UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

SEP 01 2009

John Larsen, B.S.
Radiation Safety Officer
Lee Memorial Hospital
420 West High Street
Dowagiac, MI 49047

Dear Mr. Larsen:

This refers to the undated facsimile letter received July 17, 2009, requesting revisions to your facility diagram. We are voiding your request at this time because your request was unsigned. We will void your request without prejudice to resubmission. Please submit the additional information as requested in the enclosed "Request for Additional Information".

When you resubmit your request please state that the resubmission is additional information to **Voided Control 318336.** We will resume our review upon receipt of your response. Please note, that a "voided request" is an administrative procedure that puts your amendment request "on hold" until you reactive it by a written response. The "voided request" is regarded as "good" because it gives you time to prepare a quality response.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Sincerely,

William P. Reichhold

William P. Reichhold
Materials Licensing Branch

License No. 21-32287-01
Docket No. 030-35603
Enclosure: Request for Additional Information

REQUEST FOR ADDITIONAL INFORMATION

Telephone (630) 829-9839
FAX (630) 515-1078

To: John Larsen, B.S., Radiation Safety Officer
Location: Lee Memorial Hospital
Date: September 1, 2009

We need the following additional information to complete our review of your request.

A request for an amendment to your NRC license must be signed by the licensee's management. The individual who signs the request should be identified by title of the office held. The management representative must be authorized to make binding commitments and to sign official documents on behalf of the licensee. Please see Item 13, in Section 8.31, "Certification" of NUREG-1556, Volume 9, Revision 2 (copy enclosed).
Please resubmit your request signed by a management representative who is authorized to make binding commitments and to sign official document on behalf of the licensee.

The Nuclear Regulatory Commission (NRC) issued Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses in NUREG-1556, Volume 9, Revision 2, in January 2008, to provide guidance for completing an application for the medical use licensees. NUREG-1556, Volume 9, Revision 2, outlines the necessary information needed for a facility diagram. Please see "Facility Diagram" in Item 9, Section 8.16, in NUREG-1556, Volume 9, Revision 2 (copy enclosed). Please make sure to include the following information on your revised facility diagram:

1. **Please put the address of the facility on the facility diagram.**

2. **Please specify the room number where radionuclides will be used or stored. If there are no room numbers, please state so.**

3. **If you will be using "PET" radionuclides please indicate the location of a "Quiet Room". If you will not be using "PET" radionuclides please state so.**

4. **Please indicate the principle use of each area adjacent to rooms or areas where radionuclides are used or stored. Please specify the room numbers for rooms that are adjacent to areas or rooms where radionuclides are used or stored. If there are no room numbers please state so.**

5. **Please specify what is above and below rooms or areas where radionuclides are used or stored.**

Please resubmit your request as additional information to Voided Control 318336. We will resume our review upon receipt of your response. Please note, that a "void" is an administrative procedure that puts your amendment request "on hold" until you reactive it by a written response. It costs you nothing, gives you time to prepare a quality response, and is regarded as a "good thing".

Please call me at 630-829-9839 if you have any questions.

From the desk of

Bill Reichhold

Bill Reichhold

8.30 ITEM 12: FEES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulation: 10 CFR 170.31.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

Note: There is no fee category associated with the authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs for noncommercial distribution to medical use consortium members.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

8.31 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. These representatives must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An application for licensing a medical facility must be signed by the applicant's or licensee's management. The individual who signs the application should be identified by title of the office held. As discussed previously in Section 3, "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the Radiation Protection Program. Management includes the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. The NRC will return all unsigned applications for proper signature.

Note: It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.51.
- Under 10 CFR 35.14, licensees must notify NRC within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

8.15 ITEM 9: FACILITIES AND EQUIPMENT

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.12(b)(1), 10 CFR 35.18(a).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in 10 CFR 30.33(a)(2), 35.12(b)(1), and 35.18(a). Applications will be approved if, among other things, "the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property." Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, types of radioactive emissions, quantity and form of radioactive materials possessed, production of PET radioactive drugs under 30.32(j) authorization). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Response from Applicant: Refer to Sections 8.16 through 8.20 for guidance.

8.16 ITEM 9: FACILITY DIAGRAM

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1901, 10 CFR 20.1902, 10 CFR 20.2102, 10 CFR 30.33(a)(2),

10 CFR 35.12, 10 CFR 35.14, 10 CFR 35.18(a)(3), 10 CFR 35.75, 10 CFR 35.315(a), 10 CFR 35.415, 10 CFR 35.615.

Criteria: In order to issue a license, the NRC must find that facilities and equipment must be adequate to protect health and minimize danger to life or property as required under 10 CFR 30.33(a) and/or 35.18(a).

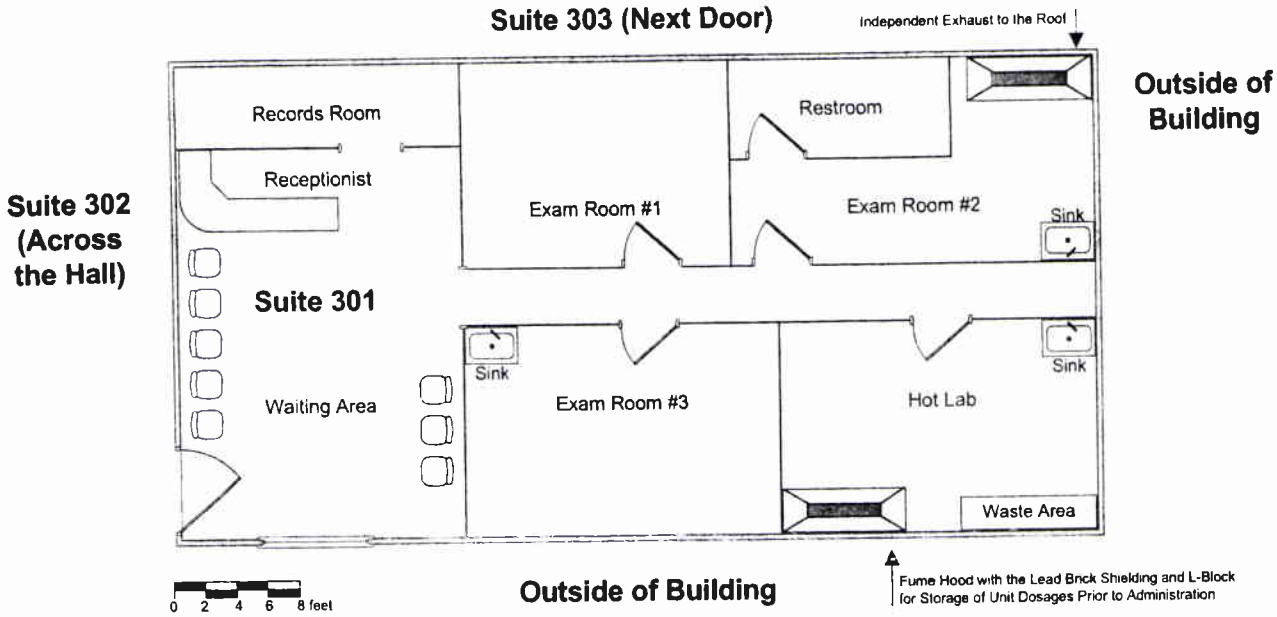
Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The facility diagram should include the room or rooms and adjacent areas where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 10 CFR 2.390." (See Section 5.2.)

If the applicant receives PET radionuclides from either an offsite or onsite PET radionuclide production facility by direct transfer tube to a PET radioactive drug production area, the facility diagram should include the direct transfer tube as well as a diagram of the PET radioactive production area.

For types of use permitted by 10 CFR 35.100 and 35.200, applicants should provide room numbers for areas in which byproduct materials are used or prepared for use (i.e., "hot labs"). (See Figure 8.1 for a sample attachment to 9.1.) If the applicant has a radionuclide delivery line from a PET radionuclide/radioactive drug production area in the 10 CFR 35.100 or 35.200 medical use area, a description of the room, location, and delivery line should be provided. A discussion of the shielding associated with the delivery line, including shielding calculations, should also be provided.

Attachment 9.1
SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



- Suite 301 is on the top floor.
- Suite 301 is located at a corner of the building.
- Suite 302 is occupied by an accounting firm.
- Suite 303 is occupied by a law firm.
- Directly below Suite 301 is an insurance company.

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10142002

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, the facility diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8.1 Facility Diagram for Nuclear Medicine Suite

Most applicants requesting the use of PET radioactive drugs will designate an area or room as a "quiet room" where patients wait after the PET radioactive drug is administered. This room should be included in the facility diagram. The location and design of the "quiet room" should be considered when implementing the ALARA requirements in 10 CFR 20.1101. The applicable public dose limits are discussed in Section 8.33 of this document.

When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. For types of use permitted by 10 CFR 35.300 and 35.400, applicants should provide the above information and, in addition, they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75. The discussion should include a description of shielding, if applicable. For types of use permitted by 10 CFR 35.500, the applicant should provide the room numbers of use.

For types of use permitted by 10 CFR 35.600, and production of PET radioactive drugs, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. Applicants should also describe the equipment used in the PET radioactive drug production area (e.g., hot cells, remote manipulation devices in the hot

cells, equipment and/or method used to physically transfer PET radionuclides during the chemical synthesis, "real-time" effluent (stack) monitoring equipment). When preparing applications for use under 10 CFR 35.1000, applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

All limited specific medical use licensees are required by 10 CFR 35.13 to obtain a license amendment before adding to or changing an area of use identified in the application or on the license. This includes additions and relocations of areas where PET radionuclides are produced or additions and locations of a radionuclide/radioactive drug delivery line from the PET radionuclide production area to a 10 CFR 35.100 or a 35.200 medical use area. However, other changes and additions to the 10 CFR 35.100 and 35.200 medical use areas do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes. The broad-scope medical use licensee does not have to notify NRC of changes that do not require a license amendment.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

The applicant should demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

  Note: If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by NRC. If applicants elect to use portable shielding, they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

- Requesting prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of 10 CFR 20.1301 will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in 10 CFR 20.1301(a). A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA (10 CFR 20.1101) must be developed (see 10 CFR 20.1301(d)).

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or

scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber (also called a beam catcher).

- "For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall."
- "For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall."

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

Response from Applicant: All medical use applicants, including broad-scope medical use applicants, are required to provide facility diagrams. The applicant should follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly. Provide the following on the facility diagrams:

- Drawings should be to scale, and the scale used should be indicated;
- Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored; location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility, or production area of PET radioactive drugs under 10 CFR 30.32(j), as provided above under the heading "Discussion"; and areas where higher energy gamma-emitting radionuclides (e.g., PET radionuclides) are used, including a "quiet room";
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and
- Shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe; shielding for PET radionuclide direct transfer tubes; PET radioactive drug production areas).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

References: National Council on Radiation Protection and Measurements (NCRP) Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV"; Report 102, "Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)"; and Report 40, "Protection Against Radiation from Brachytherapy Sources," may be helpful in responding to the items above. In addition, NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy," and NUREG/CR-6324, "Quality Assurance for Gamma Knives," may also be helpful in responding to the items above. However, it should be noted that references to 10 CFR Part 35 in the NUREGs may be outdated because the rule was amended after these documents were published.

8.17 ITEM 9: RADIATION MONITORING INSTRUMENTS

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101, 10 CFR 20.1501, 10 CFR 20.2102, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 35.27, 10 CFR 35.61, 10 CFR 35.2061.

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Discussion: The Radiation Protection Program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for survey instrument calibration (10 CFR 20.1501). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when byproduct material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters,
- Portable or stationary dose rate or exposure rate meters,
- Area Monitors,
- Single or multichannel analyzers,
- Liquid Scintillation Counters (LSC),
- Gamma counters,

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

Dr. Noe Directive

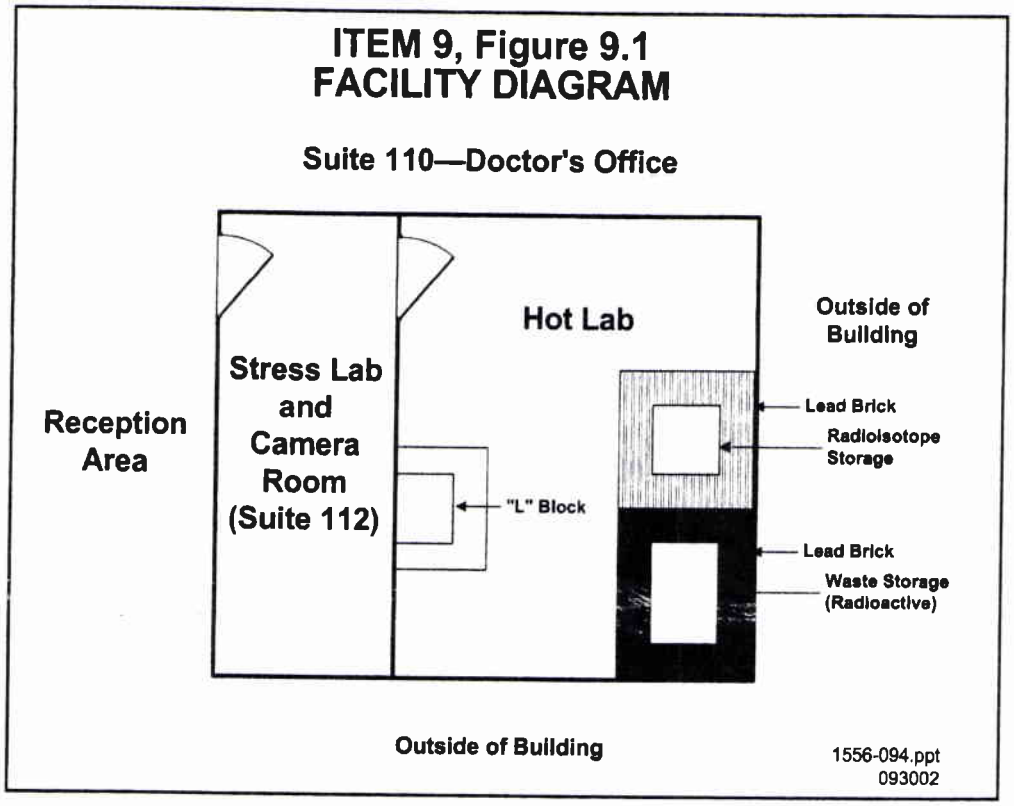

Figure E.1 Sample License Application: Facility Diagram

Notes:

1) *Radioactive material delivered to hot lab.*

2) *Counter surfaces are stainless steel and floors are seamless vinyl to facilitate cleanup and minimize permanent contamination.*

3) *Unoccupied basement located underneath facility and Suite 212 (a doctor's office) located above facility.*

4) *Description of Instrumentation:*

   Ludlum Model 14C GM Survey meter
   Ludlum Model 3 GM Survey meter
   Capintec Caprac - R600 well/wipe test counter

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, the facility diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.