NRC FORM 374 (7-95)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 79

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.

302602

Licensee	
1. Riverside Methodist Hospitals	In accordance with letter dated April 22, 1997 3. License Number 34-01055-01 is amended in its entirety to read as follows:
2. 3535 Olentangy River Road Columbus, OH 43214	4. Expiration Date August 31, 2000
	5. Docket or Reference No. 030-02669

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
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 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. As needed
G. Uranium depleted in Uranium-235	G. Cadmium plated metal	G. As needed

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
H. Iodine-131	H. Iodomethylnorcholesterol manufactured by and received from the Nuclear Pharmacy of the University of Michigan	H. 10 millicuries
I. Cesium-137	I. Sealed source (Shepherd Model 6810)	I. One source not to exceed 300 millicuries total
J. Strontium-90	J. Sealed sources (Radiochemical Center Model SIC-7)	J. 2 sources not to exceed 10 millicuries each, 20 millicuries total
K. Cesium-137	K. Sealed sources (Amersham Corp. Model CDC.SP1)	K. 1.1 curie total (No single source to exceed 20 millicuries)
L. Iridium-192	L. Sealed sources (Byk Mallinckrodt Model CI L BV)	L. 2 sources not to exceed 12 curies each

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. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-01055-01

Docket or Reference Number
030-02669

Amendment No. 79

9. (Continued)

F. In vitro studies.

G. Shielding in a linear accelerator.

H. For adrenal imaging used in accordance with Notice of Claimed Investigational Exemption for a New Drug (IND) Number 16,833.

I. For use in S. L. Shepherd & Associates Model 28.10 calibrator for calibration of licensee's survey meters.

J. For use in Nuclear Enterprises Model 2503 Thimble Ionization Chamber Calibrator.

K. To be used in Nucletron Selectron-LDR remote afterloading device for intraluminal and intracavitary treatment of cancer.

L. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, and intraluminal radiotherapy in accordance with License Condition 18. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

10. Location of Use: 3535 Olentangy River Road, Columbus, Ohio.

11. Radiation Safety Officer: John Niemkiewicz

12. 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. Gordon C. Taylor, M.D.	10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 31.11 and Cesium-137 for use in remote afterloading device.
B. James V. Blazek, M.D.	10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 31.11 and Cesium-137 for use in remote afterloading device.
C. James M. Falko, M.D.	10 CFR 35.300.
D. Daniel R. McFarland, M.D.	10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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12. (Continued)

Authorized Users	Material and Use
E. John E. Baumert, Jr., M.D.	10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
F. Ralph C. Kennaugh, M.D.	10 CFR 35.300 (excluding I-131 for hyperthyroidism and thyroid carcinoma therapy) 35.400, Cesium-137 and Iridium-192 for use in remote afterloading device.
G. Swaminathan Jayaraman, Ph.D.	Cesium-137 (from 35.400 sealed sources and the S. L. Shepherd & Associates calibrator) for calibration of instruments, and Strontium-90 contained in the Nuclear Enterprises Thimble Ionization Chamber Calibrator.
H. Nariosang M. Kandawalla, M.D.	Material identified in Item 6.K.
I. Herbert Derman, M.D.	Material identified in Item 6.K.
J. Mark J. Crnkovich, M.D.	10 CFR 35.300 (excluding I-131 for hyperthyroidism and thyroid carcinoma therapy) 35.400 and Cesium-137 and Iridium-192 for use in remote afterloading devices.
K. Thomas J. Pedrick, M.D.	10 CFR 35.300 (excluding I-131 for hyperthyroidism and thyroid carcinoma therapy) 35.400 and Cesium-137 and Iridium-192 for use in remote afterloading devices.
L. Phillip B. Shaffer, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.

13. 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.

14. 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:

(i) 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. For the Selectron - LDR, the maximum radiation levels at 10 centimeters from the surface of the source head shall not exceed 1.0 milliroentgens per hour.

(ii) All areas adjacent to the treatment room with 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 20.101, 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 20.105(b) 10 CFR 20.

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

15. 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 Selectron-LDR and MicroSelectron-HDR irradiation devices.

B. Any maintenance or repair operations on the irradiators 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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Docket or Reference Number
030-02669

Amendment No. 79

16. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 3535 Olentangy River Road, Columbus, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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

19. 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."

20. 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 March 27, 1990;

    B. Letters dated October 26, 1987; January 8, 1990; March 20, 1990 (with attachments); June 5, 1990; and July 16, 1991;

    C. Letters dated August 14, 1991 (excluding "Administrative Controls"), September 27, 1993 (with attachments, excluding 10 CFR 20.105 exemption request), November 10, 1993 (with attachments, excluding 10 CFR 20.105 exemption request), December 7, 1993; January 17, 1994 (with attachments) June 27, 1994, April 22, 1997; and

    D. Letter received August 28, 1991.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 05 1997

By Evelyn R. Watson
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 2B
Exp. Date: 20000831
Fee Comments: SHIELDING ONLY
Decom Fin Assur Reqd: N

RC

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: GRANT/RIVERSIDE METHODIST HOSPITALS
   Received Date: 970506
   Docket No: 3002669
   Control No.: 302602
   License No.: 34-01055-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: ~~X~~
   Check No.: ~~X~~

   * Addl. Supp 39734-RC

3. COMMENTS

   Signed D. Hensley
   Date 5-9-97

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

1. Fee Category and Amount: 7C 2B FEE NOT REQUIRED

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

3. OTHER

   Signed JC
   Date 5/12/97

MAY 19 1997

Log	May 7 III
Remitter	
Check No.	
Amount	
Fee Category	7C 2B
Type of Fee	A32D
Date Check Rec'd	
Date Completed	5/12/97
By:	JC

97 MAY 12 PM 4:45

Grant/Riverside
Methodist Hospitals
OhioHealth

Riverside Methodist Hospital
3535 Olentangy River Road
Columbus, Ohio 43214-3998
614 | 566-5000
www.grmh.org

April 22, 1997

Ms. Evelyn R. Matson
U.S. Nuclear Regulatory Commission, Region III
801 Warrensville Road
Lisle, IL 60532-4351

Re: Radiopharmaceutical distribution from Riverside Methodist Hospitals, control # 399934.

Dear Ms. Matson:

Enclosed is additional information regarding control #399934. We had originally requested authorization to transfer radiopharmaceutical materials to Grant Medical Center by letter, dated February 12, 1996.

I will be glad to answer any questions you may have or to provide a[dditional] information. I can be reached at (614) 566-5714.

Thank you for your help and attention to our request.

Sincerely,

John Niemkiewicz

John Niemkiewicz, Ph.D.
Chief Medical Physicist
Department of Radiation Oncology
Riverside Methodist Hospitals
3535 Olentangy River Road
Columbus, OH 43214

Cont'l # 399934
FEE NOT REQUIRED

RECEIVED
MAY 06 1997
REGION III
302602
MAY 06 1997

PM: 5-5-97

Riverside Methodist Hospitals

REQUEST FOR AUTHORIZATION TO TRANSFER RADIOPHARMACEUTICALS

In accordance with current NRC regulations, authorization is requested to transfer 10CFR35.100, 35.200, 35.300, and 31.11 radioactive materials from Riverside Methodist Hospitals (license #35-01055-01) to Grant Medical Center (license #35-03424-02). The reason that we request authorization to transfer byproduct materials is one of economics. We intend to prepare radiopharmaceutical unit doses at the Riverside Methodist Hospitals nuclear pharmacy, then distribute the unit doses to Grant Medical Center and/or other OhioHealth owned facilities. Cost efficiency will be achieved by savings on delivery charges and the ability to receive quantity discounts from the commercial radiopharmaceutical vendor. We do not wish to become a commercial nuclear pharmacy. In summary, we wish to consolidate our radiopharmaceutical preparation activities at Riverside Methodist Hospitals and to distribute radiopharmaceutical unit doses to NRC licensed sites that are OhioHealth owned, which is currently only Grant Medical Center.

Riverside Methodist Hospitals is located at 3535 Olentangy River Road, and Grant Medical Center is located at 111 S. Grant Avenue, in Columbus, Ohio. Both sites are administratively and geographically separate and have separate NRC licenses (Fig. 5).

Items 1 through 10 of NRC form 313 will remain as specified in Riverside Methodist Hospitals current license (#35-01055-01) with the following additions:

I. <u>Preparation of radioactive materials to be transferred</u>

Bulk radioactive materials and kits will be provided to Riverside Methodist Hospitals by a NRC licensed commercial radiophamaceutical vendor, which is currently Syncor International Corporation (Syncor) located at 3025 14th Avenue, Columbus, Ohio, 43219. Syncor holds NRC license #04-26507-01MD. Grant Medical Center, and/or other OhioHealth owned facilities, will order unit doses from Riverside Methodist Hospitals, where a licensed nuclear pharmacist, or his designee, will prepare the requested unit doses. A label will be affixed to each syringe, and the label will contain information as to the radionuclide, its apparent chemical form, the quantity, and the date of assay. Figure 1 shows a sample syringe label.

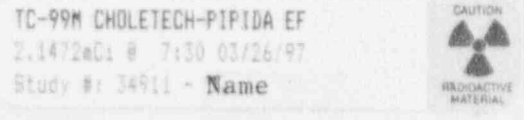


Figure 1: Sample syringe label.

II. Packaging of radioactive materials for transport

Each unit dose radiopharmaceutical syringe will be placed in a lead-lined unit dose container. This is the "containment system" as defined in U.S. Department of Transportation (DOT) regulation 173.403. Each unit dose container will be shrink-wrapped and labeled. Figure 2 shows a sample container label.

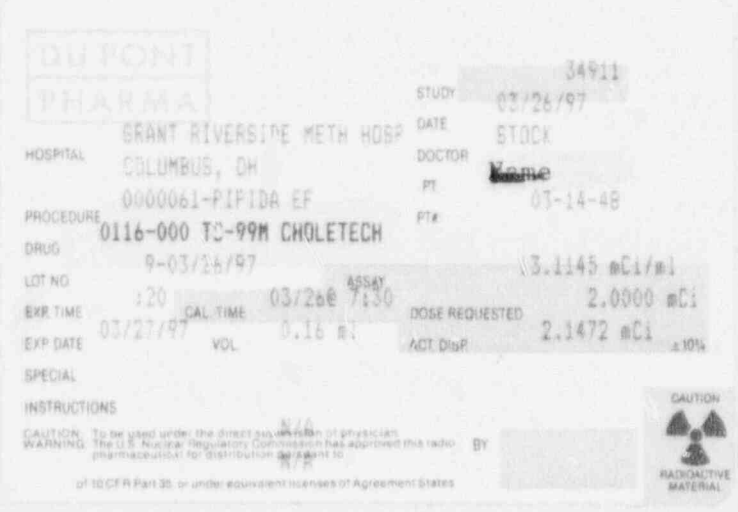


Figure 2: Sample unit dose container label.

Each container will be placed in a special shielded carrier which can hold up to twelve unit dose containers. This carrier is the "freight container" as defined in DOT 173.403. Also, the special shielded carriers to be used will be certified as a USA DOT-7A Type A package. In addition, a security seal will be used on each carrier in accordance with 49CFR173.412 (b) and each carrier will be labeled with the appropriate "Radioactive" label. Figures 3 and 4 show sample labels that will be used on the shielded carriers.

Both the unit dose containers and the special shielded carriers will be provided by the radiopharmaceutical supplier.

Therapy and multi-dose materials will be transported in lead containers, also provided by the radiopharmaceutical supplier. A label will be affixed to each container and will contain information as to the radionuclide, its apparent chemical form, the quantity, and the date of assay.

III. Transfer procedures between Riverside Methodist Hospitals campus and Grant Medical Center campus and/or other OhioHealth owned facilities

A. Supplier/recipient designation

Riverside Methodist Hospitals will be designated as the supplier of the radioactive materials, and Grant Medical Center, and/or other OhioHealth owned facilities, will be the recipients. However, Grant Medical Center, and/or other OhioHealth owned facilities, may return unused radioactive materials or radioactive waste materials to Riverside Methodist Hospitals via the same transport system and using the same containers with proper labels.

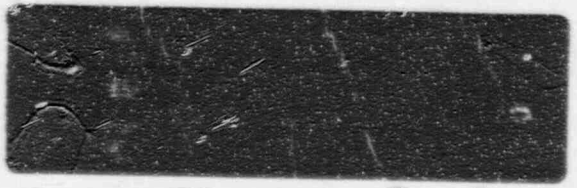
B. Transportation personnel and vehicles

Radioactive materials prepared at Riverside Methodist Hospitals will be transported to Grant Medical Center, and/or other OhioHealth owned facilities, by the radiopharmaceutical supplier using their trained personnel and vehicles. The radiopharmaceutical supplier will transport these materials according to U.S.N.R.C. and D.O.T. regulations, and within the specifications and requirements stated in their NRC license.

IV. Receipt and package opening procedures

The receipt and package opening procedures will be as indicated in the current license for each site.

Figure 3: Sample carrier label.



This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN 2910.

RADIOACTIVE

Figure 4: Sample carrier label.

Organizational Chart

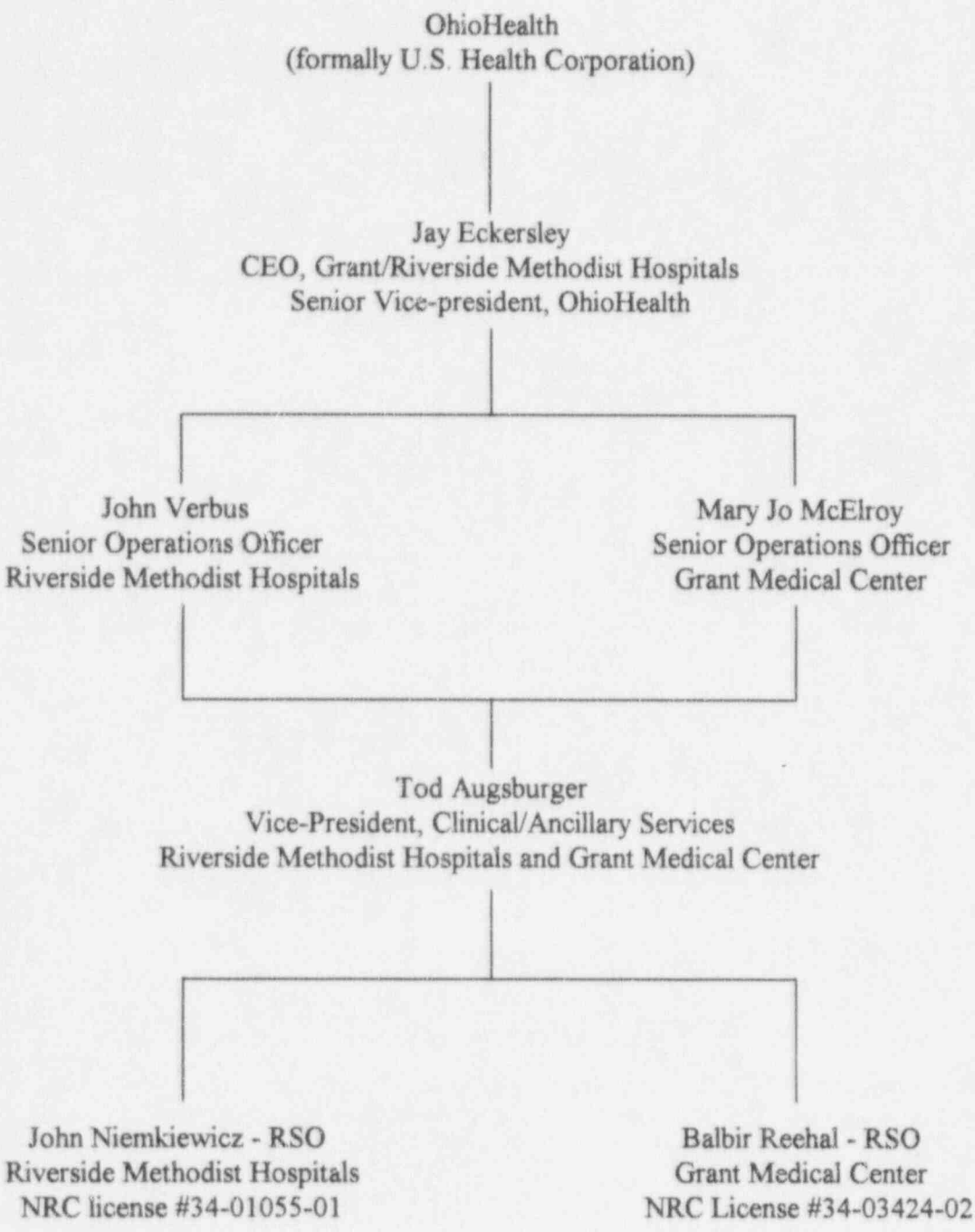


Figure 5. Organizational chart.

JUN 05 1997

John Niemkiewicz, Ph.D.
Department of Radiation Oncology
Riverside Methodist Hospitals
3535 Olentangy River Road
Columbus, OH 4321

Dear Dr. Niemkiewicz:

Enclosed is Amendment No. 79 to your NRC Material License No. 34-01055-01 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 that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

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.)

302602

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
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 34-01055-01
Docket No.: 030-02669

Enclosure: Amendment No. 79

DOCUMENT NAME: M:\03002669.CL7

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OFFICE	DNMS/RIII	N							
NAME	ERMatson:brt								
DATE	06/ 4 /97								

OFFICIAL RECORD COPY

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

May 12, 1997

John Niemkiewicz, M.S.
Radiation Safety Officer
Grant/Riverside Methodist Hospitals
Department of Radiology
3535 Olentangy River Road
Columbus, OH 43214

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 04/22/97)

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. 302602
License No. 34-01055-01