

TRANSMISSION VERIFICATION REPORT

TIME : 10/26/2006 08:27
NAME : USNRC
FAX : 6308299782
TEL : 6308299782

DATE, TIME 10/26 08:24
FAX NO./NAME 82487990473
DURATION 00:02:51
PAGE(S) 08
RESULT OK
MODE STANDARD



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

TELEFAX TRANSMITTAL

DATE: October 26, 2006 NUMBER OF PAGES: 8
(Including this page)

SEND TO: Anthony Bennett, M.D. - Radiation Safety Officer

LOCATION: Advanced Virtual Radiology

FAX NUMBER: (248) 799-0473

☒ **VERIFY BY CALLING**

SENDER

FROM:
(SENDER) **Bill Reichhold**

TELEPHONE NUMBER (630) 829-9839 FAX NUMBER (630) 515-1259
or
(630) 829-9782

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



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

TELEFAX TRANSMITTAL

DATE: October 26, 2006 NUMBER OF PAGES: 8
(Including this page)

SEND TO: Anthony Bennett, M.D. - Radiation Safety Officer

LOCATION: Advanced Virtual Radiology

FAX NUMBER: (248) 799-0473 ☒ **VERIFY BY CALLING**
SENDER

FROM:
(SENDER) **Bill Reichhold**

TELEPHONE NUMBER **(630) 829-9839** FAX NUMBER **(630) 515-1259**
or
(630) 829-9782

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

MESSAGE

Please see accompanying documents.

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 have 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 complete the review of your request.

- 1. Our records show that your application dated March 30, 2006, specified your location of use as 13225 Northline Street, Southgate, Michigan. However, License Condition 10 does not list your current location of use. Please specify the address of your current location of use.**
- 2. Please specify the address of the new facility.**
- 3. Please provide the following information describing the new facility:**
 - a. Please provide a diagram of the new facility (see accompanying sample sketches).**
 - b. Please specify the scale (for example, 1 inch = 1 foot) of the sketch of the new facility, OR specify the room dimensions.**
 - c. Please indicate the location, room numbers and principle use of each room or area where byproduct material is prepared, used or stored.**
 - d. Please indicate the location, room numbers and principal use of each adjacent room (for example, hallway, office, file room, toilet, etc.) including the areas above and below areas where radionuclides are prepared, used or stored.**
- 4. We cannot add the new facility to your license until we have received and reviewed the “close-out” survey from Complete Health Systems, Inc. We need to verify that all radiation levels and radioactive contamination are within the regulatory limits before we can add this new facility to your license as a location of use.**
- 5. We need the following information regarding the Radiation Safety Officer's (RSO) availability to oversee two locations of use:**
 - a. We are concerned that Dr. Bennett may not have sufficient time and the availability to oversee the radiation safety programs at both facilities if we add a new location of use. Please describe how Dr. Bennett will ensure that his oversight of the new location of use will not degrade the radiation safety program at your current facility.**
 - b. Please specify the amount of time it will take Dr. Bennett to respond to an emergency involving radioactive materials when he is not present at the new facility. Describe the mechanisms for alerting the RSO and responding to unsafe practices and urgent situations that may occur at the new facility and your current facility.**

- c. Please describe any previous commitments Dr. Bennett has as the RSO and/or authorized user at any other NRC licensed facility.
 - d. Please describe how Dr. Bennett will divide his time between both facilities so that he will be able to adequately perform his duties as the Radiation Safety Officer
6. Currently, we have your license program listed as a "medical institution". Please clarify if your program is a "medical institution" (defined as, an *organization in which more than one medical discipline is practiced*, 10 CFR 35.2) or a "medical private practice".

Please send a facsimile of your response to the above within 7 days and refer to control **315642**. Please call me at 630-829-9839 if you have any questions.

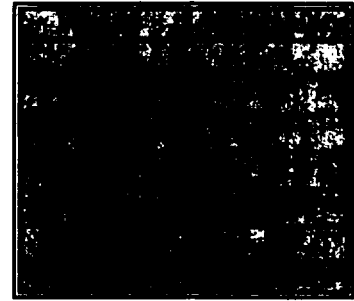
From the desk of:

Bill Reichhold

Bill Reichhold

8.15 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.



Criteria: In order to issue a license, the Commission 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 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.

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"). 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, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. 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.

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, except for areas of use where byproduct material is used only in accordance with 10 CFR 35.100 or 10 CFR 35.200.

Licensees are required by 10 CFR 35.14 to notify NRC within 30 days following changes in areas of use for 10 CFR 35.100 and 10 CFR 35.200 byproduct material.

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.

Attachment 9.1

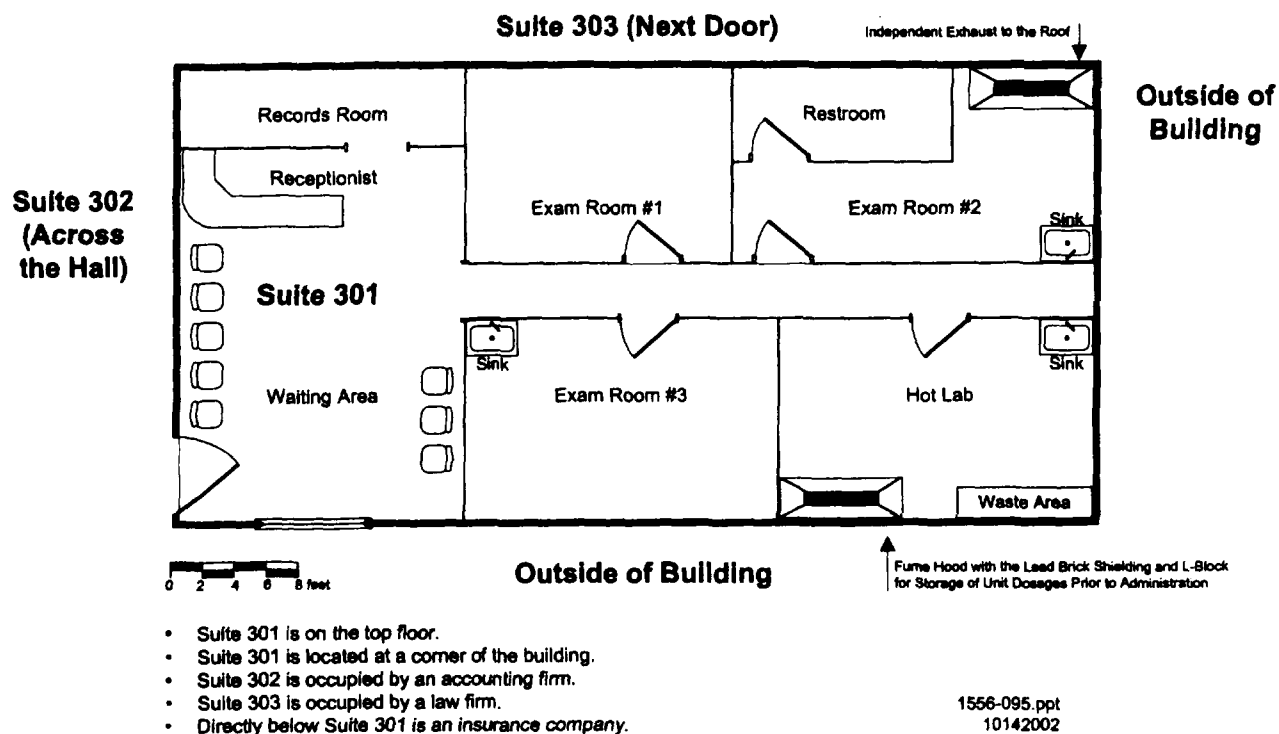


Figure 8.1 Facility Diagram for Nuclear Medicine Suite

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.

CONTENTS OF AN APPLICATION

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: Provide the following on the facility diagrams:

- ➔ Drawings should be to scale, and indicate the scale used.
- ➔ Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion"
- ➔ 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, etc.).

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.

Dr. Noe Directive

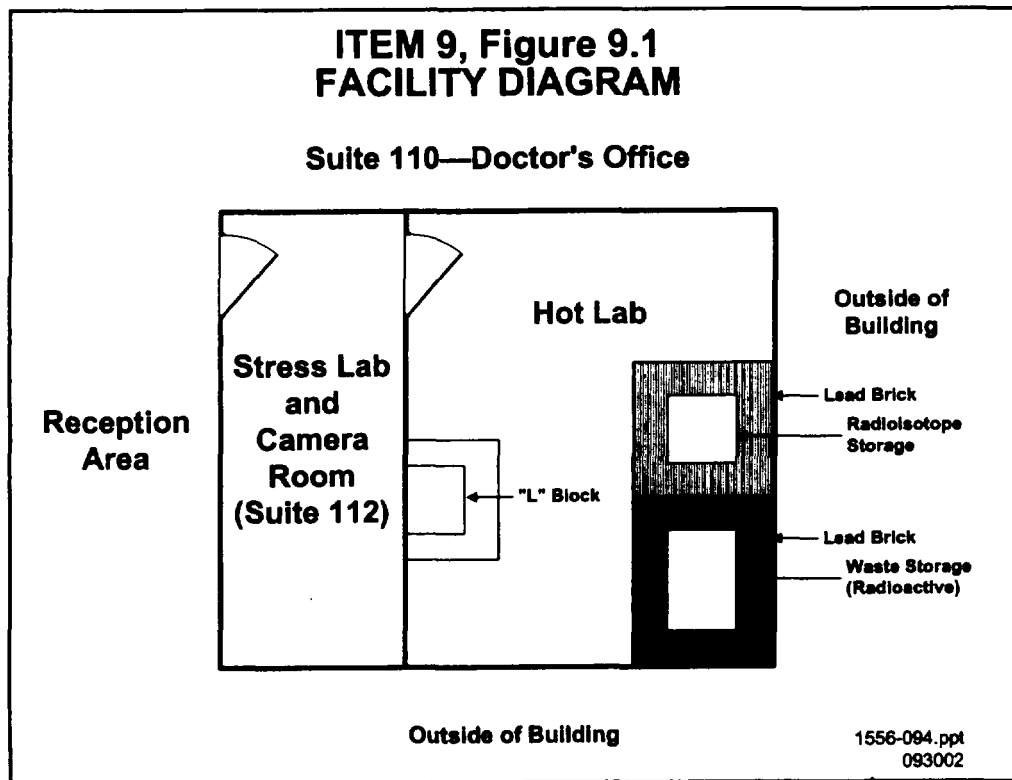


Figure E.1 Sample License Application: Facility Diagram

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.