NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 81

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.

302375

Licensee	
1. Oakwood Hospital and Medical Center 2. 18101 Oakwood Boulevard Dearborn, MI 48123-2500	In accordance with letter dated February 24, 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	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

030071

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-04515-01

Docket or Reference Number
030-02051

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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.
C. James I. Breckenfeld, M.D.	10 CFR 35.100, 35.200, 35.300, (excluding iodine-131 for thyroid carcinoma), and 31.11.

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Authorized Users	Material and Use
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.
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, 35.20 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.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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).

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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

    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), and February 24, 1997 (excluding release for unrestricted use, old storage room 37X).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date March 17, 1997

By Loren J. Hueter
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: 970227
   Docket No: 3002051
   Control No.: 302375
   License No.: 21-04515-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 500
   Check No.: 201048

3. COMMENTS

Signed D. Hersey
Date 2-28-97

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

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

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

3. OTHER

Signed AC 3/3/97
Date

MAR 10 1997

Log Mar 2 III
Remitter
Check No. 201048
Amount (A500) $440 Refund $60
Fee Category (7C 3E 2B)
Type of Fee Amd
Date Check Rec'd 3/
Date Completed 3/3/97
By: AC

97 MAR -3 AM 11:43

Oakwood Hospital
& Medical Center

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

313.593.7000

Oakwood
Healthcare System

February 24, 1997

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

RE: Request for Amendment to NRC License Number 21-04515-01

Enclosed please find a check for $500 to cover the request for the following change to our NRC license:

1. Move our Radiation Oncology Sealed Radioactive Source storage safe from Room 37X to Room CG-116A in the newly constructed addition to our Radiation Oncology Department. A layout of the new room is enclosed. Furthermore it is hereby confirmed that:

   - The new storage room will be properly posted with warning labels according to CFR 10 part 20.

   - Once the sources are moved to room CG-116A, a complete radiation survey as stated in CFR 10 part 20 will be performed around the room and the results will be provided to your office.

   - The new room CG-116A will be kept locked at all times and the keys will be kept with the Radiation Oncology Physicists.

   - After the sources are removed from the old storage room 37X and moved to the new room CG-116A, a radiation survey of the room 37X and a wipe test of the work area will be performed. The results of this survey and wipe test will be provided to your office. Once it is established that there is no radiation hazard associated with the use of the room 37X, all radiation warning signs and labels will be removed. The room 37X will then be cleared for general purpose use.

2. Please delete Alan R. Hennessey, M.D., Arthur J. Bady, M.D., T. G. McDonald, M.D. from our license as they are no longer practicing here.

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

LLL/mh
c: David S. Yates, M.D., Radiation Safety Officer

RECEIVED
FEB 27 1997
REGION III

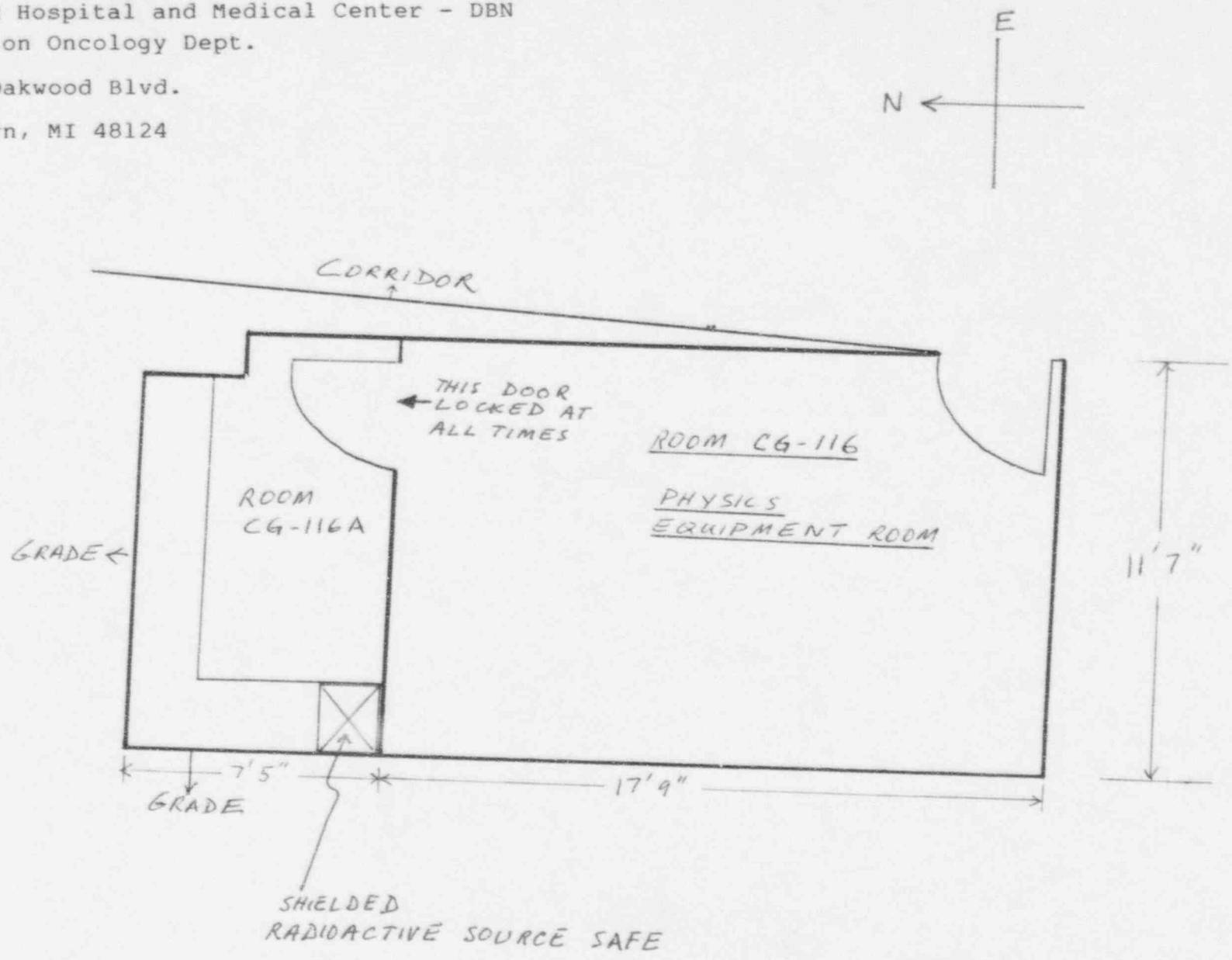
Pm: 2-24-97

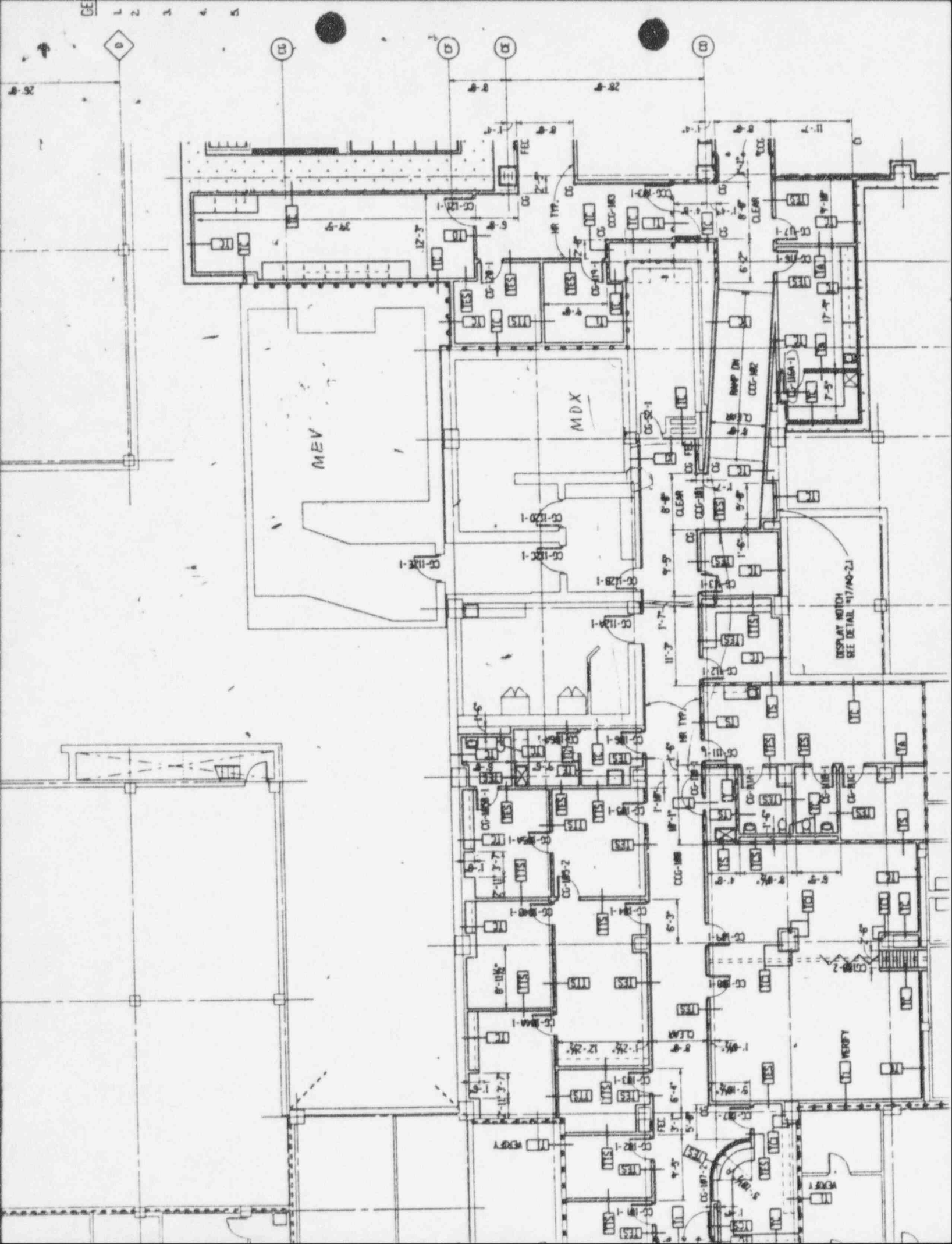
FEB 27 1997
302375

Oakwood Hospital and Medical Center - DBN
Radiation Oncology Dept.

18101 Oakwood Blvd.

Dearborn, MI 48124




MEV
MDX
DISPLAY NOTCH
SEE DETAIL 4/7/A0-21
RAMP DN
CLEAR
VESTIBULE

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: Oakwood Hospital & Medical Center

ADDRESS: Attn: Loretta L. Lee, Sr. Vice President

ADDRESS: 18101 Oakwood Boulevard

CITY: Dearborn STATE: MI ZIP: 48123-2500

TRANS CODE: PX

TRANS TYPE: FE FUND: X5280 JOB CODE: _____ AMOUNT: $60"

TRANS TYPE: IR FUND: R1435 JOB CODE: INTR AMOUNT: _____

TRANS TYPE: IR FUND: R1099 JOB CODE: ADCH AMOUNT: _____

TRANS TYPE: IR FUND: R1099 JOB CODE: FINE AMOUNT: _____

TOTAL REFUND AMOUNT: $60"

COMMENTS: Lic 21-04515-01/CK 201048/rgst 2/24/97 rqst

(limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Critchfield DATE: March 5, 1997

AUTHORIZED BY: Wanda Jackson DATE: 3/5/97

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

Mar 2 III
TC AND #440
CK 201048 ~~$60~~ PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION
Dtd 2/7/97
302375

MAR 25 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. 81 to your NRC Material License No. 21-04515-01 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.

This amendment deletes Doctors Alan R. Hennessey, M.D., Arthur J. Bady, M.D. and T. G. McDonald, M.D., from your license as authorized users and authorizes you to move your Radiation Oncology Sealed Radioactive Source storage safe from Room 37X to Room CG-116A, as requested.

As discussed by telecon with Dr. Taljit Sandhu, Ph.D., of your staff, on March 11, 1997, this amendment does not permit you to release your old storage room. room 37X, until we receive and review your close-out survey for that room. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

1. A diagram of your old facility with survey and wipe test results keyed to specific locations. Also, please provide a diagram of the entire floor on which Room 37X is located and identify Room 37X.

2. The name of the person performing the survey.

3. The date the survey was performed.

4. The instrument(s) used for exposure rate measurements and for analysis of the wipes.

5. Background readings.

302375

6. The date that the survey instrument was last calibrated.

Please provide the above data as additional information to Control No. 302375 to preclude an additional amendment fee. Also, please request that we expedite our review and that a copy of the amendment releasing the facility for unrestricted use be sent by facsimile to you as soon as it is signed.

If you have any questions, please call me at (630) 829-9829.

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 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. 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 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
Loren J. Hueter
Nuclear Materials Licensing Branch

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

Enclosures:
1. Decontamination Guide
2. Amendment No. 81
3. 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	W							
NAME	LHUETER:jaw								
DATE	03/17/97								

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME

DATE 3-11-97

O VISIT O CONFERENCE Ø TELEPHONE

O INCOMING
Ø OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Tajit Sandhu, Ph.D. of Radiological Physics Department

ORGANIZATION (OFFICE, DEPT. ETC.): Oakwood Hospital and Medical Center

TELEPHONE NO.: 313-593-7564 FAX -8844

SUBJECT

CN 302375

SUMMARY

Dr Sandhu confirmed that there are actually two safes, side by side, both with locks. Both will be moved and kept side by side in room CG-116A. The survey they submit for new facility after safes are mounted will include outside above grade and room above.

Dr. Sandhu confirmed that they have not had any leaking sources stored in the 2 safes or room 37X.

We discussed the need for 2 amendments (only one fee) to cover move to new storage location and release of old storage facility. He agreed to provide a floor diagram of floor on which Rm 37X is located, showing its specific location for any future reference, and diagram of Rm 37X keyed to locations of survey and wipes for closeout.

I agreed to FAX copy of both amendments to expedite matters.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION: Loren Hunter

SIGNATURE: Loren Hunter

DATE: 3-11-97

ACTION TAKEN

SIGNATURE TITLE DATE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

March 3, 1997

David S. Yates, M.D.
Radiation Safety Officer
Oakwood Hospital and Medical Center
18101 Oakwood Boulevard
Dearborn, MI 48123-2500

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 02/24/97)

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 X Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ 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.

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

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 required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 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. 302375
License No. 21-04515-01