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

OCT 0 1 2008

Rodney A. Dunseath, D.O.
Radiation Safety Officer
Arnett Clinic, LLC
2600 Greenbush Street
Lafayette, IN 47904

Dear Dr. Dunseath:

This refers to the letter dated July 29, 2008, requesting an amendment to change the name and address of use on your NRC license. We need to void your request at this time, because we need additional information regarding your request. The request appears to be signed by an entity (Michael Skehan, M.D., of Clarian Arnett Health Medical Group) other than a representative of Arnett Clinic, LLC (in the past April Sauer, has signed the amendment requests). Please resubmit your request signed by a representative of Arnett Clinic, LLC, that is authorized to make binding commitments and to sign official documents on behalf of Arnett Clinic, LLC. If Michael Skehan, M.D. is authorized to make binding commitments and to sign official documents on behalf of Arnett Clinic, LLC, please state so. Also, if the name change includes a change of control for Arnett Clinic, LLC, we will need additional information as describe in the enclosed memo. Also, there was no facility diagram for the new address of use accompanying the letter dated July 29, 2008. Please see the information needed for the new facility diagram in the enclosed memo. We will void your request without prejudice to resubmission. If you wish to purse these matters, please submit the additional information as requested in the enclosed memo.

When you resubmit your request please state that the resubmission is additional information to **Voided Control 317387.** 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. 13-32535-02
Docket No. 030-37189
Enclosure: Memo

Memo

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

FAX (630) 515-1078

To: Rodney A. Dunseath, D.O., Radiation Safety Officer
Location: Arnett Clinic, LLC
Date: September 29, 2008
Subject: Additional Information

We need the following additional information before we can complete the review of your amendment request.

The request dated July 29, 2008, appears to be signed by an entity (Michael Skehan, M.D., Clarian Arnett Health Medical Group) other than Arnett Clinic, LLC (in the past April Sauer has signed the amendment requests for Arnett Clinic, LLC). Please resubmit the amendment request signed by a representative of Arnett Clinic, LLC, that is authorized to make binding commitments and to sign official documents on behalf of Arnett Clinic, LLC. Please see Item 13, Certification, from NUREG-1556, Volume 9, Revision 2, copy enclosed. If Michael Skehan, M.D. is authorized to sign official documents for Arnett Clinic, LLC, please state so.

If Arnett Clinic, LLC has transferred control of their NRC license to Clarian Arnett Health Medical Group, please submit the information requested in Appendix G, "Information Needed for Transfer of Control", from NUREG-1556, Volume 9, Revision 2, copy enclosed. Also, please provide documentation that the transferor (Arnett Clinic, LLC) and transferee (Clarian Arnett Health Medical Group) agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee (Clarian Arnett Health Medical Group) is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

Please submit a diagram of the new facility at 5165 McCarty Lane, Lafayette, Indiana. Please see Item 9, "Facility Diagram" from NUREG-1556, Volume 9, Revision 2, (copy enclosed) and respond to the section "Response from Applicant". Please put the address of the new facility on the facility diagram.

If you will be performing close-out surveys of the "old" facilities, please include the following information for each facility:

The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contaminations should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

a. A history of all radionuclides used at your old facility.

b. A current copy of the leak test results for the sealed sources used at your old facility. Also a history of leaking sealed sources (if any).

c. A diagram of your old facility with survey and wipe test results keyed to specific locations. Please record your survey results using the appropriate units as described in 10 CFR 30.36 (j) (2) (i) (copy enclosed).

d. The name of the person performing the survey.

e. The date the survey was performed.

f. The instrument(s) used for exposure rate measurements and for analysis of the wipes.

g. Background readings.

h. The date that the survey instrument was last calibrated.

i. Confirm that all radioactive waste has been decayed to background radiation or has been transferred to a radioactive waste broker for disposal.

Please resubmit your response to the above as additional information to **Voided Control 317387**. 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.

8.31 ITEM 13: CERTIFICATION

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

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).

APPENDIX G

Information Needed for Transfer of Control

Information Needed for Transfer of Control

The following information is taken from NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses."

Definitions

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom NRC may contact if more information is needed.

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

3. Describe any changes in the organization, location, facilities, equipment, or procedures that relate to the licensed program.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

6. Confirm that the transferee will abide by all constraints, conditions, requirements, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

- 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.

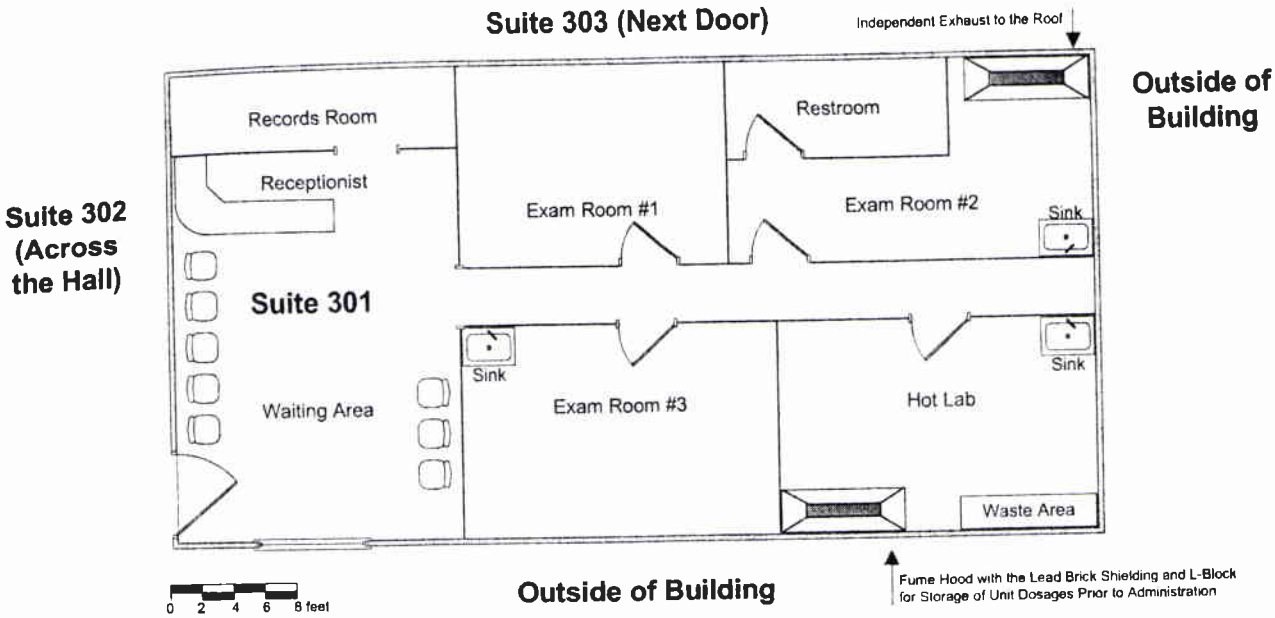
Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 10 CFR 2.390." (See Section 5.2.)

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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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.

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

Dr. Noe Directive

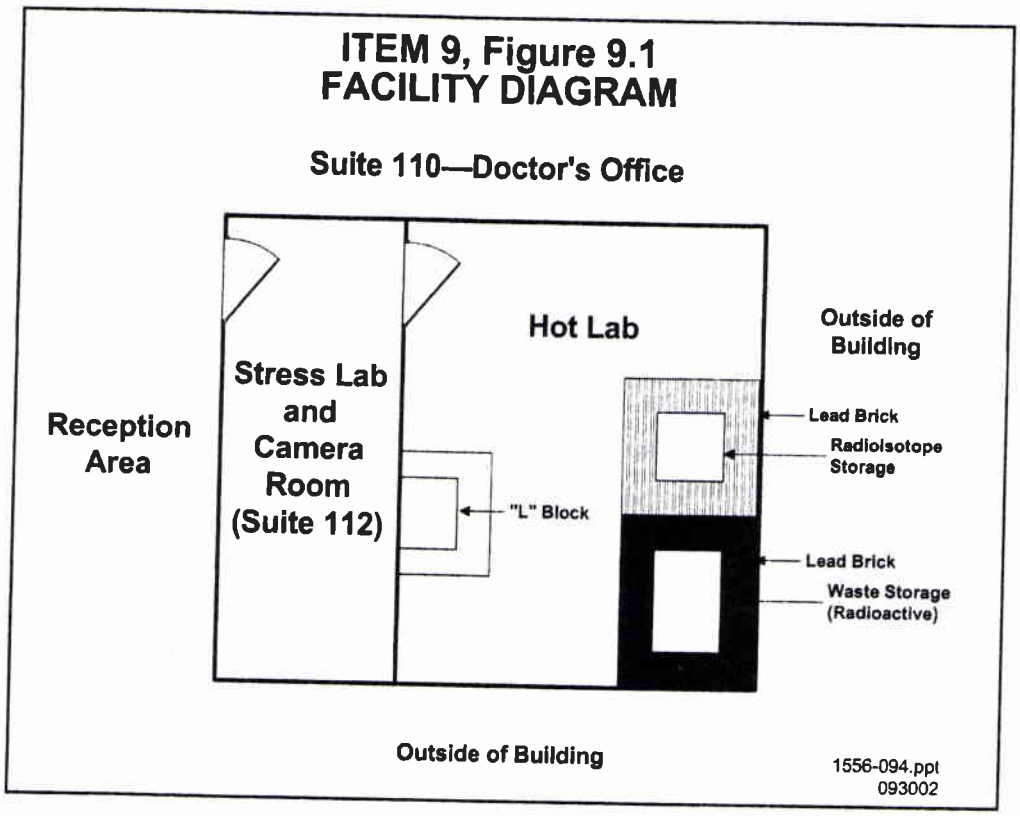

Figure E.1 Sample License Application: Facility Diagram

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.

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed--for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that: