

TRANSMISSION VERIFICATION REPORT

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

**TELEFAX TRANSMITTAL**

DATE February 29, 2008

NUMBER OF PAGES 8

SEND TO James Stokes, M.D., Radiation Safety Officer

LOCATION Mercy Cardiology Clinic, Inc. NRC License 24-32420-01

FAX NUMBER (314) 251-5802

VERIFY BY CALLING

FROM: Bill Reichhold  
(Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.



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**NOTICE**


This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank You.

The following additional information is needed to review your request.

1. Please resubmit a larger sketch of the facility diagram. I am unable to see any of the details on the facility diagram. Please see sample diagrams in the accompanying documents.
2. Please put the complete address of the facility on the facility diagram. We have numerous facility diagrams in our files and it would be helpful to be able to identify the facility with the address on the diagram.
3. Please describe what is above and below the rooms or areas where radionuclides are used or stored. Please see accompanying information.

Please send a facsimile (630- 515-1078) of your response to the above within 7 days and refer to control 316784 . Please call me at 630-829-9839 if you have any questions.

From the desk of:

  
Bill Reichhold

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**

**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.

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

**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.

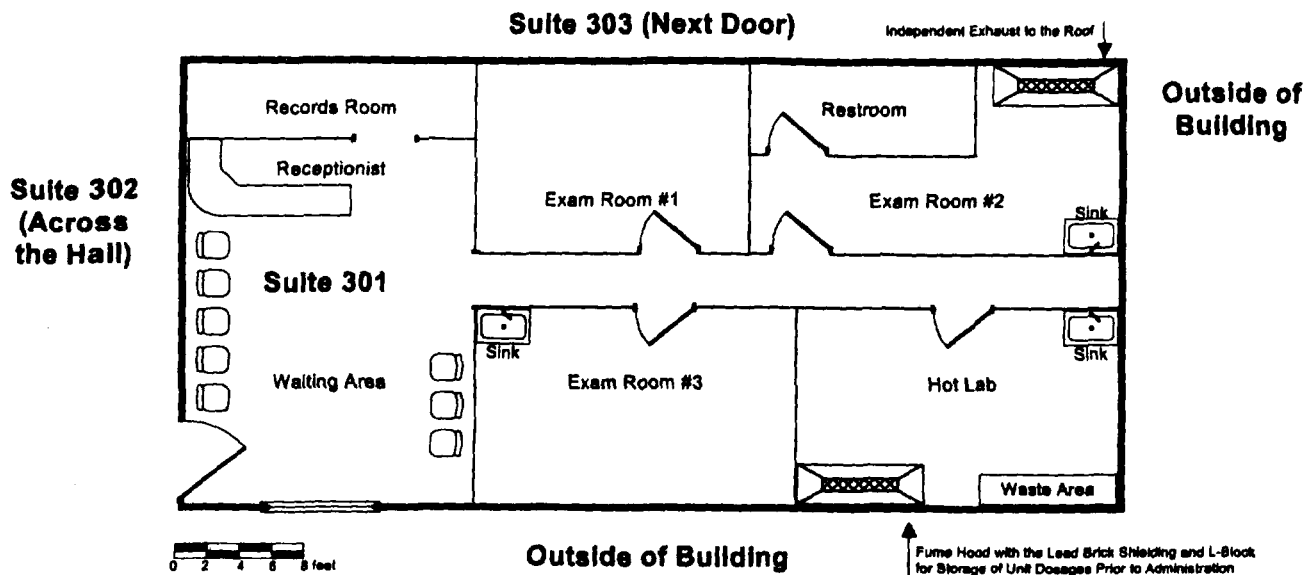
Drawings and diagrams that provide exact location of materials or depict specific locations of safety or security equipment should be marked as, "security-related information - withhold under 10 CFR 2.390." See Section 5.2.

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, this should be included in the facility diagram 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 should also be provided, including shielding calculations.

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.

1556-095.ppt  
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**

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 35.100 or 35.200 medical use area. However, other changes and additions to the 35.100 and 35.200 medical use area 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.
- 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 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.

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

## CONTENTS OF AN APPLICATION

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 sensitive security-related 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 identify areas where higher energy gamma-emitting radionuclides (e.g., PET radionuclides) are used;
- 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; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including 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**

**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 30.33(a)(2), 10 CFR 35.27, 10 CFR 35.61, 10 CFR 35.2061.

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

**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.

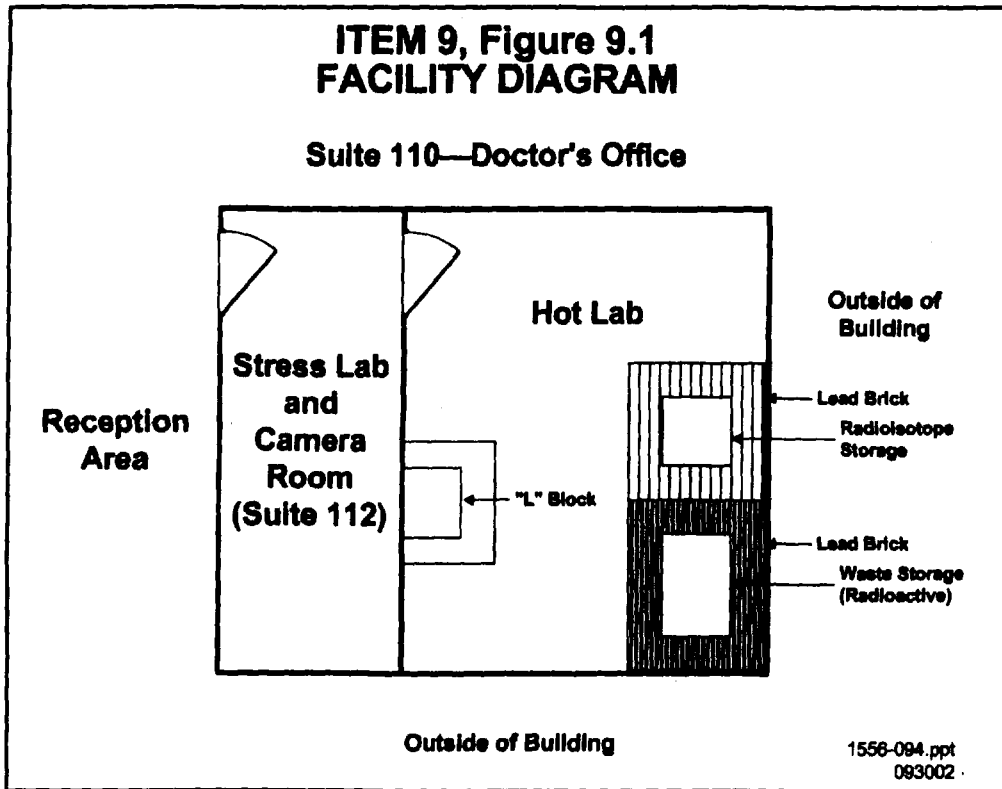
For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- 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;
- Proportional counters;
- Solid state detectors; and
- Hand and foot contamination monitors.



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.