#### TRANSMISSION VERIFICATION REPORT

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

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## 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: _(Including this page)	8
SEND TO	: Anthony Bennett, M.D.	- Radiation Safety Officer	
LOCATIO	N: Advanced Virtual Ra	diology	
FAX NUM	IBER: (248) 799-0473	VERIFY BY CALLIN	/G
FROM: (SENDER) B	ill Reichhold		
TELEPHO	NE NUMBER (630) 829-98	•	or
lf you do no	at receive the complete fax tra	(630) ansmittal, please contact the s	<b>829-9782</b> 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:	Octo	ber 26, 2006		BER OF PAGES: ing this page)	8
SEND TO:	Ant	hony Bennett, M.D.	- Radi	ation Safety Officer	
LOCATION	N: <u>A</u>	dvanced Virtual Rac	diology	<u> </u>	<u> </u>
FAX NUM	BER:	(248) 799-0473		☑ VERIFY BY CALLING	G
FROM: (SENDER) Bi	II Reid	chhold			
TELEPHON	NE NU	MBER <b>(630) 829-98</b>	<b>839</b> F	FAX NUMBER (630) 5	
		e the complete fax tra t the telephone numbe		al, please contact the se	29-9782 ender as
MESSAGE					
Please see	accor	npanying documents	S.		

### 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.

- 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

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#### U.S. NUCLEAR REGULATORY COMMISSION

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#### Licwater

#### **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

Licensee			
. Advanced Virtual Radiology	3.	3. License number 21-32618-01	
. 441 Franklin Wright Blvd.	4.	4. Expiration date May 31, 2016	
Lake Orion, MI 48362	5.	5. Docket No. 030-37194 Reference No.	
Byproduct, source, and/or special nuclear material	7. Chemical and/or p	hysical form 8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed	
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed	

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.

# CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at
- 11. The Radiation Safety Officer for this license is Anthony Bennett, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for medical use as indicated:

## 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.

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## Attachment 9.1 Suite 303 (Next Door) **Outside of** Records Room Restroom Building Receptionist Suite 302 Exam Room #1 Exam Room #2 (Across the Hall) Suite 301 Waiting Area Exam Room #3 Hot Lab Waste Ares e Hood with the Lead Brick Shielding and L-Block lorage of Unit Dosages Prior to Administration **Outside of Building**

Figure 8.1 Facility Diagram for Nuclear Medicine Suite

Suite 301 is on the top floor.

Suite 301 is located at a comer 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.

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 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

# ITEM 9, Figure 9.1 FACILITY DIAGRAM Suite 110-Doctor's Office **Outside** of **Hot Lab** Building Stress Lab aad Brick and Reception Radioisotope Camera Storage Area Room " Block (Suite 112) Waste Storage (Radioactive) **Outside of Building** 1556-094.ppt 093002

## **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.