

## MATERIALS LICENSE

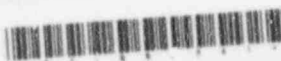
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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 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.

302329

Licensee		In accordance with letter dated February 7, 1997	
1. Lakewood Hospital		3. License Number 34-01197-01 is amended in its entirety as follows:	
2. 14519 Detroit Avenue Lakewood, OH 44107		4. Expiration Date September 30, 2003	
		5. Docket or Reference No. 030-02671	
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 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	
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits 110098	D. As needed	

## 9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200 (excluding xenon-133).
- C. Medical use described in 10 CFR 35.300.
- D. In vitro studies.



COPY

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

34-01197-01

Docket or Reference Number

030-02671

Amendment No. 42

CONDITIONS

10. Location of Use: 14519 Detroit Avenue, Lakewood, Ohio.
11. A. Radiation Safety Officer: Kathleen Cunningham, B.S., C.N.M.T.  
B. Alternate Radiation Safety Officer: Gopal B. Saha, Ph.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 UsersMaterial and Use

William J. Fayen, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 (excluding iodine-131 for thyroid  
carcinoma) and 31.11

Prasan Kumar J. Vasavada, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 (excluding iodine-131 for thyroid  
carcinoma) and 31.11

James K. O'Donnell, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 and 31.11

David H. Feiglin, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 and 31.11

Sebastian Cook, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 (excluding iodine-131 for thyroid  
carcinoma) and 31.11

Raymundo Go, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 and 31.11

Shanker Raja, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 and 31.11

Donald Newman, M.D.

10 CFR 35.100, 35.200 (excluding xenon-133),  
35.300 and 31.11

13. The licensee shall maintain records of information related to decommissioning at the location listed in Condition 10. of this license as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

COPY

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

34-01197-01

Docket or Reference Number

030-02671

Amendment No. 42

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 U.S. 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 April 22, 1993 (excluding Item 12); and
- B. Letters dated September 7, 1993, February 7, 1997 and March 21, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

MAR 31 1997

By

*Loren J. Hunter*

Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)  
INFORMATION FROM LTS

R8

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

Program Code: 02120  
Status Code: 0  
Fee Category: 7C  
Exp. Date: 20030930  
Fee Comments: OPERATED BY HOSP. ASS  
Decom Fin Assur Req'd: N  
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: LAKEWOOD HOSPITAL  
Received Date: 970218  
Docket No: 3002671  
Control No.: 302329  
License No.: 34-01197-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 440  
Check No.: 108916

3. COMMENTS

Signed  
Date

D. Hersey  
2-25-97

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

1. Fee Category and Amount:

7C \$440

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

Amendment  
Renewal  
License

3. OTHER

Signed  
Date

SC 2/24/97

MAR 03 1997

Log	Feb 10 III
Remitter	
Check No.	108916
Amount	\$440
Fee Category	7C
Type of Fee	AmD
Date Check Rec'd	2/21/97
Date Completed	2/24/97
By:	SC





# LAKEWOOD HOSPITAL

14519 Detroit Avenue, Lakewood, Ohio 44107-4383

(216) 521-4200

February 7, 1997

U.S.N.R.C. Region III  
Materials Licensing Section  
801 Warrenville Road  
Lisle, Illinois 60532

RE: Lakewood Hospital  
License #34-01197-01

To Whom It May Concern:

Please amend the above referenced License to reflect the following:

1. Delete Sebastian Cook, M.D. as the Radiation Safety Officer.
2. Add Ms. Kathleen Cunningham as the Radiation Safety Officer. Enclosed please find a letter documenting Ms. Cunningham's training as outlined on the appropriate Supplement along with a statement of experience for the position of Radiation Safety Officer.
3. An alternate Radiation Safety Officer is Gopal B. Saha, Ph.D. For training and experience, refer to NRC License #34-01386-01. Dr. Saha will be the alternate Radiation Safety Officer if and when Ms. Cunningham is not available.

For day to day operations of this License, Ms. Cunningham will be directly responsible for Radiation Safety. There is a clear line of communication between Ms. Cunningham and Administration.

4. Enclosed you will find the Closeout Survey of the Cardiac Stress Room. Please delete reference to this area on our license.
5. Also enclosed is a check for \$440.00 to amend our license.

Should you have any questions, please don't hesitate to contact me directly at (216) 529-7200.

Sincerely,

*Mark E. Wiedt*

Mark E. Wiedt  
Administrative Director  
Department of Radiation Control

RECEIVED

FEB 18 1997

REGION III

30232.9

Pm: 2-12-97



# LAKEWOOD HOSPITAL

14519 Detroit Avenue, Lakewood, Ohio 44107-4383 (216) 521-4200

February 5, 1997

U.S.N.R.C. Region III  
Materials Licensing Section  
801 Warrenville Road  
Lisle, Illinois 60532

To Whom It May Concern:

This is to document that Ms. Kathleen Cunningham has performed the functions of a radiation safety technologist under the supervision of a radiation safety officer for the past five years. Under supervision Ms. Cunningham has:

1. Investigated overexposure, accidents, spills, uses, transfers, disposals, losses, misadministrations and other deviations from approved radiation safety practices and has implemented corrective actions as necessary.
2. Established implemented written policies and procedures for:
  - a. Authorizing the purchase of byproduct material;
  - b. Receiving and opening packages of byproduct material;
  - c. Storing byproduct material;
  - d. Keeping an inventory record of byproduct material
  - e. Using byproduct material safely;
  - f. Taking emergency action if control of byproduct material is lost;
  - g. Performing periodic radiation surveys;
  - h. Performing checks of survey instruments and other safety equipment;
  - i. Disposing of byproduct material;
  - j. Training personnel who work in or frequent areas where byproduct material is used or stored;
  - k. Keeping a copy of all records and reports required by the Commission regulations, a copy of Commission regulations, a copy of each licensing request and license and amendments and the written policies and procedures required by the regulations;
3. Evaluated the byproduct material program annually.
4. Assisted in investigation of exposure levels which have exceeded established investigational levels for the cause of the exposure.

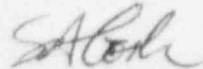
In addition, Ms. Cunningham assisted in preparing the hospital's Radiation Safety Plan. She also served as a resource person for other departments in addressing radiation related concerns. Ms. Cunningham has conducted radiation training sessions to non-occupationally exposed persons; and has reported to the Radiation Safety Committee.

Ms. Cunningham has been a member of the Radiation Safety Committee at Lakewood Hospital since March, 1992 and is well aware of the duties and responsibilities of the Radiation Safety Officer in assuring that employees and the public are protected from radiation hazards. I feel Ms. Cunningham possesses the requisite knowledge and experience to be a dedicated, capable Radiation Safety Officer.

Ms. Cunningham will be granted full authority in the position of RSO to control activities related to radiation safety.

In addition, Ms. Cunningham's position as the Nuclear Medicine Supervisor will not be jeopardized in the event she exercises authority related to RSO decisions.

Sincerely,



Sebastian A. Cook, M.D.  
Radiation Safety Officer

# TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER  
Kathleen Cunningham B.S. (Nuclear Medicine Technology),  
C.N.M.T., A.R.R.T.(N)

2. FOR PHYSICIANS, STATE OR  
TERRITORY WHERE LICENSED

## 3. CERTIFICATION

SPECIALTY BOARD  
A

CATEGORY  
B

MONTH AND YEAR CERTIFIED  
C

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	June June 1983 - 84 University of Cincinnati	100 hours	200 hours
b. RADIATION PROTECTION	University of Cincinnati June 1983 - June 1984	40 hours	50 hours
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Cincinnati June 1983 - June 1984	30 hours	20 hours
d. RADIATION BIOLOGY	University of Cincinnati Winter 84 quarter	30 hours	----
e. RADIOPHARMACEUTICAL CHEMISTRY	University of Cincinnati June 1983 - June 1984	60 hours	175 hours

## 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Tc 99M	2,000 mCi	University Hospitals of Cleveland	11,200	Clinical
Ga67	6.5 mCi	University Hosp of Cleve/Lakewood Hospital	250	Clinical
Tl 201	20 mCi	University Hosp of Cleve/Lakewood Hospital	3,300	Clinical
I131	250 mCi	University Hospitals of Cleveland	125	Clinical
I 123	.400 mCi	University Hosp of Cleve/Lakewood Hospital	400	Clinical
Co57	.00065 mCi	University Hosp of Cleve/Lakewood Hospital	75	Clinical
IN 111	2.5 mCi	University Hosp of Cleve/Lakewood Hospital	200	Clinical
Xenon	40 mCi	University Hospitals of Cleveland	1500	Clinical



CARDIAC SUITE CLOSEOUT SURVEY

Completed on 12/19/94 by Chuck Giomuso, Medical Physicist and Kathy Cunningham, Nuclear Medicine Supervisor.

GM - E - 520

Serial Number 2551

Background	=	.02 MR/hr
Sink	=	.02 MR/hr
Floor Location 1	=	.02 MR/hr
Floor Location 2	=	.02 MR/hr
Floor Location 3	=	.02 MR/hr
Floor Location 4	=	.02 MR/hr

Wipes - Performed in well counter on Atomlab 930  
Trigger 2,000 dpm  
Wipes 80 dpm

No removable contamination found, room releasable to the public.

*Kathleen A. Cunningham*  
*Nuclear Medicine Supervisor*

WIPE REPORT: RESULTS

TIME: 11:0

[illegible]

MAR 31 1997

Mark E. Wiedt  
Administrative Director  
Department of Radiology, Lakewood Hospital  
14519 Detroit Avenue  
Lakewood, OH 44107-4383

Dear Mr. Wiedt:

Enclosed is Amendment No. 42 to your NRC Material License No. 34-01197-01 in accordance with your request.

Please note that this amendment, in part, authorizes you to release for unrestricted use, your cardiac stress facility for which you provided a diagram and closeout survey data.

Also, this letter confirms our discussion by telecon on February 28, 1997, of the need to notify us promptly and amend your license if your radiation safety officer terminates employment or will be gone for more than a relatively short term leave of absence.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
  - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

302329

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;
  - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

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

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



M. Wiedt

-3-

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By  
Loren J. Hueter  
Nuclear Materials Licensing Branch

License No. 34-01197-01  
Docket No. 030-02671

Enclosures:

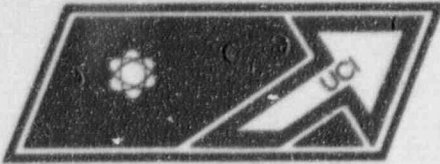
1. Amendment No. 42
2. NRC Form 313

DOCUMENT NAME: M:\03002671.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	LJHueter:brt	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DATE	03/24/97	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

OFFICIAL RECORD COPY



UNIVERSAL CONSULTANTS, INC.

CONSULTING PHYSICS GROUP

35888 Center Ridge Road, Suite #7

North Ridgeville, Ohio 44039

(216) 327-9432 Fax (216) 327-6280

March 21, 1997

U.S. Nuclear Regulatory Commission  
Region III  
Materials Licensing  
Attn: Mr. Loren Heutter  
801 Warrenville Road  
Lisle, Illinois 60532-4351

RE: Control #302329

Dear Mr. Heutter:

With respect to the above control number and Lakewood Hospital closeout survey results, recently submitted to you, I would like to supply you with additional information regarding this survey. On 12/19/94, I completed the closeout survey to include wipe testing of 5 locations. The diagram submitted to you has been amended to include the locations. Additionally, the last use of radioactive materials in this room was 12/94 and included Tl-201 and Technetium-99m. The approximate quantities were 3 mCi and 25 mCi respectively.

You had also indicated that you needed the location of the Cardiac Room in relation to the hospital. Note that it is located on the ground floor in the Cardiac Department. Should you require a blueprint of this exact location, please contact Mr. Mark Weidt at Lakewood Hospital.

I trust this information will allow you to complete your review of the paper work.

Sincerely,

*Charles Anthony Giomuso*  
Charles Anthony Giomuso  
Health Physicist

CAG:ker  
Enclosures

cc: Mr. Mark Weidt

RECEIVED

MAR 26 1997

PM: 3-21-97  
REGION III

# FACILITIES AND EQUIPMENT DIAGRAM LAKEWOOD HOSPITAL

Lead Castle

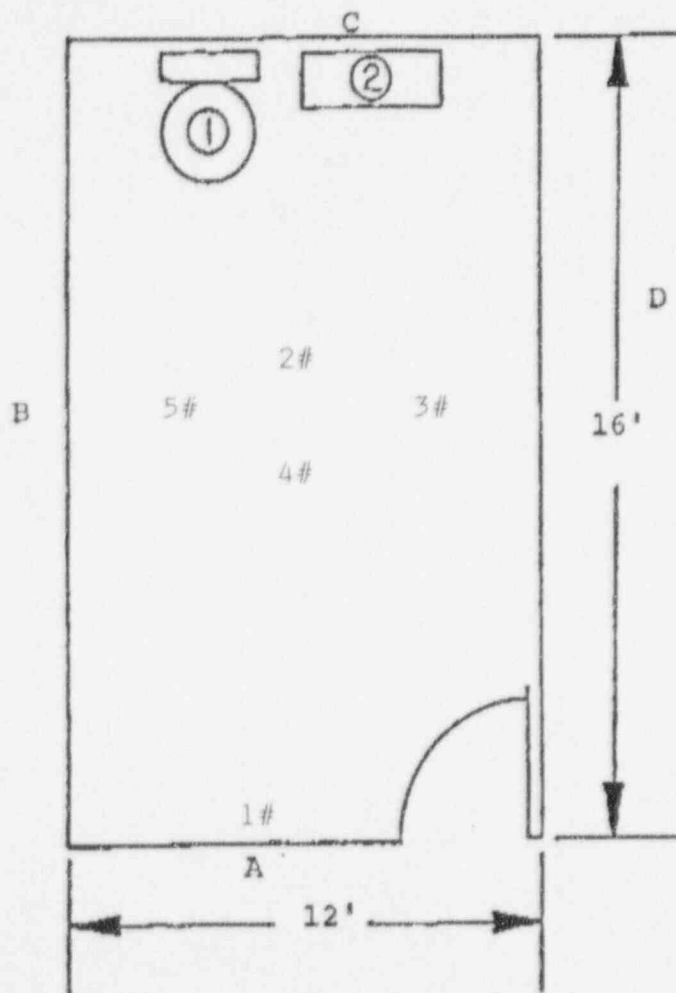
Lead Shielding

- \_\_\_\_ Survey Equipment
- \_\_\_\_ Uptake/Well
- 1   Camera
- \_\_\_\_ Lockable Door
- \_\_\_\_ Receipt Area
- \_\_\_\_ Generator
- \_\_\_\_ Kit/Dose Preparation
- \_\_\_\_ Isotope Storage
- \_\_\_\_ Waste Storage
- \_\_\_\_ Dose Calibrator
- \_\_\_\_ Fume Hood
- 2   Computer Console

## Adjacent Areas

- A   Hallway
- B   Treadmill Room
- C   Office
- D   Hallway

____	L x ____	W x ____	H x ____	T
____	L x ____	W x ____	H x ____	T
____	L x ____	W x ____	H x ____	T
____	L x ____	W x ____	H x ____	T



	Area	Wipe Results
#1	Sink	80 dpms
#2	Floor Location #1	80 dpms
#3	Floor Location #2	80 dpms
#4	Floor Location #3	80 dpms
#5	Floor Location #4	80 dpms

N  
↑

Room Cardiac Imaging  
Scale: Not to Scale

Item #9  
Page 9-172  
Prepared: 4/12/93  
Lic#34-01197-01

## CONVERSATION RECORD

TIME

DATE

2-28-97

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Mark Wiedt, Admin Dir.  
Dept. of Radiology

Oakwood Hospital

216-  
529-7200

SUBJECT

CN 302329

SUMMARY

1. Mark confirmed that Dr. Labaction Cook is to be deleted as RSO but remain on license as an auth. user.
2. We discussed our willingness to name an alternate RSO to fill in for RSO during short absences, and to be responsible to and report to the RSO. But if RSO terminates or is to be absent for more than relatively short terms then they should amend license & name new RSO. He specifically asked about maternity leave for a couple months. I stated that should not require RSO change.
3. He agreed to FAX copy of additional info on instant survey of casino stress facility, i.e.
  - a. when material last used in facility?
  - b. Dotspe(s) & activity?
  - c. Diagram of facility keyed to wipe locations & results.Will have his assistant, Charles Diomicio, of Universal Consultants, FAX response for item 3 followed by hard copy.  
Will ref. CN 302329 and report in 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Loren Hunter

2-28-97

ACTION TAKEN

SIGNATURE

TITLE

DATE





UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

February 20, 1997

Kathleen Cunningham  
Radiation Safety Officer  
Lakewood Hospital  
14519 Detroit Avenue  
Lakewood, OH 44107

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter Dated 02/07/97)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License      ☒ Amendment      ☐ Renewal  
☐ Termination      ☐ Auth User (Amendment not required)  
☐ Other \_\_\_\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

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

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302329  
License No. 34-01197-01