Memo

FROM THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION 3
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

FAX (630) 515-1259
or
(630) 829-9782

To: Anthony Bennett, M.D.
Location: Advanced Virtual Radiology
Date: March 19, 2007
Subject: Additional Information Needed for Amendment Request

The following additional information is needed to complete the review of your request.

1. Please sign your amendment request. We will not complete your amendment request without a signed amendment request. Please see accompanying documents from page 8-56, 8.30, Item 13, "Certification" from NUREG-1556, Volume 9, Revision 1.

2. **We do not** have drawings and supporting documents for the new location at G-1128 S. Linden Road, Suite 11, Flint, Michigan. This was the **mailing address** for Complete Health Systems **NOT** the location of use. No facility drawings of G-1128 S. Linden Road, Suite 11, Flint, Michigan, were submitted to the NRC. If you wish to add a new location of use at G-1128 S. Linden Road, Suite 11, Flint, Michigan, please provide the following information:

   a. Please provide a diagram of the new facility.

   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.

Please see accompanying documents.

3. **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.

4. 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.

5. Your letter dated November 8, 2006, did not adequately respond to all of the information we requested in our Memo dated November 8, 2006. 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 submit your request as additional information to **Voided Control 315954.** 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

Advanced Virtual Radiography
441 Franklin Wright Blvd.
Lake Orion, MI 48362
November 8, 2006

A
030-37194
21-32618-01

Mr. Bill Reichhold
US Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

Dear Mr. Reichhold,

I am writing in response to your fax of 10/26/06. The reference control #315642.

The address of the new location is:

Complete Health
G-1128 S. Linden Road, Ste 11
Flint, MI 48532

It is currently operating under its own license #21-32543-01. All drawings and supporting documents should be available under its application.

My time will be split between the two sites but I will readily available to each site by phone when not at that particular site. I will be reachable in the time it takes to make a phone call. As Complete Health is not a new nuclear cardiology site, the technologists working at the new site have been working at that site for some time and are very familiar with all operating and emergency procedures. I will regularly review procedures and be in close contact with the staff at both facilities.

I hope this information provides what you need to act on our amendment application. I apologize for not getting this information to you in the 7 days you requested. Time was required to perform the close-out survey of the Complete Health license.

If you have any further questions, feel free to contact our medical physicist, Vincent McCormick, M.S. at 734-395-9323.

Thank you for your action on our request,

← Missing Signature

Anthony Bennett, M.D.

ML070170112

315954

17 JAN 2007

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 below.

Licensee	
1. Advanced Virtual Radiology	3. License number 21-32618-01
2. 441 Franklin Wright Blvd. Lake Orion, MI 48362	4. Expiration date May 31, 2016
	5. Docket No. 030-37194 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical 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

9. Authorized use:

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

Missing address ↓

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:

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-32618-01

Docket or Reference Number
030-37194

Authorized Users	Material and Use
Anthony Bennett, M.D.	10 CFR 35.100 and 35.200

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated March 30, 2006; and

    B. Facsimile dated Mary 5, 2006.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

By _____
James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III

implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. NRC Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," provides additional information.

Response from Applicant: Provide the following statement:

"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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92."

8.29 ITEM 12: FEES

Regulations: 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.

8.30 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. 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).

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

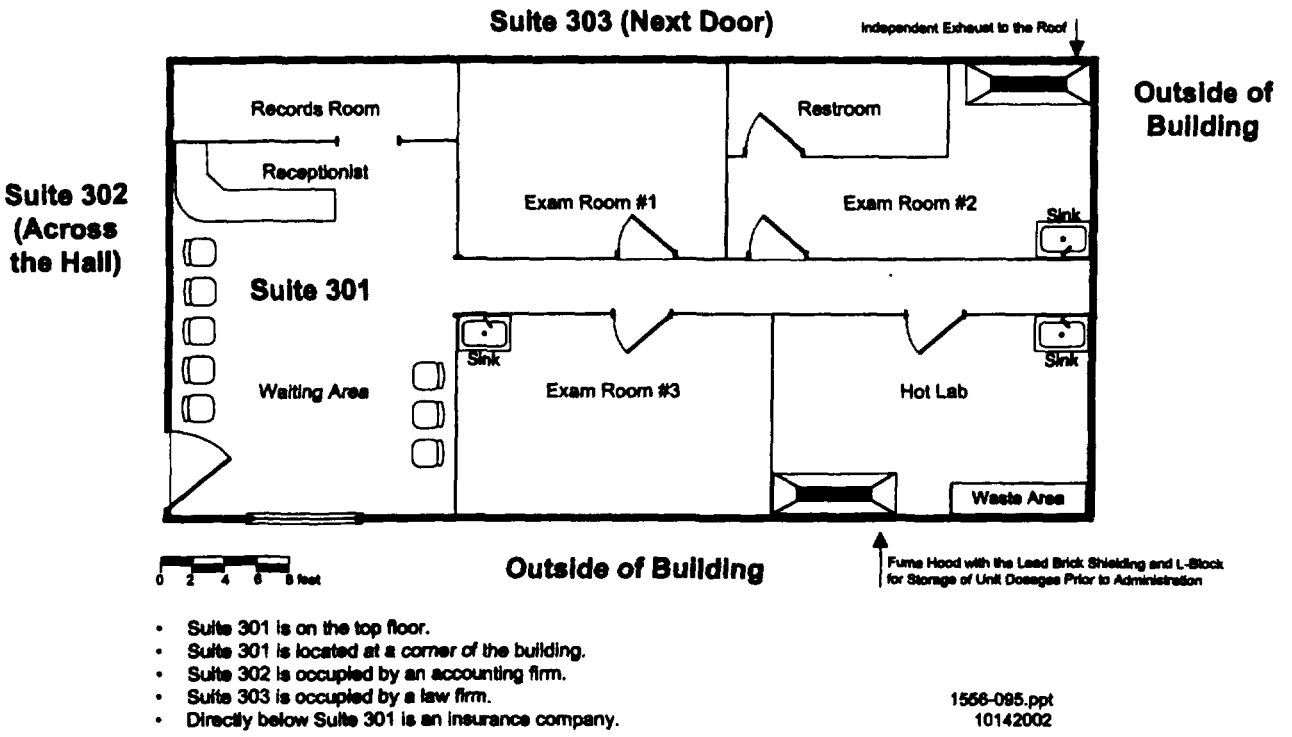

Figure 8.1 Facility Diagram for Nuclear Medicine Suite

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.

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

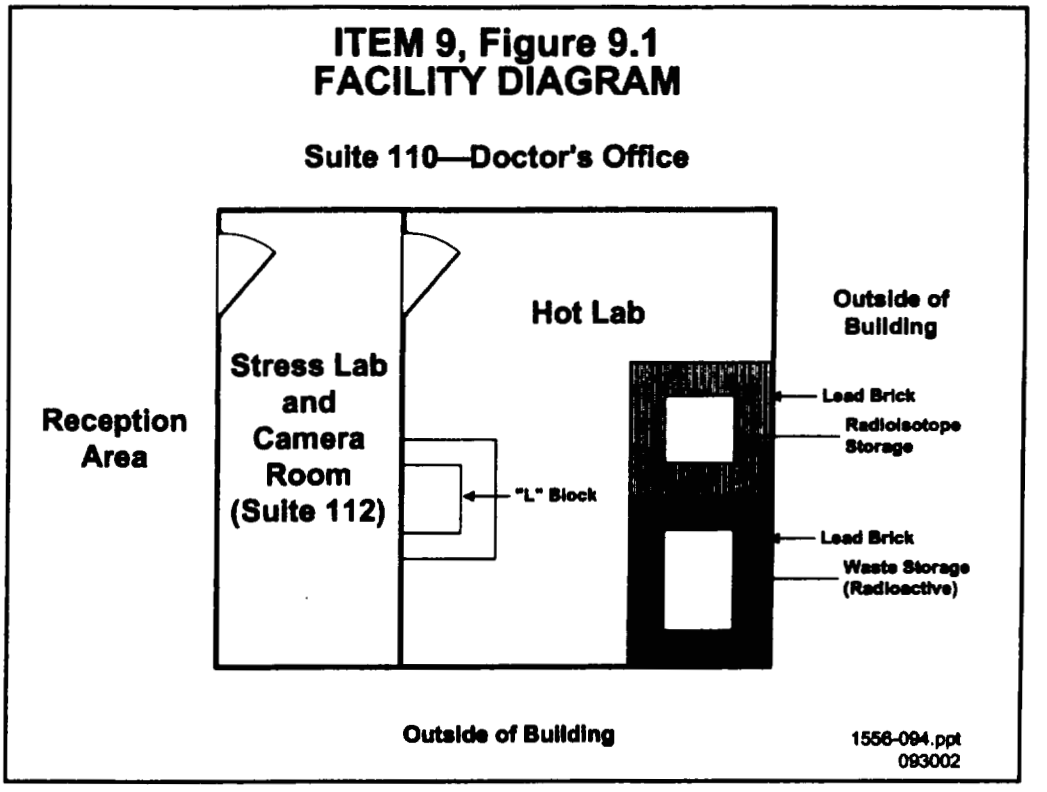

Figure E.1 Sample License Application: Facility Diagram

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.