

MATERIALS LICENSE

Amendment No. 47

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.

302167

<p>Licensee</p> <p>1. St. Vincent Mercy Medical Center</p> <p>2. 2213 Cherry Street Toledo, Ohio 43608</p>	<p>In accordance with letter dated December 11, 1996</p> <p>3. License Number 34-01216-03 is amended in its entirety to read as follows:</p> <p>4. Expiration Date December 31, 2000</p> <p>5. Docket or Reference No. 030-02672</p>	
<p>6. Byproduct, Source, and/or Special Nuclear Material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Any byproduct material identified in 10 CFR 35.300</p> <p>D. Any byproduct material identified in 10 CFR 35.400</p> <p>E. Any byproduct material identified in 10 CFR 35.500</p> <p>F. Any byproduct material identified in 10 CFR 31.11</p> <p>G. Cesium-137</p>	<p>7. Chemical and/or Physical Form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200</p> <p>C. Any radiopharmaceutical identified in 10 CFR 35.300</p> <p>D. Any radiopharmaceutical identified in 10 CFR 35.400</p> <p>E. Any radiopharmaceutical identified in 10 CFR 35.500</p> <p>F. Prepackaged Kits</p> <p>G. Sealed source (3M Model No. 4P6E)</p>	<p>8. Maximum Amount that Licensee May Possess at Any One Time Under This License</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. As needed</p> <p>D. 2200 millicuries</p> <p>E. As needed</p> <p>F. As needed</p> <p>G. One source not to exceed 1 curie</p>

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PDR ADOCK 03002672
C PDR

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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- | | | |
|---|---|---|
| 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. Iridium-192 | H. Pre-cut wire (obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements) | H. No single wire to exceed 200 millicuries. Total possession limit not to exceed 600 millicuries |
| I. Uranium depleted in Uranium-235 | I. Cadmium plated metal | I. Not to exceed 999 kilograms |

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.
- F. In vitro studies.
- G. To be used in a J. L. Shepherd and Associates Model No. 28 Series, Submodel 28-6 calibrator for calibration of survey instruments of the licensee and as a service to customers.
- H. For interstitial treatment of cancer.
- I. Shielding in a linear accelerator.

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CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at 2213 Cherry Street, Toledo, Ohio.
- B. Licensed material listed in Subitems 6.A., 6.B., and 6.C. (excluding gases, aerosols and iodine-131 over 30 millicuries) may also be used at the licensee's facility located at 2200 Jefferson Avenue, Toledo, Ohio.
11. Radiation Safety Officer: Kathryn J. Royen, Ph.D.
12. Authorized Users:
- A. R. E. Myers, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 31.11 and iridium-192 wire.
- B. E. P. Ho, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 wire.
- C. G. B. Glasberg, M.D., for material in 10 CFR 35.100, 35.200 (excluding generators), 35.500 and 31.11.
- D. P.M. Royen, M.D., for material in 10 CFR 35.100, 35.200, 35.500 and 31.11.
- E. D. E. Hoover, M.D., for material in 10 CFR 35.100, 35.200 (excluding generators), 35.300, 35.500 and 31.11.
- F. M. F. Fadell, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- G. S. E. Gordon, M.D., for material in 10 CFR 35.100, 35.200, 35.500 and 31.11.
- H. S. L. Mayes, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- I. R. W. Siders, M.D., for materials in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- J. R. B. Doerfler, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- K. T. T. Loh, M.D., for materials in 10 CFR 35.100, 35.200, 35.500 and 31.11.
- L. S. S. Manion, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.

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- M. G. W. Marsa, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 wire.
- N. C. I. Mah, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 wire.
- O. S. R. Zeidner, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 wire.
- P. W. K. Mueller, M.D., for material in 10 CFR 35.300 and 35.400 and iridium-192 wire.
- Q. R. K. Ahuja, M.D., for material in 10 CFR 35.300 and 35.400 and iridium-192 wire.
- R. A. Konski, M.D., for material in 10 CFR 35.300 and 35.400 and iridium-192 wire.
- S. K. J. Royen, Ph.D., for material in Subitem 6.G.
- T. Yogesh P. Patel, M.D., for material in 10 CFR 35.100, 35.200, 35.300, 35.500 and 31.11.
- U. Antoinette L. LaValley, M.D., for material in 10 CFR 35.100, 35.200, 35.500 and 31.11.
- V. Shayle B. Patzik, M.D., for material in 10 CFR 35.100, 35.200, 35.500 and 31.11.
- W. John F. Brunner, M.D., for material in 10 CFR 35.100, 35.200 (excluding generators) and 35.300 (not to exceed 30 millicuries of iodine-131 per treatment).
- X. John E. Brunner, M.D., for material in 10 CFR 35.100 and 35.300 (not to exceed 30 millicuries of iodine-131 per treatment).
- Y. Jyoti Chakravarty, M.D., for material in 10 CFR 35.100 and 35.300 (not to exceed 30 millicuries of iodine-131 per treatment).
- Z. Jeffrey M. Boorstein, M.D., for material in 10 CFR 35.100, 35.200, 35.500 and 31.11.
13. Notwithstanding the requirements of 10 CFR 35.400 (d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon as a sealed source in seeds for interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

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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. 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. Applications dated May 31, 1990 and February 21, 1995; and
- B. Letters dated October 18, 1990 (with attachments) and December 11, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 12/30/96

By

James Mullawey
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C 3P
Exp. Date: 20001231
Fee Comments: 3P EFF 6/12/95
Decom Fin Assur Req'd: N
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. VINCENT MEDICAL CENTER
Received Date: 961224
Docket No: 3002672
Control No.: 302167
License No.: 34-01216-03
Action Type: Amendment

2. FEE ATTACHED

Amount: 440.00
Check No.: 203907

3. COMMENTS

Signed
Date

Maria Pearson
12/27/96

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

1. Fee Category and Amount:

7C 3P \$440

2. Correct Fee Paid. Application may be processed for:

Amendment
Renewal
License

3. OTHER

Signed
Date

SC
1/10/97

Log	Jan 4 III
Remitter	
Check No.	203907
Amount	\$440
Fee Category	7C 3P
Type of Fee	AMD
Date Check Rec'd	1/7/97
Date Completed	1/19/97
By:	SC

JAN 15 1997

EXHIBIT 1

NRC FORM 313 (1-84) 10 CFR 30.32, 33, 34, 35 and 40		U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OMS 3190-0120 Expires 5-31-87									
APPLICATION FOR MATERIAL LICENSE											
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.											
FEDERAL AGENCIES FILE APPLICATIONS WITH: U.S. NUCLEAR REGULATORY COMMISSION DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS WASHINGTON, DC 20545 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN: CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR MATERIAL SECTION B 831 PARK AVENUE KING OF PRUSSIA, PA 19406 ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION II MATERIAL RADIATION PROTECTION SECTION 101 MARIETTA STREET, SUITE 2900 ATLANTA, GA 30323		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION III MATERIALS LICENSING SECTION 799 ROOSEVELT ROAD GLEN ELLYN, IL 60137 ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION IV MATERIAL RADIATION PROTECTION SECTION 611 RYAN PLAZA DRIVE, SUITE 1000 ARLINGTON, TX 76011 ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION V MATERIAL RADIATION PROTECTION SECTION 1460 MARIA LANE, SUITE 210 WALNUT CREEK, CA 94596									
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL. IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.											
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>34-01216-03</u> <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>02002672</u>		2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code) St. Vincent Medical Center 2213 Cherry Street Toledo, Ohio 43608									
3. ADDRESS/ES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED St. Vincent campus: 2213 Cherry Street Toledo, OH 43608		Mercy campus: 2200 Jefferson Avenue Toledo, OH 43624									
4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Kathryn J. Royen, Ph.D., R.S.O.		TELEPHONE NUMBER (419) 251-4044									
SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.											
5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED									
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE		8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS									
9. FACILITIES AND EQUIPMENT		10. RADIATION SAFETY PROGRAM									
11. WASTE MANAGEMENT		12. LICENSEE FEES (See 10 CFR 170 and Section 170.21) FEE CATEGORY <u>10CFR170.31.7</u> AMOUNT ENCLOSURE \$ <u>440.00</u>									
13. CERTIFICATION (Must be completed by applicant): THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1946 (22 STAT. 749) MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.											
SIGNATURE - CERTIFYING OFFICER <i>Steven L. Mickus</i>		TYPED/PRINTED NAME Steven L. Mickus									
TITLE President and CEO		DATE 12/24/96									
14. VOLUNTARY ECONOMIC DATA											
A. ANNUAL RECEIPTS <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>< \$250K</td> <td>\$1M - 3 \$M</td> </tr> <tr> <td>\$250K - \$500K</td> <td>\$3 \$M - 7 \$M</td> </tr> <tr> <td>\$500K - 750K</td> <td>\$7M - 10M</td> </tr> <tr> <td>\$750K - 1M</td> <td>> \$10M</td> </tr> </table>		< \$250K	\$1M - 3 \$M	\$250K - \$500K	\$3 \$M - 7 \$M	\$500K - 750K	\$7M - 10M	\$750K - 1M	> \$10M	B. NUMBER OF EMPLOYEES (Year for entire facility including outside contractors) C. NUMBER OF BEDS	
< \$250K	\$1M - 3 \$M										
\$250K - \$500K	\$3 \$M - 7 \$M										
\$500K - 750K	\$7M - 10M										
\$750K - 1M	> \$10M										
D. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Salary and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence)		YES <input type="checkbox"/> NO <input type="checkbox"/>									
FOR NRC USE ONLY											
TYPE OF FEE AMOUNT RECEIVED		FEE LOG CHECK NUMBER									
FEE CATEGORY COMMENTS		APPROVED BY DATE									

PRIVACY ACT STATEMENT ON THE REVERSE

DEC 26 1996

EXH-3

DEC 24 1996

REGION III

PM 12/24/96 302167

EXHIBIT 1 (Continued)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555



December 11, 1996

St. Vincent Medical Center

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4531
Attention: Materials Licensing Division

Re: Request for Amendment to USNRC License No. 34-01216-03
**Special Request: Please expedite the review of this
request to ensure the continuity of
patient care**

Dear Sirs:

Please amend our Byproduct Materials License No. 34-01216-03 to include the items listed in the Sections below.

The precipitating cause for this amendment is that on December 31, 1996, Mercy Hospital (USNRC License No. 34-00305-03) will cease hospital operations and the clinical activities which remain open will be continued under the direction of St. Vincent Medical Center. **This is not a change in ownership of St. Vincent Medical Center.**

The intent of this amendment is divided into four Sections:

- Section 1. Notification is made that St. Vincent Medical Center and Mercy Hospital will change their respective names
- Section 2. The request for St. Vincent Medical Center (USNRC License No. 34-01216-03) to begin licensed activities at the Mercy Hospital site on the same date that Mercy Hospital terminates its license.
- Section 3. Pertinent sections from Regulatory Guide 10.8 are included to reflect the clinical operations that will continue on the Mercy Hospital site as well as the Authorized Users who will practice at the respective sites.
- Section 4. A declaration that the applicable sections of St. Vincent Medical Center's Quality Management Program will be implemented on the Mercy Hospital site as well.

Accordingly, **St. Vincent Medical Center, 2213 Cherry Street, Toledo, OH 43608 (USNRC License No. 34-01216-03)** requests to add the location formerly known as **Mercy Hospital, 2200 Jefferson Avenue, Toledo, OH 43624 (USNRC License No. 34-00305-03)** to its license as a second site of medical use of byproduct materials. NRC Form 313 is submitted with this letter, indicating St. Vincent Medical Center's intent to amend its Byproduct Materials License.

St. Vincent Medical Center, Toledo, OH
Byproducts Materials No. 34-01216-03
Request for Multi Site Licensure: December 11, 1996

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(excluding attachments)

As of December 31, 1996, Mercy Hospital will decommission its license and submit closeout surveys of all areas utilizing byproduct materials for medical use.

As of January 1, 1997, St. Vincent Medical Center is requesting, under a **Continuity of Care Consideration**, to be licensed to provide nuclear medicine services at the Mercy Hospital location, referred to hereafter in this request as the "Mercy Healthcare campus", the address of which is 2200 Jefferson Avenue, Toledo, OH 43624.

In accordance with **10.CFR.170.31.7.c.**, a license amendment fee of **\$440** is attached to this letter. This license amendment fee was verified through your Washington office (Ms. Shirley Crutchfield, telephone conversation December 11, 1996).

Section 1. Notification of Change of Name

Effective January 1, **St. Vincent Medical Center**, the Licensee, will change its name to **St. Vincent Mercy Medical Center** to reflect the addition of the former Mercy Hospital services to St. Vincent Medical Center. The site formerly known as **Mercy Hospital** will change its name to **Mercy Healthcare Center**.

Section 2. Request for Multi-site licensure

License reviewer please note:

The following format reflects the requirements for multi-site licensure contained in the USNRC Document "Guidance for Multi-Site Licenses", PG1-23, 4/30/96. The following format lists the requirements, as appropriate, verbatim, in Section 3.1. through Section 3.5 *in italics*; the St. Vincent Medical Center response follows each Section's requirement.

3.1.A. Focus

The adequacy of the licensee's radiation safety program and management oversight...with particular attention to delegation of responsibility and established reciprocal lines of communication between users and management:

SVMC Response:

The Radiation Safety Program currently in effect at St. Vincent Medical Center will be extended to apply to the Mercy Healthcare campus. The management currently supervising the areas involved in byproducts materials use at St. Vincent will supervise those areas on the Mercy Healthcare campus as well. Therefore, the delegation of responsibility and lines of communication currently in place at St. Vincent will apply to the Mercy Healthcare campus.

3.1.B. Description of Multi-Site

SVMC Response:

The designation of the Mercy Healthcare campus as a second site of use for materials for which St. Vincent Medical Center is currently licensed is requested because the addresses of use are geographically separated. Each

campus will be under the direction of the same Radiation Safety Officer, the same Radiation Safety Committee, and the same Administrative Management.

Furthermore, the nature of licensed material use and operations at each site are the same: byproduct materials for medical use.

This requested multi-site use is therefore the same as noted in Item 3.1.B.(3):
Medical licensees with facilities at more than one geographical location.

3.1.C. Number of Sites

SVMC Response:

Two sites of use are requested by St. Vincent Medical Center: one site is on the St. Vincent campus and the second is on the Mercy Healthcare campus.

3.2. Program Management Structure

3.2.A. General information

- (1) The licensee should document an administrative structure, organization, and procedures adequate to ensure safe operation by users at all facilities.*
- (2) The application should include an organizational chart depicting the licensee's management structure, reporting paths, and flow of authority.*
- (3) ...the application should provide a clear enunciation of the management structure and related authority for implementation and conduct of the radiation safety program at each facility...control of license material and facilities as well as ownership should be clearly specified...*

SVMC Response:

By January 1, 1997, Mercy Hospital will cease to exist as a hospital and will, instead, function as an enhanced outpatient services center. Please reference the attached letter, dated December 9, 1996 submitted as ATTACHMENT A, which describes the future planned use of the Mercy Hospital campus. Administration and support for those clinical services offered on the Mercy campus will be provided by St. Vincent Medical Center.

With specific reference to the Byproduct Material procedures performed there, the same administrators, managers, Radiation Safety Officer and Radiation Safety Committee currently providing oversight for the St. Vincent site of use will be responsible for the Mercy Healthcare campus site of use.

- (1) At the level of Chief Executive Officer for St. Vincent Medical Center and lower, the administrative structure, organization, and procedures to be used at the Mercy Healthcare campus location are the same as are currently on file with the USNRC with the St. Vincent Medical Center license.
- (2) The pertinent sections of the St. Vincent Mercy Medical Center Organizational Chart, depicting the management structure and its connection to the Nuclear Medicine service on the Mercy Healthcare campus, including the reporting paths, and flow of authority is attached to this request as ATTACHMENT B.

- (3) As depicted in the organizational descriptions provided in (1) and (2) above, this change in structure does not represent a joint operating agreement, nor are the two licensees uniting to form an association with duplications of administrative oversight.

3.2.B. Corporate Management

(1) Senior Management

- (a) Management oversight and mechanisms to ensure adequate control over day-to-day licensed activities at each site, including assignment of duties and allocation of necessary resources:*

SVMC Response:

Since the site on the Mercy Healthcare campus will be managed as a section of the St. Vincent Medical Center Department of Nuclear Medicine, the management of the site on the Mercy Healthcare campus will be by the same individuals managing the Nuclear Medicine Department at St. Vincent Medical Center, and the existing Radiation Safety Officer and Radiation Safety Committee at St. Vincent Medical Center will extend its authority and supervision to the Mercy Healthcare campus.

Management oversight over procedures involving the use of radioactive material and support of the Radiation Safety Program is provided directly by Senior Administration membership on the St. Vincent Medical Center Radiation Safety Committee, and by Senior Administration delegation of authority to the Radiation Safety Officer and the Radiation Safety Committee (currently on file with the USNRC), and to the Radiology Administrator and Nuclear Imaging Manager for their respective responsibilities over the sites of use. These individuals, with the approval of the Radiation Safety Committee, assign duties and allocate resources necessary for the safe use of the radioactive materials and enforcement of the Radiation Safety Program. The Authorized Users also accept responsibility for the safe receipt, use, and storage of radionuclides, both directly and by their direction of the certified nuclear medicine technologists.

- (b) Statement of delegation of authority to the RSO and RSC signed by senior management:*

SVMC Response:

The Statement of the Delegation of Authority to the St. Vincent Medical Center Radiation Safety Officer and Radiation Safety Committee by Senior Management is currently on file with the USNRC (letter dated May 31, 1990)

In order to assure the timely review of this request, by signature on this letter, Senior Management reaffirms compliance with the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F. to Regulatory Guide 10.8, Revision 2. Kathryn J. Royen, Ph.D., the current Radiation Safety Officer, will extend her responsibility to the site on the

Mercy Healthcare campus, and the current Radiation Safety Committee will extend its review functions and authority to the site on the Mercy Healthcare campus.

- (c) *Assurance that the RSO has sufficient time to perform duties, appropriate staff support, and provisions for RSO absence:*

SVMC Response:

The RSO is provided with sufficient time to perform her duties as they are expanded to this additional site. Since the RSO is also the Director of the Department of Medical Physics, the physicist staff in that department provides support for Radiation Safety responsibilities and provides coverage for the RSO in her absence.

- (d) *Periodic site tours and meetings with site management, the RSO, and the RSC:*

SVMC Response:

Since the Mercy Healthcare campus site will be under the direction of the current St. Vincent Medical Center administrative structure, RSO, and RSC structure, senior management will continue, through its current relationship with those entities, to conduct periodic tours and meetings as required, and to add issues pertinent to the Mercy Healthcare campus to those which it currently reviews.

- (e) *Mechanisms for reporting to informing management of unsafe practices and incidents, and the management role in responding to such circumstances.*

SVMC Response:

Since the Mercy Healthcare campus site will be under the direction of the current St. Vincent Medical Center administrative structure, RSO, and RSC structure, the mechanisms for reporting, informing management, and management response to unsafe practices and incidents will continue, including the Mercy Healthcare campus as one of its sites of review and oversight.

Under current procedure, incidents are reported to the Hospital Safety office and/or to the Radiation Safety Officer who, as needed, responds immediately to manage the incidents in accordance with hospital guidelines. The Radiation Safety Officer reports such issues to the Radiation Safety Committee and to Management, who direct the further management of the issues and make recommendations and changes in procedures to prevent a reoccurrence of such incidents.

- (f) *Methods and checks established to ensure that the RSO possesses and reviews current regulations.*

SVMC Response:

The RSO is on the GPO mailing list for receipt of documents pertinent to licensure, which include Code of Federal Regulations proposed changes and final rules pertinent to licensed activities. The RSO also receives the NMSS Newsletters, and information from professional organizations such as the American Association of Physicists in

Medicine, the Health Physics Society, the Society of Nuclear Medicine, and the American College of Radiology.

As part of her job description, the RSO reviews these documents and reports changes to the RSC for procedural implementation as required.

(g) *Chain of authority for ensuring compliance with regulatory requirements:*

SVMC Response:

The organizational chart (**ATTACHMENT B**) indicates the chain of authority which ensures compliance with regulatory requirements.

As notified by the RSO/RSC, Administration enacts policies/procedures to ensure compliance with regulatory requirements.

(h) *Assurance that senior management has an active role in sharing program responsibilities with the RSO when an RSC is not established:*

SVMC Response:

Not applicable. The St. Vincent Medical Center RSC will provide oversight of the Radiation Safety Program as it applies to the Mercy Healthcare campus as well.

(i) *Review of and involvement with program audits and evaluations, through membership on the RSC or otherwise.*

SVMC Response:

Senior management will continue its involvement with program audits and evaluations, through membership on the RSC and through its administrative oversight of personnel responsible for policies and procedures pertinent to regulatory issues and radiation safety.

(2) Site Management

The licensee should provide a written explanation of the role of site management to assist with the tasks of program management as outlined above for senior management.

SVMC Response:

As described previously, Mercy Healthcare campus site management at the senior, middle, and lower management levels will be performed by the same individuals who provide management at those respective levels at St. Vincent Medical Center. Their tasks pertinent to program management at the Mercy Healthcare campus will be the same as those performed on the St. Vincent campus.

It is the intent to send a Nuclear Medicine technologist from the St. Vincent campus to the Mercy Healthcare campus daily for 1 to 2 hours to perform the patient studies. That individual would then return to the St. Vincent campus. Supervision of and feedback from that individual would therefore be on a daily basis. Should increased volume in the future allow the expansion of the nuclear medicine technologists' time on the Mercy Healthcare campus to full time, supervision and feedback

methods will be adjusted accordingly. Regardless of staffing levels, the Authorized Users practicing on the Mercy Healthcare campus will provide continual supervision over clinical procedures.

3.2.C. Radiation Safety Officer

The licensee should provide a written description of the RSO's role and duties to ensure compliance with regulations, license conditions, and good radiation safety practices. Although the tasks of the RSO may be delegated to other personnel, the responsibility and authority over the tasks remain with the RSO.

SVMC Response:

The RSO's role and duties to ensure compliance with regulations, license conditions, and good radiation safety practices comply with those pertinent sections of 10.CFR.35., (specifically, but not limited to 10.CFR.35.21 and 10.CFR.35.900.) and to specific requirements as outlined in Appendices F and G in Regulatory Guide 10.8. These duties are currently on file with the USNRC by reference to these Appendices in the letter dated May 31, 1990.

Applicants should provide a written description of the office location, phone number, and telefacsimile number of the location where the RSO will be situated.

SVMC Response:

The RSO information follows:

Kathryn J. Royen, Ph.D., D.A.B.R., Radiation Safety Officer
Department of Medical Physics
St. Vincent Medical Center
2213 Cherry Street
Toledo, OH 43608
Phone (419)251-4044
Beeper (419)251-9200
FAX (419)251-3801

The duties and responsibilities of the RSO should be specified in writing and should include:

- (1) Frequency of reporting to, and meeting with, executive and site management, and the RSC.*

SVMC Response:

The RSO meets with and, as necessary, reports to executive and site management officials in the following forums:

Operations Team Meetings--Biweekly
Division Meetings--Biweekly
Radiology/Nuclear Medicine Department Meetings--Biweekly
Radiation Safety Meetings--Quarterly

The RSO has an open line of communication with all levels of management through the Hospital E-mail system, and, due to the quick feedback, reports and manages some issues through that venue.

The RSO meets with the RSC on a quarterly basis.

- (2) *Regular site visits, monitoring (e.g. facility/site surveys and review of reports and records for each site), and feedback to site personnel, as well as support staff, to ensure that daily operations at each site include radiation safety activities, approved procedures, safe practices, and compliance with regulations and licensing conditions.*

SVMC Response:

The RSO will make site visits as needed, and no less often than quarterly, to the Mercy Healthcare campus. Records will be reviewed on a monthly/quarterly basis (depending on the type of record). Feedback to site personnel and support staff will be ongoing, since the personnel for the site will have their primary job responsibility on the St. Vincent campus (see 3.2.B.(2) above).

Daily operational procedures as they apply to radiation safety activities, approved procedures, safe practices, and compliance with regulations and licensing conditions will be the same as currently in effect on the St. Vincent campus. That is, the policy and the procedure manuals which apply to the St. Vincent campus will also apply to the Mercy Healthcare campus.

- (3) *Periodic, interactive program audits at each site, indicating audit frequency and reporting commensurate with site operations*

SVMC Response:

Program audits will be performed by the RSO no less often than quarterly and more frequently if needed and/or as recommended by the Radiation Safety Committee.

The Mercy Healthcare campus site will be included in quarterly and annual ALARA reports to the Radiation Safety Committee.

All audits will be interactive.

- (4) *Mechanisms for being alerted and responding to unsafe practices and urgent situations that may occur at any site*

SVMC Response:

Phone numbers for individuals to be contacted in case of emergency, unsafe practice alerts, and other urgent situations will be posted at the site. These individuals will include the RSO, Supervisor, and at least one Authorized User. Since some of the Authorized Users will also be practicing at the site, and their numbers will be included in the emergency contact list, and instructions to contact them immediately will be made.

All such situations will be managed in accordance with current St. Vincent policy and will be reported by the RSO to the Radiation Safety Committee, and, if necessary, to regulatory agencies.

NRC Form 3, in addition to other required (State and Federal) documentation, will be posted at the Mercy Healthcare campus, just as it is currently at the St. Vincent site.

- (5) *Authority to make decisions and terminate unsafe practices and activities jeopardizing the safety of workers, the public, or environment.*

SVMC Response:

The RSO will extend the authority currently delegated to her to make decisions and terminate unsafe practices and activities jeopardizing the safety of workers, the public, or environment to the Mercy Healthcare campus.

3.2.D. Radiation Safety Support Staff

The RSO may be supported by a staff who assist in the maintenance and control of the licensed program at each site...Site personnel may also be enlisted to assist the RSO...The RSO may delegate some of his/her radiation safety tasks to these individuals; however, the authority and responsibility remain with the RSO.

SVMC Response:

Support staff for the RSO included the Medical Physics staff, the manager and senior technologists in Nuclear Medicine, and, on occasion, the Nuclear Medicine staff technologists. All duties delegated by the RSO are reviewed by the RSO in a timely manner.

Support Staff duties should be clearly specified, including provisions for reporting to the RSO, should be clearly specified, in writing, with sufficient time allotted for completion.

SVMC Response:

Support staff duties are assigned on an as needed basis, for example, when the RSO is not on site or is on vacation. Reporting to the RSO is also dependent upon the situation, and can be done in less than an hour to several days (in the case of vacation).

None of the RSO duties as specified in 10.CFR.35.21 or in Appendices F and G of Regulatory Guide 10.8 are routinely delegated to support staff, nor will they be for the Mercy Healthcare campus.

Provisions for regular interaction and feedback from the RSO, management, and RSC should be specified.

SVMC Response:

With the exception of vacations, the RSO has regular feedback with her support staff on a daily basis. The RSO then presents information as necessary to management and the RSC. If it becomes necessary for the support staff to report a problem in the RSO's management, they are instructed to report to individuals from management and Authorized Users who are also members of the Radiation Safety Committee.

3.2.E. Radiation Safety Committee

The necessity for a RSC should be assessed by the license reviewer on the basis of program scope and the need for assistance with radiation safety program oversight from a committee of individuals with varied specializations...Specific areas that applicants should address include:

- (1) *Appointment of representatives from each site, as well as the RSO and senior management.*

SVMC Response:

The RSC with its current membership contains individuals who will also have responsibilities on the Mercy Healthcare campus. The RSC membership, therefore, will not change.

- (2) *Establishment of a routine meeting schedule*

SVMC Response:

The RSC continues to meet quarterly; that frequency will continue when this amendment request is granted.

- (3) *Review of program audits and evaluations*

SVMC Response:

The program audits and evaluations that are currently in place on the RSC agenda will include information generated from the Mercy Healthcare campus as well.

- (4) *Statement of duties, emphasizing program development, implementation, and oversight*

SVMC Response:

The duties of the RSC, are currently on file with the USNRC in the letter dated May 31, 1990, and are in compliance with 10.CFR.35.22 and with Appendices F and G of Regulatory Guide 10.8. Those duties will extend to the Mercy Healthcare campus.

- (5) *Quorum requirements*

SVMC Response:

Quorum requirements, as defined on 10.CFR.35.22.(3), will continue to be maintained as the Mercy Healthcare campus is added as a second site of use to the St. Vincent license.

3.2.F. Communication

In those cases where there are multiple oversight levels....

SVMC Response:

Not applicable. The oversight levels are the same as currently on file with the USNRC for the St. Vincent license. There are no multiple oversight levels.

3.3 Records

As provided in 10.CFR.30.52, each licensee is to make its records available for NRC review, on reasonable notice. The license applicant should indicate point-of-contact information for NRC notification and inquiry about records.

SVMC Response:

For access to records, the NRC should notify the

RSO, Kathryn J. Royen, Ph.D., Phone (419)251-4044, FAX (419)251-3801,
Department of Medical Physics, St. Vincent Medical Center, 2213 Cherry Street,
Toledo, Ohio 43608,
or, the

Administrative Director of Radiology, Chuck Hayden, Phone (419)251-4393, FAX
(419)251-3863, Department of Radiology, St. Vincent Medical Center, 2213
Cherry Street, Toledo, OH 43608

The licensee may also choose to identify locations where the records will be maintained for NRC review.

SVMC Response:

The records generated on the Mercy Healthcare campus, with the exception of the RSC meeting minutes and other documentation pertinent jointly to the two sites, will be maintained on the Mercy Healthcare campus, 2200 Jefferson Avenue, Toledo, OH 43624.

The records generated on the St. Vincent campus, including the RSC meeting minutes and other documentation pertinent jointly to the two sites, will be maintained on the St. Vincent Campus, 2213 Cherry Street, Toledo, OH 43624.

3.4 Additional Program Areas for Review

The licensee should provide specific information, including the following areas:

(1) Transportation of licensed material (including radioactive waste) between sites

SVMC Response:

Since the radioactive material used at the Mercy Healthcare campus will be delivered to that site by a central distributing pharmacy, or the patients injected on the St. Vincent campus will be sent to the Mercy Healthcare campus for delayed imaging procedures, licensed material, including radioactive waste will not need to be transported between the two sites.

On the unlikely occasion when the transportation of licensed material is necessary, it will be done by an Authorized User.

(2) Applicability of decommissioning requirements

SVMC Response:

Mercy Hospital is terminating its license and will provide decommissioning information in accordance with guidelines and directives provided by the USNRC: including, but not limited to, NRC Form 314, and information required in the USNRC document "Guidelines for Decontamination of Facilities and equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material".

Decommissioning documents are therefore not contained in this amendment request but will be sent to the USNRC under separate cover by Mercy Hospital in a timely manner.

(3) *Sharing of safety equipment*

SVMC Response:

Since Mercy Hospital offered a full nuclear medicine service, the safety equipment necessary to continue the sections of the service which St. Vincent Medical Center has intent to offer will be kept on the Mercy Healthcare campus. It should therefore not be necessary to share equipment except, perhaps as a backup in the event of equipment failure.

In the future, equipment may be shared as older equipment is replaced. However, such sharing will be so designed so as not to compromise any of the critical aspects of the radiation safety program.

(4) *Coordination among sites for inventory control of licensed material with the intended focus of continually monitoring types and quantities of material, thereby ensuring that regulatory possession limits are not exceeded.*

SVMC Response:

It is the intent that each site file for separate regulatory possession limits. That is, St. Vincent will maintain its possession limits as currently on its license and the Mercy Healthcare campus will have possession limits defined for it. Under this arrangement, each site can monitor its own radionuclide inventory for type and quantity of material with respect to its regulatory possession limits.

3.5 Resources

This section is not applicable to licensee, since it describes resource burdens for the license reviewer.

Section 3. Description of the Mercy Healthcare campus site in accordance with Regulatory Guide 10.8, Revision 2

License reviewer please note:

This section describes, in accordance with Regulatory Guide 10.8, the pertinent information regarding the receipt, storage, use, and disposal of byproduct materials for medical use on the Mercy Healthcare campus.

NRC Form 313 is attached to this request, and the Items on that form which are pertinent to the amendment follow.

Item 5 Radioactive Material and Item 6 Purpose:

Byproduct Material	Chemical/Physical Form	Amount	Purpose
Material in §35.100	Any radiopharmaceutical identified in §35.100	As needed	Medical use
Material in §35.200, with the exception of aerosols and gases	Any radiopharmaceutical identified in §35.200	As needed	Medical use
Material in §35.300	Any radiopharmaceutical identified in §35.300	As needed	Medical use

Item 7. Individuals Responsible for Radiation Safety Programs--Their Training and Experience

7.1 Authorized Users for Medical Use

License Reviewer please note: Some of the Authorized Users currently on the St. Vincent Medical Center license are also requesting to practice with the materials authorized for use on the Mercy Healthcare campus. They therefore will practice on both the St. Vincent campus and the Mercy Healthcare campus. They are Drs. Myers, Glassberg, Royen PM, Hoover, Fadell, Gordon, Mayes, Siders, Doerfler, Loh, Manion, Patel, LaValley, Boorstein, and Patzik, as noted in the table below.

Three Authorized Users currently on the Mercy Hospital license are requesting to practice with the materials authorized for use on the Mercy Healthcare campus only. Their use of the materials is restricted by medical privilege to specific radionuclides in specific forms for thyroid uptake, imaging, and hyperthyroid treatment only. They are Drs. Brunner J.F., Brunner J.E., and Chakravarty, as noted in the table below.

The remaining Authorized Users currently on the St. Vincent Medical Center license will practice only at the St. Vincent campus. No change is therefore requested in this amendment for these individuals. They are Ho, Marsa, Mah, Zeidner, Mueller, Ahuja, Konski, Royen KJ.

The names of two Authorized Users currently on the St. Vincent Medical Center license should be deleted. They are Pinsky, and Eggleston, as noted in the table below.

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
R.E. Myers, M.D.	10CFR 35.100, 200, and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus.	St. Vincent Medical Center: 34-01216-03
G.B. Glassberg, M.D.	10CFR 35.100 and 200 (excluding generators for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
P.M. Royen, M.D.	10CFR 100 and 200 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
D.E. Hoover, M.D.	10CFR 100 and 200 (excluding generators), for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
M.F. Fadell, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
S.E. Gordon, M.D.	10CFR 35.100 and 200 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
S.L. Mayes, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
R.W. Siders, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
R.B. Doerfler, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
T.T. Loh, M.D.	10CFR 35.100 and 200 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
S.S. Manion, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
Y.P. Patel, M.D.	10CFR 35.100, 200 and 300 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
A.L. LaValley, M.D.	10CFR 35.100 and 200 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
J.M. Boorstein, M.D.	10CFR 35.100 and 200 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03
S.B. Patzik, M.D.	10CFR 35.100, 200, and 31.11 for use on the St. Vincent campus as well as the Mercy Healthcare campus	St. Vincent Medical Center: 34-01216-03

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
J.F. Brunner, M.D.	<ol style="list-style-type: none"> 1. 10CFR 35.100, restricted as follows: <ul style="list-style-type: none"> •Iodine 131 as sodium iodide in amounts less than 100 μCi for the determination of thyroid function by uptake studies, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only. 2. 10CFR35.200, restricted as follows: <ul style="list-style-type: none"> •Iodine 131 as sodium iodide in amounts less than 100 μCi for thyroid imaging studies, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only. •Technetium 99m as sodium pertechnetate for thyroid imaging on the Mercy Healthcare campus only 3. 10CFR35.300, restricted as follows: <ul style="list-style-type: none"> •Iodine 131 as sodium iodide in amounts less than 30 mCi for the treatment of thyrotoxicosis, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only. 	Mercy Hospital: 34-00305-03

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
J.E. Brunner, M.D.	<p>1. 10CFR 35.100, restricted as follows:</p> <ul style="list-style-type: none"> •Iodine 131 as sodium iodide in amounts less than 100 μCi for the determination of thyroid function by uptake studies, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only. <p>2. 10CFR35.300, restricted as follows:</p> <p>Iodine 131 as sodium iodide in amounts less than 30 mCi for the treatment of thyrotoxicosis, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only</p>	Mercy Hospital: 34-00305-03

Requested Authorized User	Requested Use	Authorized User currently approved for the Requested Use under USNRC License No.:
Chakravarty, J.	<ol style="list-style-type: none"> 1. 10CFR 35.100, restricted as follows: •Iodine 131 as sodium iodide in amounts less than 100 μCi for the determination of thyroid function by uptake studies, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only. 2. 10CFR35.300, restricted as follows: •Iodine 131 as sodium iodide in amounts less than 30 mCi for the treatment of thyrotoxicosis, in compliance with the facility's Quality Management Program, on the Mercy Healthcare campus only 	Mercy Hospital: 34-00305-03
Please delete William Eggleston M.D. as an Authorized User on the St. Vincent Medical Center License. He will retire from practice effective February 3, 1997 and will practice in the interim (until that retirement date) under the supervision of an Authorized User.		
Please note that on the Amendment issued pursuant to this request, S.T. Pinsky, M.D. should be deleted as an Authorized User. Notification of his change in status was sent to the USNRC on July 27, 1995 following his retirement from practice on July 8, 1995.		

Item 7.2 Authorized Users for Nonmedical Use

Not applicable on the Mercy Healthcare campus.

Item 7.3 Radiation Safety Officer

Kathryn J. Royen, Ph.D., D.A.B.R., Director, Radiation Medicine, and Radiation Safety Officer at St. Vincent Medical Center under USNRC License No. 34-01216-03, will extend her present RSO duties to provide oversight of the radiation safety program, procedures, and practices on the St. Vincent Medical Center Mercy Healthcare campus. Dr. Royen is a full-time employee of St. Vincent Medical Center, and is listed as an Authorized User on the St. Vincent Medical Center license.

Item 8. Model Training Program

St. Vincent Medical Center will extend and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

Groups of Workers Receiving Training	Type of Training	Frequency of Training
Technologists	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Nursing	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Clerical Staff	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Housekeeping	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Security	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Maintenance	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2
Student Technologists	Lecture, demonstration, or printed material	As defined in Appendix A to the Regulatory Guide 10.8, Revision 2

Item 9. Facilities and Equipment

9.1 Annotated Drawing

Byproduct materials for Medical Use will be performed in the area known as the "RIA Lab", (sublicensed amounts of Iodine-125 are used for lab testing in this facility as well). This "RIA Lab" diagram is appended as **ATTACHMENT C**.

In this drawing,

- the scale is 1/4" = 1 foot
- the direction North is noted
- the room numbers and principal use of each room is noted
- no shielding outside of the lead blocks in the hot lab is present
- the location of the fixed area monitor and the lead blocks in the hot lab is noted
- waste storage is behind the lead bricks in the hot lab
- central radiopharmacy delivery is directly to the hot lab

9.2 Survey Instrument Calibration

St. Vincent Medical Center will extend and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

9.3 Dose Calibrator Calibration

St. Vincent Medical Center will extend and implement the model procedure for calibrating the dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

9.4 Personnel Monitor Program

St. Vincent Medical Center will extend and implement the model personnel external exposure monitoring program that was published in Appendix D to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

9.5 Imaging Equipment

Not applicable

9.6 Other Equipment and Facilities

Not applicable

Item 10. Radiation Safety Program

10.1 Radiation Safety Committee/Radiation Safety Officer

St. Vincent Medical Center will extend and implement the Radiation Safety Committee Charter and Radiation Safety Officer delegation that was published in Appendix F to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.2 ALARA Program

St. Vincent Medical Center will extend and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.3 Leak Test

St. Vincent Medical Center will extend and implement the model procedure for leak testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.4 Safe Use of Radiopharmaceuticals

St. Vincent Medical Center will extend and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.5 Spill Procedures

St. Vincent Medical Center will extend and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.6 Ordering and Receiving

St. Vincent Medical Center will extend and implement the model guidance for ordering and receiving radioactive materials that was published in Appendix K to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.7 Opening Packages

St. Vincent Medical Center will extend and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.8 Unit Dosage Records

St. Vincent Medical Center will extend and implement the model unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.9 Multidose Vial Records

Not applicable.

10.10 Molybdenum Concentration Records

Not applicable.

10.11 Implant Source Use Records

Not applicable

10.12 Area Survey Procedures

St. Vincent Medical Center will extend and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

10.13 Air Concentration Control

Not applicable

10.14 Radiopharmaceutical Therapy

Not applicable

10.15 Implant Therapy

Not applicable

10.16 Other Safety Procedures

Not applicable

Item 11. Waste Disposal

11.1 Waste Disposal

St. Vincent Medical Center will extend and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2., currently on file with the USNRC in its letter dated May 31, 1990, to the Mercy Healthcare Campus.

11.2 Other Waste Disposal

Not applicable.

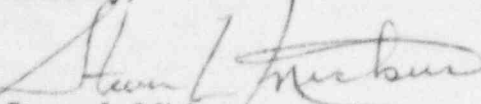
Section 4. Quality Management Program

St. Vincent Medical Center will extend its Quality Management Program, currently on file with the USNRC for the use of Sodium Iodide (as I-131 and I-125) Radiopharmaceuticals in amounts greater than 30 μ Ci and less than 30 mCi, to the Mercy Healthcare campus. The portions of the St. Vincent Quality Management Program specific to Radionuclide Therapy (including Iodine-131 in amounts 30 mCi and greater) and Brachytherapy will continue to apply only to the St. Vincent campus.

Thank you in advance for your consideration of this amendment to our license. For your convenience, this letter is being submitted in duplicate to facilitate your review process.

Should you require further information, please contact Dr. Kathryn Royen, Radiation Safety Officer (419)251-4044, or H. Terrence Smith, Vice President, Legal Services, Mercy Health Systems Northern Region (419) 251-4627.

Sincerely,



Steven L. Mickus
President and CEO

Attachments:

USNRC Form 313

Check payment for Amendment Request

ATTACHMENT A: Letter dated December 9, 1996

ATTACHMENT B: Organizational Chart

ATTACHMENT C: Annotated Drawing of Facility



Mercy Hospital, Tiffin	1822 Cherry Street
Mercy Hospital, Toledo	Toledo, Ohio
Mercy Hospital, Willard	43608
St. Charles Hospital	(419) 251-0700
St. Vincent Medical Center	

ATTACHMENT A
ST. VINCENT MEDICAL CENTER
34-01216-03
December 11, 1996 Amendment Request

December 9, 1996

Dear Medical Staff Member,

After a detailed review of current and future community health needs - including considerable input from physicians and staff - plans for reconfiguring the Mercy Hospital, Toledo campus into an enhanced outpatient services center are finalized. Building on a history of community service and quality care, the new Mercy Hospital, Toledo will be a campus designed to provide quality, accessible healthcare services for patients, physicians and payors. We are pleased to share with you the scope of outpatient services which will be offered:

- Outpatient surgery, including preadmission testing, extended recovery and endoscopy services
- Mercy Health Center outpatient clinics
- Mercy Family Practice Center
- Walk-in/AfterHours services
- Endocrine and Diabetes Care Center
- Diagnostic Radiology Services, including general radiology, ultrasound, and mammography
- EKG Laboratory
- EMG testing
- Pathology services, including an outpatient clinical lab, fine needle aspirations and frozen section work
- Outpatient Pharmacy

Also reflective of Mercy Health System's commitment to a successful outpatient campus are nearly \$2 million in capital investments to enhance existing outpatient capabilities. This includes an estimated \$1.4 million for such significant improvements as remodeling of the emergency area for relocation of the outpatient clinics to the first floor to enhance patient convenience; the relocation of the pre-admission testing area to the second floor to be adjacent to various diagnostic services; and renovations to the main lobby, driveways, sidewalk and patient parking areas. Nearly \$600,000 is scheduled for clinical equipment purchases to further improve outpatient capabilities. The above capital investments only apply to outpatient services and not to the substantial investments that will be made to enhance Mercy College and establish the regional support campus, as announced earlier this fall.

This outpatient services plan lays a solid foundation which will support growth and expansion of the Mercy campus in the future. It further develops Mercy Hospital, Toledo's role in fulfilling the mission of the Sisters of Mercy by providing quality healthcare services and meeting the needs of the community.

As you know, Mercy Hospital, Toledo will no longer admit inpatients or provide emergency services as of December 22, 1996, and will no longer provide acute inpatient services effective December 31. The outpatient services stated above will be offered at Mercy as of January 1, although implementation of the complete outpatient services plan will take place during the first half of 1997. We will keep you informed of its progress.

We appreciate your support and involvement, and look forward to our continued working relationship as we create a system of care that provides your patients with high quality, compassionate healthcare services. If you have any questions about these plans or other reconfiguration efforts, please feel free to contact us.

Sincerely,

A handwritten signature in dark ink, appearing to read "Peter M. Dziad, M.D.", written over a light background.

Peter M. Dziad, M.D.
Chief of Staff
Mercy Hospital, Toledo

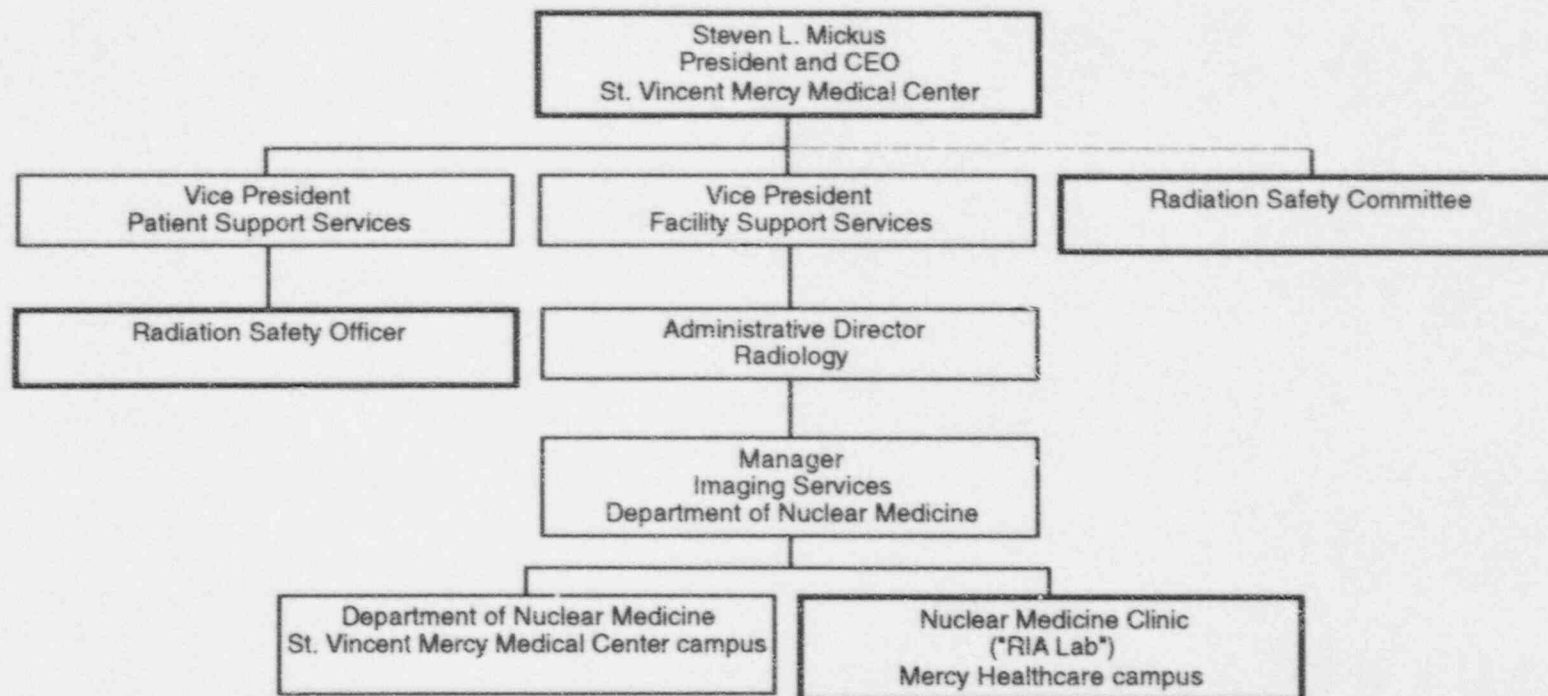
A handwritten signature in dark ink, appearing to read "Cathleen K. Nelson", written over a light background.

Cathleen K. Nelson
President & CEO
Mercy/St. Charles Hospitals

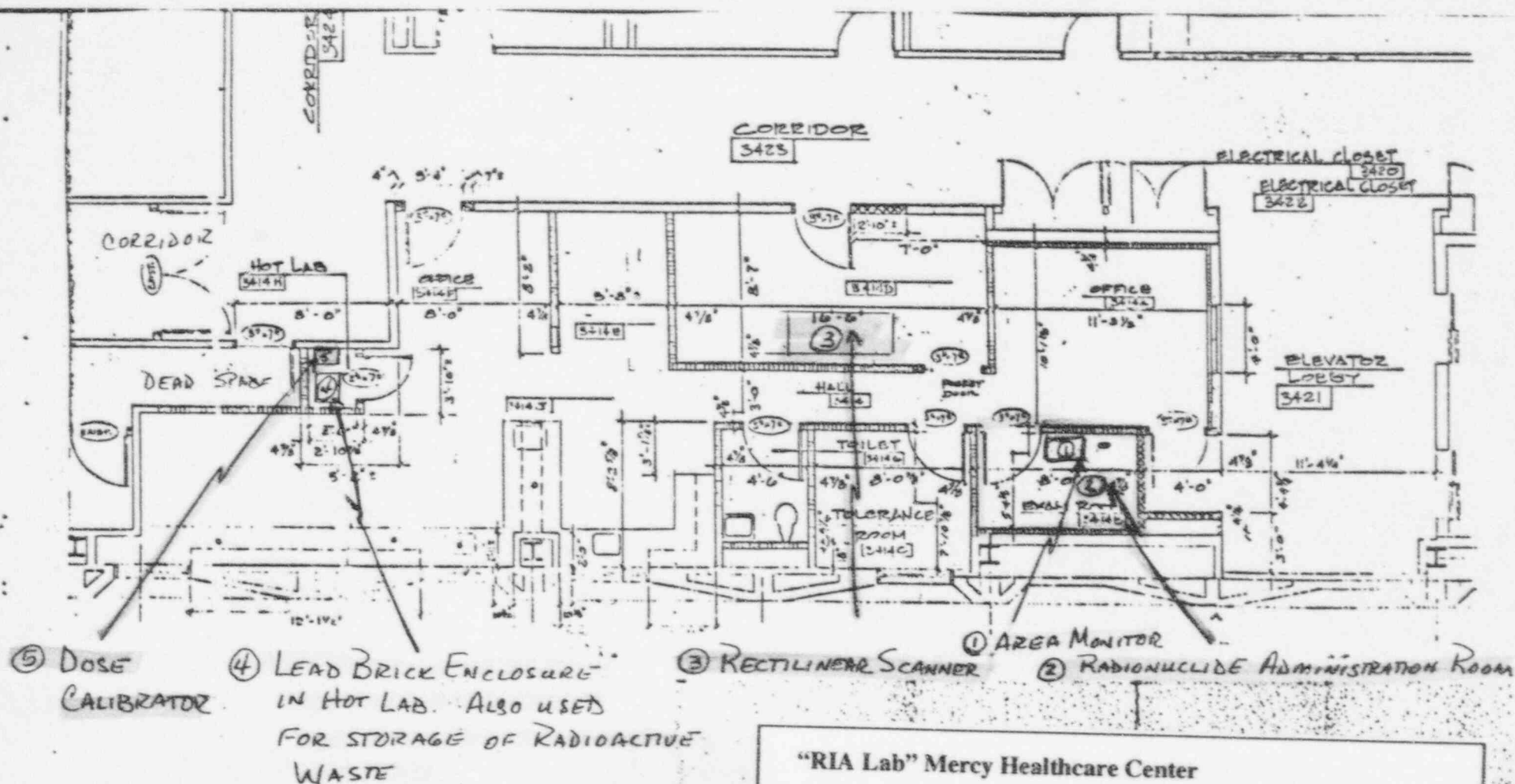
A handwritten signature in dark ink, appearing to read "Steven L. Mickus", written over a light background.

Steven L. Mickus
President & CEO
St. Vincent Medical Center

**St. Vincent Mercy Medical Center Organizational Chart:
Chain of Authority and Reporting Structure from Nuclear Medicine Service, Mercy
Healthcare Center to President and CEO**



NORTH



"RIA Lab" Mercy Healthcare Center
Nuclear Medicine Services on the MercyHealthcare campus

JAN 08 1997

Steven L. Mickus
President and CEO
St. Vicent Mercy Medical Center
2213 Cherry Street
Toledo, OH 43608

Dear Mr. Mickus:

Enclosed is Amendment No. 47 to your NRC Material License No. 34-01216-03 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 also note that the expiration date on your NRC license was extended 5 years in accordance with 10 CFR 30.36(2).

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).

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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

S. Mickus

-3-

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
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No.: 34-01216-03

Docket No.: 030-02672

Enclosure: Amendment No. 47

cc: Kathy Royen, Ph.D.
Radiation Safety Officer

DOCUMENT NAME: M:\03002672.CL6

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