

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 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 purposes(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 laws, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301769

Licensee

1. St. Alexis Hospital Medical Center

2. 5163 Broadway Avenue
Cleveland, OH 44127In accordance with the application dated
July 5, 19963. License Number 34-05582-01 is amended
in its entirety to read as follows:

4. Expiration Date February 28, 2004

5. Docket or
Reference No. 030-027506. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Any byproduct material
identified in 10 CFR
35.100A. Any
radiopharmaceutical
identified in 10 CFR
35.100

A. As needed

B. Any byproduct material
identified in 10 CFR
35.200B. Any
radiopharmaceutical
identified in 10 CFR
35.200

B. As needed

C. Any byproduct material
identified in 10 CFR
35.300C. Any
radiopharmaceutical
identified in 10 CFR
35.300C. As needed
(not to exceed 1 curie
of I-131)

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.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at
5163 Broadway Avenue, Cleveland, Ohio.

210075

9610210305 760911
PDR ADDOCK 03002750
C PDR

COPY

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50

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

34-05582-01

Docket or Reference Number

030-02750

Amendment No. 39

11. Radiation Safety Officer: Charles Doyle, M.D.
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. Bradley Arthur Blackburn, M.D.	10 CFR 35.100 and 35.200.
B. Mary Anne King, M.D.	10 CFR 35.100 and 35.200.
C. Deodutt V. Patel, M.D.	10 CFR 35.100 and 35.200.
D. Eugene A. White, M.D.	10 CFR 35.100 and 35.200.
E. Bernard T. Archer, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
F. Victor J. Demarco, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
G. Robert J. Jacobson, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
H. James E. Lalak, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
I. Robert J. Lazarony, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
J. Bruce H. Robson, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
K. Glenn E. Sykora, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
L. A. Mervyn Thynne, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding Iodine-131 for thyroid carcinoma therapy).
M. Amir Seyed Baghery, M.D.	10 CFR 35.100, 35.200 and 35.300.
N. S. Bruce Deville, M.D.	10 CFR 35.100, 35.200 and 35.300.
O. Charles Doyle, M.D.	10 CFR 35.100, 35.200 and 35.300.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

34-05582-01

Docket or Reference Number

030-02750

Amendment No. 39

12. (Continued)

Authorized Users

Material and Use

P. Laurance B. Grossman, M.D.	10 CFR 35.100, 35.200 and 35.300.
Q. R. A. Siwik, M.D.	10 CFR 35.100, 35.200 and 35.300.
R. Riaz Tarar, M.D.	10 CFR 35.100, 35.200 and 35.300.
S. Shardul Vibhaker, M.D.	10 CFR 35.100, 35.200 and 35.300.

13. 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.

14. 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 December 21, 1993 and July 5, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

9/11/96

By

Michael E. Webb

Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20040228
Fee Comments: CODE 21
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. LEXIS HOSPITAL MEDICAL CENTER
Received Date: 960826
Docket No: 3002750
Control No.: 301769
License No.: 34-05582-01
Action Type: Amendment

2. FEE ATTACHED

Amount: \$430.00
Check No.: 010544

3. COMMENTS

Signed
Date

Marcia P. Payer
8/27/96

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

1. Fee Category and Amount: 7C \$440

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

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC
10/1/96

1996 AUG 29 PM 4:25

Log	Aug 14 11
Remitter	
Check No.	10544 / 11145
Amount	\$430.00 / \$10
Fee Category	7C
Type of Fee	Amnd
Date Check Rec'd	8/29/96
Date Completed	10/1/96
By	SC

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 2 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MIBB 7714, U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0123), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30333-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U. S. NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 78011-3064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94598-5268

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 JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 34-05582-01
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

St. Alexis Hospital Medical Center
5163 Broadway Avenue
Cleveland, OH 44127

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same as #2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ed Sims, Consultant
Assoc. in Medical Physics, LLC
TELEPHONE NUMBER
(216) 581-4350

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 EXPERIENCE. Refer to Item #7	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT. Refer to Item #9	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$430.00
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, 36, 39 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, 1948 AS AMENDED, 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.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

X JANICE L. MEISTER, CHIEF OPERATING OFFICER

SIGNATURE

X Janice L. Meister

DATE

7-5-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

RECEIVED
AUG 26 1996
301769
REGION III

Pm 8/23/96

AUG 26 1996

This amendment consists of two requests to our license:

- 1) Amend to add Drs. Archer, Vibhaker, Thynne and Robson as previously submitted through a 10 CFR 35.14 Notification on 11/16/95.
- 2) Amend to delete Area B, camera room, as a restricted area from our license. The room is no longer being utilized for nuclear medicine procedures. A close-out survey of Area B is enclosed, which includes surveys and wipe tests.

Attachment 7.1

AUTHORIZED USERS FOR MEDICAL USE

<u>AUTHORIZED USER</u>	<u>AUTHORIZATION</u>
B. T. Archer, M.D.	35.100, 35.200 and 35.300 (excluding I-131 for thyroid carcinoma)
Shardul Vibhaker, M.D.	35.100, 35.200 and 35.300
A. Mervyn Thynne, M.D.	35.100, 35.200 and 35.300 (excluding I-131 for thyroid carcinoma)
Bruce H. Robson, M.D.	35.100, 35.200 and 35.300 (excluding I-131 for thyroid carcinoma)

For Dr. Archer, Vibhaker and Thynne, refer to the application for license #34-01505-01 for evidence of training and experience. A copy of the NRC license for Meridia Huron Hospital is attached for reference.

For Dr. Robson, refer to the application for license #34-11232-02 for evidence of training and experience. A copy of the NRC license for Lake Hospital Systems, West, is attached for reference.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with application dated March 4, 1994	
1. Meridia Huron Hospital		3. License number 34-01505-01 is renewed in its entirety to read as follows:	
2. 13951 Terrace Road Cleveland, OH 44112		4. Expiration date June 30, 1999	
		5. Docket or Reference No 030-02680	
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 31.11	D. Prepackaged Kits	D. As needed	
E. Carbon-14	E. Any	E. 2 millicuries	
F. Hydrogen-3	F. Any	F. 10 millicuries	
G. Phosphorus-32	G. Any	G. 500 microcuries	

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

34-01505-01

Docket or Reference number

030-02680

Amendment No. 33

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. through G. To be used for in-vitro studies.

CONDITIONS

10. Location of Use: Meridia Huron Hospital, 13951 Terrace Road, Cleveland, Ohio.

11. Radiation Safety Officer: A. Mervyn Thynne, M.D.

12. Authorized Users:

B. T. Archer, M.D., for material listed in 10 CFR 35.100, 35.200, 31.11 and iodine-131 for treatment of hyperthyroidism and cardiac dysfunction.

C. C. York, M.D., for material listed in 10 CFR 35.100, 35.200, 31.11 and iodine-131 for treatment of hyperthyroidism and cardiac dysfunction.

Shardul Vibhaker, M.D., for material listed in 10 CFR 35.100, 35.200, 35.300 and 31.11.

Howard Potash, M.D., for material listed in 10 CFR 35.100, 35.200, 35.300 and 31.11.

A. Mervyn Thynne, M.D., for material listed in 10 CFR 35.100, 35.200, 31.11, and iodine-131 for treatment of hyperthyroidism and cardiac dysfunction, and strontium-89.

Burton Carey West, M.D., for material listed in Subitems 6.E., 6.F. and 6.G.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

34-01505-01

Docket or Reference number

030-02680

Amendment No. 33

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 4, 1994; and
- B. Letters dated May 13, 1993 (Item 4), and May 31, 1994.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 6-7-94

By

Peter J. Lee
Materials Licensing Section, Region III

Page 5 of 11
Prepared: 6/7/96
Lic. #34-05582-01

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with application dated May 19, 1993 and letter dated June 8, 1993	
1. Lake Hospital Systems - West Nuclear Medicine Department		3. License number 34-11232-02 is renewed in its entirety as follows:	
2. 36000 Euclid Avenue Willoughby, OH 44094		4. Expiration date April 30, 1999	
		5. Docket or Reference No. 030-18925/34-11232-01	
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 (excluding generators and Xenon-133)	B. As needed	
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 1 curie of I-131)	
9. Authorized Use:			
A. Medical use described in 10 CFR 35.100.			
B. Medical use described in 10 CFR 35.200 (excluding generators and Xenon-133).			
C. Medical use described in 10 CFR 35.300.			

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number:

34-11232-02

Docket or Reference number

030-18925/34-11232-01

Amendment No. 10

CONDITIONS

10. A. Licensed material in Items 6.A., 6.B. and 6.C. shall be used only at the licensee's facilities located at Lake Hospital Systems West, 36000 Euclid Avenue, Willoughby, Ohio.
- B. Licensed material in Items 6.A., 6.B. and 6.C. (excluding iodine-131 for thyroid carcinoma treatment) shall be used only at the licensee's facilities located at Lake Hospital Systems East, Washington at Liberty Street, Painesville, Ohio.
11. Radiation Safety Officer: Francis A. Greicius, M.D.
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. Howard Potash, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300. |
| B. James Roda, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |
| C. Victor J. DeMarco, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |
| D. Bela Frank Ballo, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |
| E. Francis A. Greicius, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |
| F. Bruce H. Robson, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |
| G. David Alan Steiger, M.D. | 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding Iodine-131 for thyroid carcinoma). |

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

34-11232-02

Docket or Reference number

030-18925/34-11232-01

Amendment No. 10

- H. Deodutt V. Patel, M.D. 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300 (excluding iodine-131 for thyroid carcinoma treatment).
- I. Bon Chul Koo, M.D. 10 CFR 35.100, and 35.200 (excluding generators and Xenon-133).
- J. David Wymer, M.D. 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300.
- K. David J. Horejs, M.D. 10 CFR 35.100, 35.200 (excluding generators and Xenon-133), and 35.300.
- L. Ronald A. Siwik, M.D. 10 CFR 35.100, 35.200 and 35.300.
- M. Howard J. Klein, M.D. 10 CFR 35.100, 35.200 and 35.300.

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

- A. Application dated May 19, 1993 (with attachments); and
- B. Letters dated June 8, 1993 and February 25, 1994.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

March 15, 1994

By

Colleen C. Casey
Materials Licensing Section, Region III

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Prepared: 6/7/96

Lic. #34-05582-01

CLOSE OUT SURVEY

Date: 6/5/96

Name: St. Alexis Hospital Medical Center
5163 Broadway Avenue
Cleveland, Ohio 44127

NRC License: #34-05582-01

Survey Instrument: Picker Model #: 655-186 Serial #: 107

Last Calibration Date of Survey Meter: 9/21/95

Check Source Reading: 1.4 mR/hr

Wipe Test Analyzer: Canberra 35 Plus

Last Calibration: 6/5/96

Wipe Test Window: 20-600 keV

Minimum Detectable Activity: 288 dpm

Well Counter Efficiency: 31.5%

Wipe Analysis Background: 937 cpm

G-M Survey Background: .02 mR/hr

Surveyor: Jim Raleigh, CNMT, RT(N)

Page 9 of 11
Prepared: 6/7/96
Lic. #34-05582-01

Area Surveyed:

A complete contact survey using a G-M survey meter on the lowest range was conducted in the imaging room. Specific areas were surveyed as identified on the attached diagram and survey results indicated no exposure levels were in excess of 0.01 mR/hr.

Surface Wipe Tests:

Surface wipe tests were performed using Nu-Con dry smears or equivalent. Surfaces wiped included multiple areas in the imaging room and floor as indicated on the attached diagram and summary sheet of wipe test results. The wipe test results were recorded in net dpm. No identifiable contamination was found.

Results:

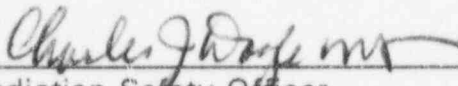
All surveys produced low background readings from the survey meter and wipe test analysis.

Conclusion:

No radiation levels above background were detected. No removable contamination was found. Signs indicating the presence of radioactive materials were removed or defaced.

Recommendations:

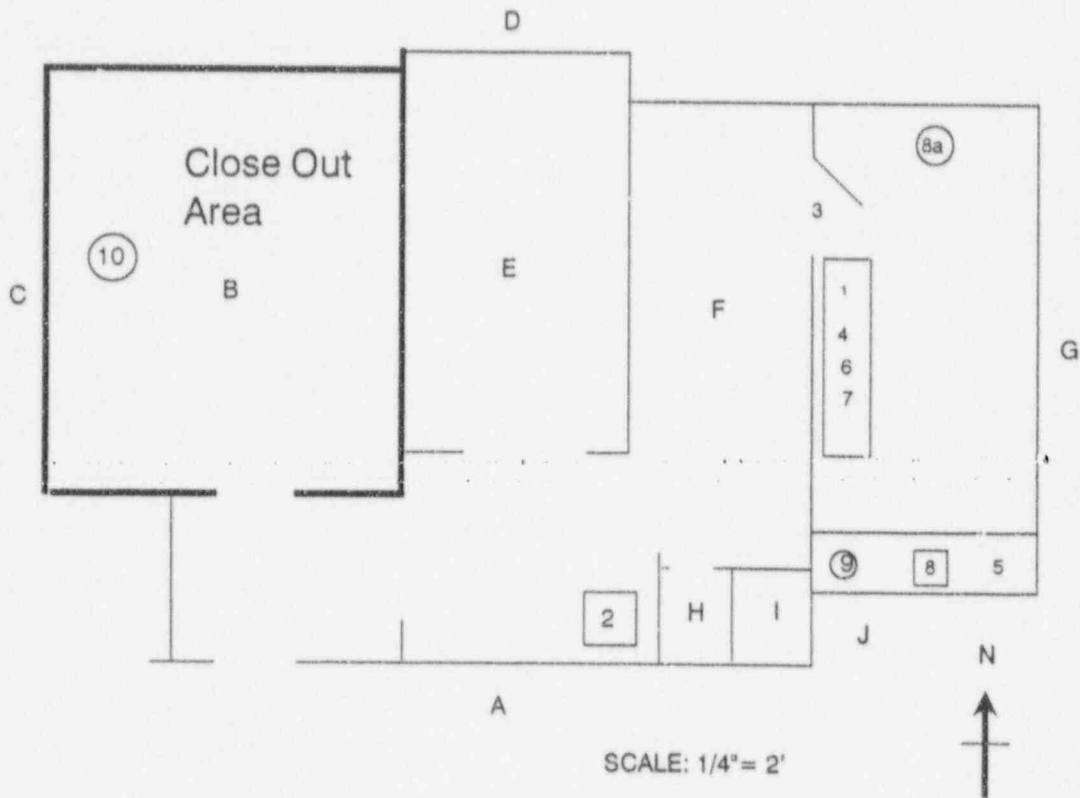
Upon acknowledgement from the NRC of the receipt and acceptance of the above survey results, the room can be released for unrestricted use.



Radiation Safety Officer

Page 10 of 11
Prepared: 6/7/96
Lic. #34-05582-01

CLOSE-OUT SURVEY



<u>Area</u>		<u>G-M Survey mR/hr</u>	<u>Wipe in net cpm</u>
1.	Sink	.02	0
2.	Sink Trap	.02	0
3.	Countertop	.02	0
4.	Imaging Room	.02	0
5.	Floor	.02	0
6.	Camera	.02	0
7.	Door Handle	.02	0
8.	Light Switch	.01	0
9.	Uptake Probe Area	.02	0
10.	Background	.02	937

LICENSE FEE REQUIREMENTS

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

ST. ALEXIS HOSPITAL MEDICAL CENTER
ATTN: JANICE L. MEISTER
CHIEF OPERATING OFFICER
5163 BROADWAY AVENUE
CLEVELAND, OHIO 44127

TYPE OF ACTION

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

REQUESTED DATE

7-5-96

LICENSE NUMBER

34-05582-01

CONTROL NUMBER

301769

I. APPLICATION FEE DUE

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

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	430.00
AMOUNT DUE	\$	10.00

☐ Your request was received without the prescribed application fee.

☒ We received your Check No. 10544 in the amount of \$ 430.00. Payment of the additional fee noted above is required.

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

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

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

SIGNATURE -- LICENSE FEE ANALYST

LFDCB

LFDCB

Shirley Crutchfield
SHIRLEY CRUTCHFIELD

9/4/96

II. FEE NOT REQUIRED

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

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

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

- ☐ INSUFFICIENT FUNDS
☐ ACCOUNT CLOSED
☐ OTHER

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

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

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

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

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

Distribution:

Pending Fee File

LFARB R/F (2)

OC/DAF/RF
OC/DAF/SF(LF-3 2.7)
Region 3

DATE

Sept. 5, 1996

OCT 07 1996

Janice L. Meister
Chief Operating Officer
St. Alexis Hospital Medical Center
5163 Broadway Avenue
Cleveland, OH 44127

Dear Ms. Meister:

This refers to your application, received on August 26, 1996, and to our telephone conversation with Mr. Ed Sims of Associates in Medical Physics, LLC, on September 4, 1996.

Enclosed is Amendment No. 39 to your NRC License No. 34-05582-01 in accordance with your request.

As discussed with Mr. Sims, your license was also updated in accordance with current NRC policy. Specifically: 1) License Condition No. 8.C. now includes a possession limit of one curie for iodine-131, and 2) License Condition No. 13, which contains a general possession limit, was added.

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) 829-9847 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
or

301769

- b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences

J. Meister

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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
Michael F. Weber
Nuclear Materials Licensing Branch

License No. 34-05582-01
Docket No. 030-02750

Enclosure: Amendment No. 39

DOCUMENT NAME: M:\03002750.CL6

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DATE	09/11/96								

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