

(07-2015)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 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. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE0B-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER</p> <p><input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>24-18678-01</u></p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>Lake Regional Health System 54 Hospital Drive Osage Beach, MO 65065</p>
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<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>Lake Regional Health System 54 Hospital Drive Osage Beach, MO 65065</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Michael E. Henze, CEO</p> <table border="1"> <tr> <td>BUSINESS TELEPHONE NUMBER</td> <td>BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td>573-348-8392</td> <td>573-216-0732</td> </tr> </table> <p>BUSINESS EMAIL ADDRESS</p> <p>mhenze@lakeregional.com</p>	BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER	573-348-8392	573-216-0732
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573-348-8392	573-216-0732				

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.

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>				
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p>				
<p>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)</p>	<p>11. WASTE MANAGEMENT.</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>AMOUNT ENCLOSED \$</td> </tr> <tr> <td></td> <td></td> </tr> </table>	FEE CATEGORY	AMOUNT ENCLOSED \$		
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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, 37, 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 62 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.

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p> <p>Michael E. Henze, CEO</p>	<p>SIGNATURE</p>	<p>DATE</p> <p>9/3/15</p>
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FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY			\$	DATE	

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

Items 5 and 6 Radioactive Material

<u>Byproduct Material</u>	<u>Chemical/Physical Form</u>	<u>Maximum Amount</u>
5a Material in 35.100	Any	As needed
5b Material in 35.200	Any	As needed

Purpose of Use

6a: Material in 35.100 will be for Medical Use in any uptake, dilution and excretion study permitted by 10 CFR 35.100.

6b: Material in 35.200 will be for Medical Use in any imaging and localization study permitted by 10 CFR 35.200.

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

7.1 Radiation Safety Officer:

Michael Joseph Vierra M.D.

Currently RSO and credentialed on NRC License 24-18678-01 (Lake Regional Health System).

Delegation of Authority as RSO for Lake Regional Health System is attached.

7.2 Authorized Users:

Michael Joseph Vierra, M.D. credentials on NRC License 24-18678-01.

John Dymond, M.D. credentials on NRC License 24-18678-01.

Zubair Khan, M.D. credentials on NRC License 24-18678-01.

Timothy McDermott, M.D. credentials on NRC License 24-18678-01.

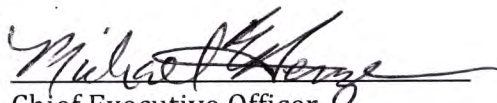


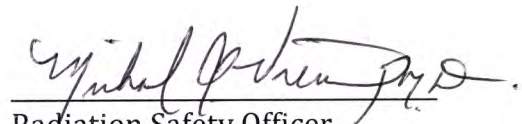
August 24, 2015

TO: Department Managers
FROM: Michael E. Henze, CEO
RE: Delegation of Authority

Dr. Michael Vierra is designated as the Rational Safety Officer (RSO), responsible for ensuring the safe use of radiation. The RSO is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective action; verifying implementation of corrective actions; and ensuring compliance with regulations. The RSO is hereby delegated the authority necessary to meet those responsibilities.

NRC Material License No. 24-18678-01
Docket No. 030-14028


Chief Executive Officer


Radiation Safety Officer

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

9.1 Facility Diagram and Equipment:

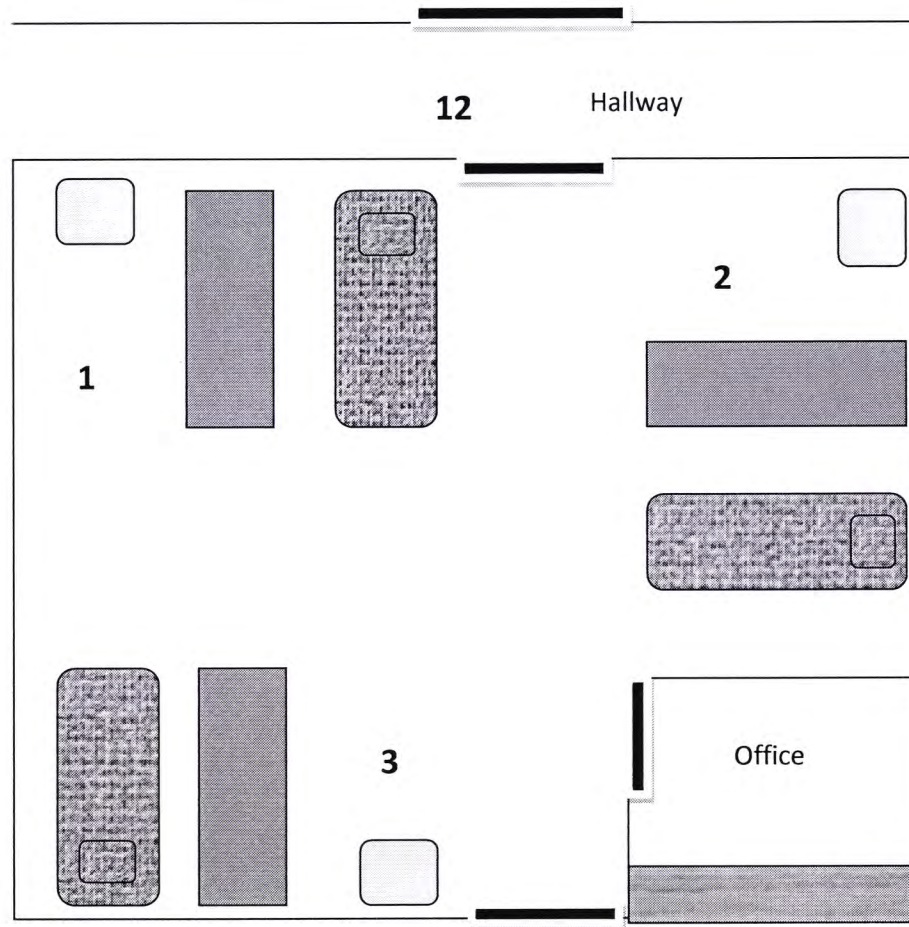
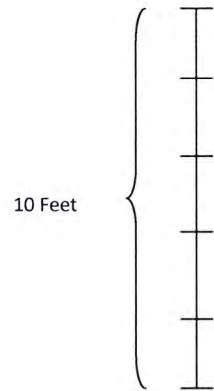
The attached annotated drawing of the department and adjacent areas indicate the scale, direction and principal use of each area. Medical isotopes are delivered as unit dose and are stored in individually shielded lead containers until time of use. There is additional 2 inch lead shielding around the area where these unit doses are stored before use.

Waste materials are held within a lead lined sharps container which are then transferred, when full, to a lead lined storage box for further decay. Both containers are located in department Hot Lab. Waste materials are held there until background levels of radiation are determined. After waste materials have reached background levels, they will be disposed into normal refuse.

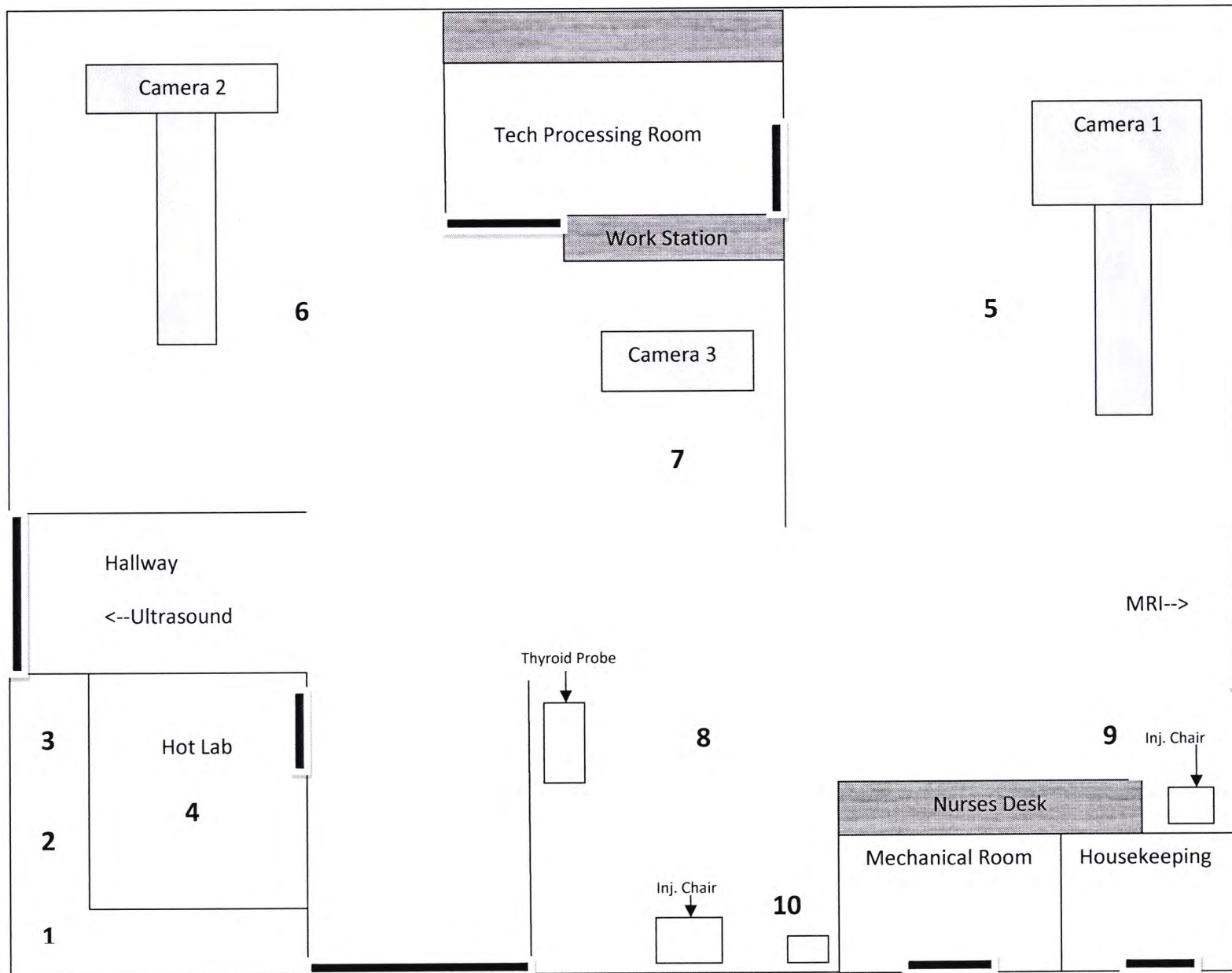
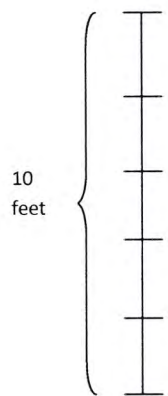
The hot lab is locked at all times with access only to nuclear technologists, nuclear medicine physicians, Diagnostic Imaging Department Head and Security. Security personnel patrol the area. Additionally, the Hospital House Supervisor has access to the area to allow delivery of any radioactive material during off duty hours.

- 1-Stress Treadmill
- 2-Stress Treadmill
- 3-Stress Treadmill

12-Hallway



- 1-Unit Dose Storage 3-Needle Box 5-Camera 1 7-Camera 3 9-Injection Chair 11-Pt. Prep. Recliner
- 2-L Shield 4-Hot Lab 6-Camera 2 8-Lab Space 10-Nurse IV Station 12-Outside Hallway



NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

9.2 Radiation Monitoring Instruments:

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and the meet the requirements of 10 CFR 36.61.

Current Instruments:

1. Ludlum Model 14C Geiger Counter, High Range Instrument with sensitivity scales of X 0.1 to X 1000.
2. Eberline Model E-530 Geiger Counter, Low Range Instrument with sensitivity scales of X 0.01 to X 10.
3. Capintec CAPRAC Wipe Test Counter, used for counting wipe tests.
4. Bicron Frisk-Tech Ratemeter for hot lab area monitoring.

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

9.3 Dose Calibrator and Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

A Capintec Radioisotope Calibrator CRC-15R is currently in use in the preparation and dosage measurement of isotopes for patient administration. In the event that the calibrator becomes in need of service or repair, another calibrator will be leased until the calibrator can be repaired or replaced. In an instance where there is a space of time where there is no suitable calibrator, such as the time duration between the calibrator malfunctioning and the receipt of a replacement calibrator, only unit dose administrations from a preparer licensed pursuant to 10 CFR 32.72 will be used.

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

10.0 Safety Procedures and Instructions

Attached are procedures required by 10 CFR 35.610

10.1 Occupational Dose:

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'

10.2 Area Surveys:

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

10.3 Safe Use of Unsealed Licensed Material:

We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

10.4 Spill/Contamination Procedures:

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

NRC FORM 313

LAKE REGIONAL HEALTH SYSTEM

8/2015

11.1 Waste Management:

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92.

FROM:

GROTEWIEL
LAKE REGIONAL HEALTH SYSTEM
54 HOSPITAL DRIVE
OSAGE BEACH, MO. 65065



X-RAY FILM
PLEASE DO NOT BEND

FIRST CLASS MAIL ENCLOSED

To: U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSING BRANCH

2443 WARRENVILLE ROAD SUITE 210

LISLE, IL. 60532-4352