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. John B. Junker, M.D.	10 CFR 35.100, 35.200, and 31.11.
B. Choon K. Lee, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.

12. (Continued)

Authorized Users	Material and Use
C. James I. Breckenfeld, M.D.	10 CFR 35.100, 35.200, 35.300, (excluding iodine-131 for thyroid carcinoma), and 31.11.
D. Jung H. Chang, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.
E. Reza Abghari, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
F. David S. Yates, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for treatment of hyperthyroidism and cardiac dysfunction), and 31.11.
G. Kyriakos C. Demetropoulos, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
H. Jerry W. Drake, M.D.	10 CFR 35.100, 35.200, and 35.300.
I. Sharon Helmer, M.D.	10 CFR 35.100, 35.200 (excluding generators), and 35.300.
J. Kenneth D. Bartold, M.D.	10 CFR 35.100, 35.200, and 35.300.
K. Arnold Herskovic, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
L. Dong Hyuck Kim, M.D.	10 CFR 35.100, 35.200, and 31.11.
M. John H. Finger, M.D.	10 CFR 35.100, 35.200, and 35.300.
N. Eric J. Groskind, M.D.	10 CFR 35.100, 35.200 and 35.300.
O. Daniel B. Schumaker, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
P. Sophia Roumanis, M.D.	10 CFR 35.100, 35.200, and 35.300.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-04515-01

Docket or Reference Number
030-02051

Amendment No. 82

12. (Continued)

Authorized Users	Material and Use
Q. Paul B. Lattin M.D.,	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
R. Donald J. Conn, M.D.,	10 CFR 35.100, 35.200 and 35.300.

B. Licensed material listed in subitem 6.G. shall be used by or under the supervision of Cheryl Starbuck upon completion of training by the vendor at installation in accordance with letters dated April 15, 1996, and May 15, 1996.

13. Notwithstanding the provisions of 10 CFR 35.400(d), the licensee may use iridium-192 seeds encased in nylon ribbon as described in letter dated February 7, 1992, for intracavitary/intraluminal treatment of cancer.

14. In addition to the possession limits in Item 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.

15. A. (1) The source(s) specified in Item 7.G. shall be tested for leakage and/or contamination at intervals not to exceed six months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within six months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

16. A. Access to the room housing the MicroSelectron-HDR irradiation device shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

17. Prior to initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron-HDR, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the source head shall not exceed 0.25 milliroentgens per hour.

(2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.1201, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301(b) 10 CFR 20.

B. Records of survey results shall be maintained for inspection by the Commission.

18. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of sources contained in the MicroSelectron-HDR irradiation device.

B. Any maintenance or repair operations on the irradiator involving work on the source head, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

19. The licensee may possess 24 curies of iridium-192 (not to exceed 12 curies per source) for use in the Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by an authorized individual.

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

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

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

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

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

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

22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated May 24, 1995 (excluding the Quality Management Program); and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-04515-01

Docket or Reference Number
030-02051

Amendment No. 82

22. (Continued)

B. Letters dated July 18, 1995, March 27, 1996 (excluding the Quality Management Program), April 15, 1996, May 15, 1996, June 19, 1996, August 5, 1996, December 18, 1996 (with attachments), February 24, 1997, and March 19, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAR 27 1997

By Loren J. Hunter
Nuclear Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02230
Status Code: 0
Fee Category: 7C 3E 2B
Exp. Date: 20010831
Fee Comments: 3E ADDED 6/18/96
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: OAKWOOD HOSPITAL AND MECICAL CENTER
   Received Date: 970327
   Docket No: 3002051
   Control No.: 302466
   License No.: 21-04515-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: *
   Check No.: *

* ADDL INFO
302375 -R8

3. COMMENTS

Signed D. Hersey
Date 3-27-97

FEE NOT REQUIRED

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

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

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

3. OTHER

Signed JC
Date 4/1/97

1997 MAR 31 PM 4:25

APR 03 1997

Log Mar 13 III
Remitter
Check No.
Amount
Fee Category (7C) 3E 2B
Type of Fee AMND
Date Check Rec'd
Date Completed 4/1/97
By: JC

Oakwood Hospital
& Medical Center

18101 Oakwood Blvd.
P.O. Box 2500
Dearborn, Michigan
48123-2500

313.593.7000

Oakwood
Healthcare System

March 19, 1997

United States Nuclear Regulatory Commission
Region III Office of Materials Licensing
801 Warrenville Road
Lisle, IL 60532-4351

RE: Additional information to **Control No. 302375**

Attached please find the following information which is being supplied in response to your request regarding the Amendment No. 81 to our NRC Materials License No. 21-04515-01:

1. A diagram of o: facility with survey and wipe test results after the storage safe was removed and moved to the new facility.
2. Radiation survey report for the new facility after the radiation source safe was moved to this facility.

We will greatly appreciate if the review of this information is expedited and a copy of the amendment releasing the old facility for unrestricted use is sent to Dr. Taljit Sandhu by facsimile (313-593-8844) as soon as it is signed.

Should you have any further questions, please contact Taljit Sandhu, Ph.D. at (313)-593-7335. We appreciate your prompt attention to this matter.

Sincerely,

Loretta L. Lee
Senior Vice President, Acute Care

c: David S. Yates, MD, Radiation Safety Officer

Enclosure: Radiation survey and wipe test report for the old area (Room 37X)
Radiation survey report for the new facility

Cont'n of 302375
FEE NOT REQUIRED

RECEIVED
MAR 2 7 1997
REGION III
302466
MAR 2 7 1997

RADIATION SURVEY FOR ROOM 37X (OLD FACILITY)

Date of Survey: March 17, 1997

Performed by: Barbara Orton, MS, ABR Certified Medical Physicist

Instrument Used: Victoreen 491, S.N. 1338

Probe model 491-30

Calibration Date: 03/04/97

Background Reading: 0.05 mR/hr

Maximum Reading in the room: 0.05 mR/hr

WIPE TEST RESULTS:

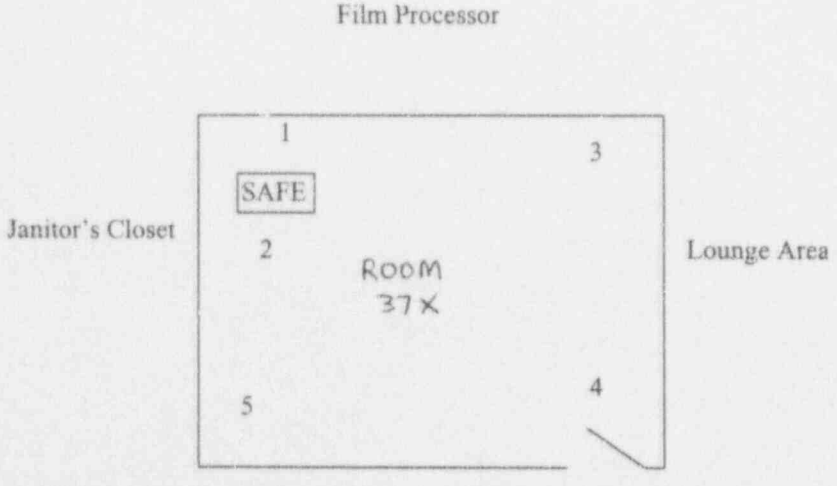
In the room layout of the old facility (Room 37X) below, wipes were taken from the areas marked 1-5.

Areas 1&2: Floor under the safe

Area 3: Floor where containers for Ir-192 have been stored

Area 4: Floor where permanent storage pig was located

Area 5: Floor in position of trash basket.



Date of Wipe tests: 3/17/97

Performed by: Barbara Orton, MS, ABR Certified Medical Physicist

Instruments Used: The Nucleus, Atomic Products, Model 187-29

MCA well chamber 187-246

Standard Reference source: Cs-137, 4.5 μCi on 11/14/80
Current Activity: 3.1 μCi

Readings were taken for 60 seconds for each wipe in a test tube.
Standard Reference Source Count : 447952
Background Count: 126

Wipe Sample	Count	Net Reading
1	120	na
2	135	9
3	135	9
4	148	22
5	121	na

None of the readings from the wipes are different from the background.

RADIATION SURVEY FOR ROOM CG-116A (NEW FACILITY)

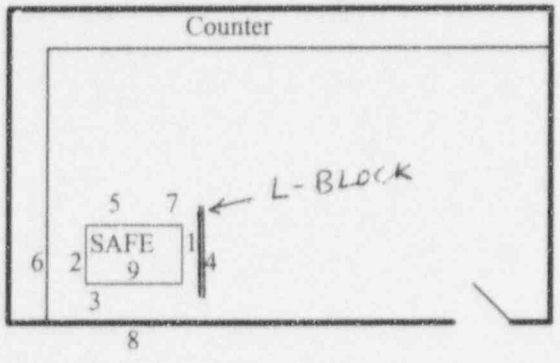
Date of Survey: March 17, 1997

Performed by: Barbara Orton, MS, ABR Certified Medical Physicist

Instrument Used: Victoreen 491, S.N. 1338
Probe model 491-30
Calibration Date: 03/04/97

Room Layout:

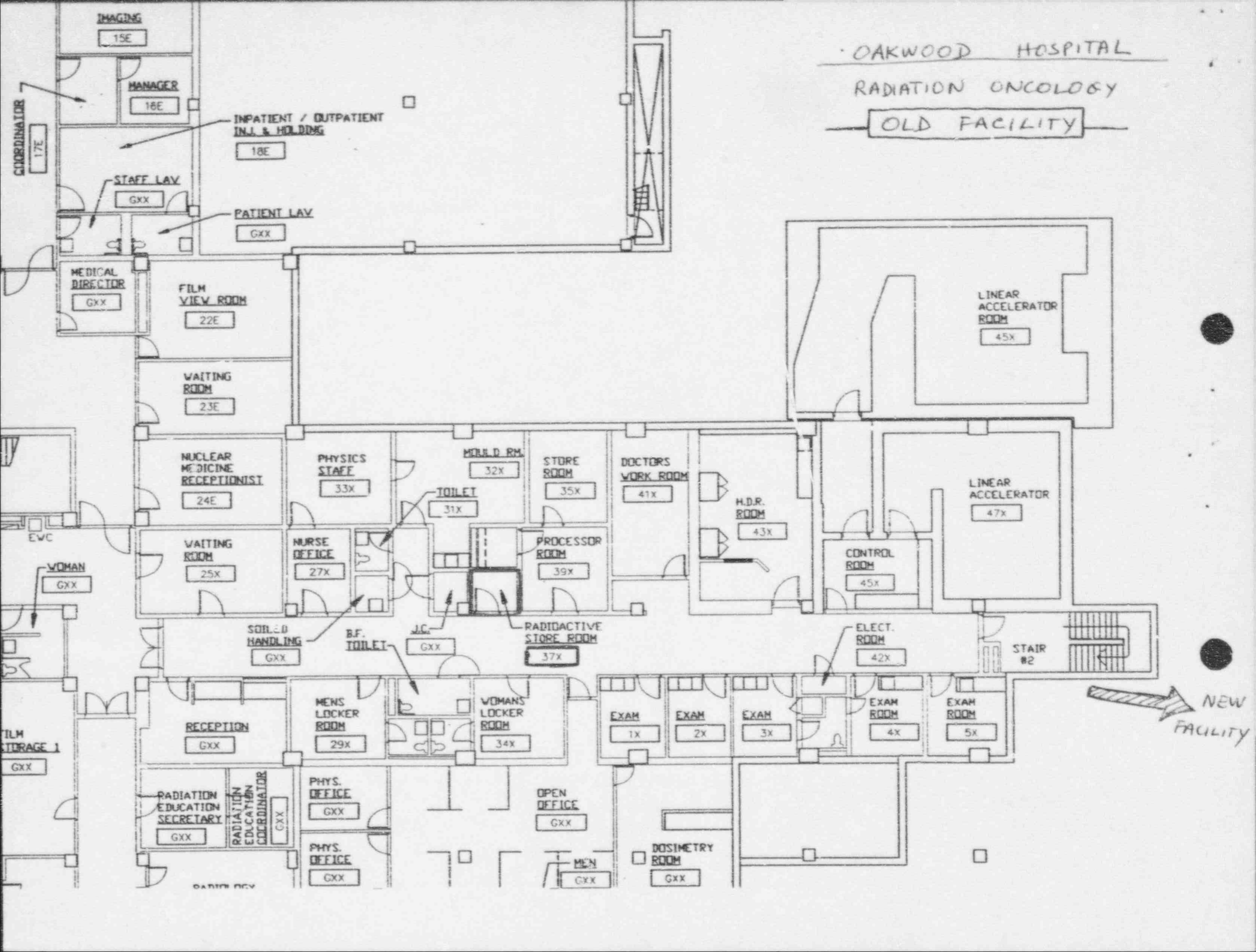
Room CG-116A

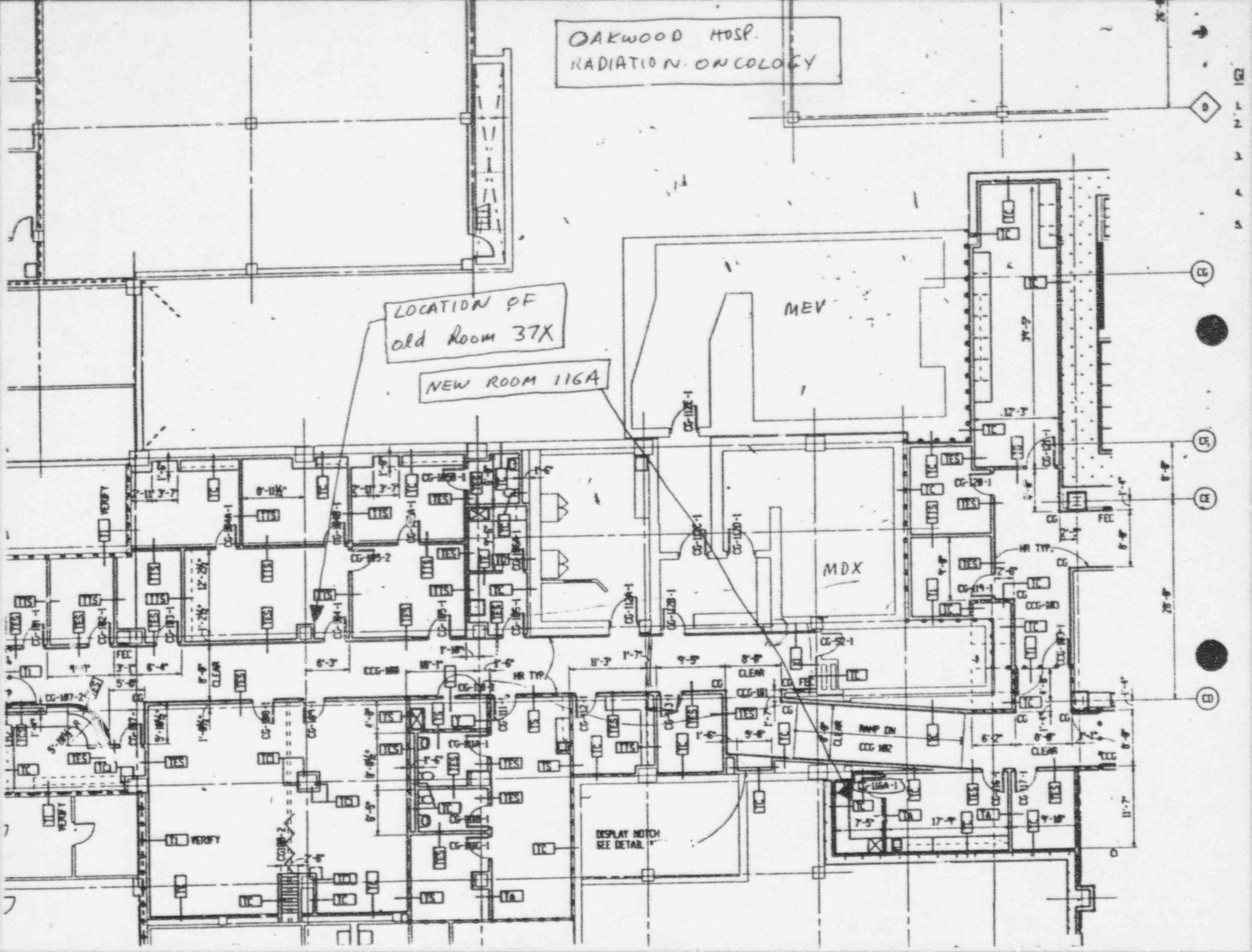


Survey around the safe:

Readings taken with safe door closed.

AREA	READING
1	6 mR/hr
2	0.1 mR/hr on the back wall of safe
3	0.1 mR/hr
4	<0.1 mR/hr (behind the L-Block)
5	0.1 mR/hr
6	<0.1 mR/hr at 1 m from the back wall of safe
7	0.2 mR/hr
8	0.1 mR/hr -- maximum reading next to the wall in the adjacent room
9	0.1 mR/hr -- Reading taken at the top surface of the safe


OAKWOOD HOSPITAL
RADIATION ONCOLOGY
OLD FACILITY
IMAGING
15E
MANAGER
16E
CHORDINATOR
17E
INPATIENT / OUTPATIENT
INJ. & HOLDING
18E
STAFF LAV
GXX
PATIENT LAV
GXX
MEDICAL DIRECTOR
GXX
FILM VIEW ROOM
22E
WAITING ROOM
23E
NUCLEAR MEDICINE RECEPTIONIST
24E
WAITING ROOM
25X
NURSE OFFICE
27X
PHYSICS STAFF
33X
MOULD RM.
32X
TOILET
31X
STORE ROOM
35X
PROCESSOR ROOM
39X
DOCTORS WORK ROOM
41X
H.D.R. ROOM
43X
LINEAR ACCELERATOR ROOM
45X
LINEAR ACCELERATOR
47X
CONTROL ROOM
45X
EWC
WOMAN
GXX
SOILED HANDLING
GXX
B.F. TOILET
J.C.
GXX
RADIOACTIVE STORE ROOM
37X
ELECT. ROOM
42X
STAIR #2
NEW FACILITY
RECEPTION
GXX
MENS LOCKER ROOM
29X
WOMANS LOCKER ROOM
34X
EXAM
1X
EXAM
2X
EXAM
3X
EXAM ROOM
4X
EXAM ROOM
5X
FILM STORAGE 1
GXX
RADIATION EDUCATION SECRETARY
GXX
RADIATION EDUCATION COORDINATOR
GXX
PHYS. OFFICE
GXX
PHYS. OFFICE
GXX
OPEN OFFICE
GXX
MEN
GXX
DOSIMETRY ROOM
GXX


OAKWOOD HOSP.
RADIATION ONCOLOGY
LOCATION OF
old Room 37X
NEW ROOM 116A
MEV
MDX
DISPLAY NOTCH
SEE DETAIL

MAR 2 7 1997

Loretta Lee
Senior Vice President
Oakwood Hospital and Medical Center
18101 Oakwood Blvd.
Dearborn, MI 48123-2500

Dear Ms. Lee:

Enclosed is Amendment No. 82 to your NRC Material License No. 21-04515-01 in accordance with your request.

This amendment authorizes you to release for unrestricted use your former storage room, 37X, based on the results of your close-out surveys submitted with your letter dated March 19, 1997.

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 an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license 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. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

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

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

   f. 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 Statement of Policy and Procedure 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
Loren J. Hueter
Nuclear Materials Licensing Branch

License No. 21-04515-01
Docket No. 030-02051

Enclosures:
1. Amendment No. 82
2. NRC Form 313

DOCUMENT NAME: M:\03002051.CL7
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	N							
NAME	LJHueter:brt	LJH							
DATE	03/27/97								

OFFICIAL RECORD COPY