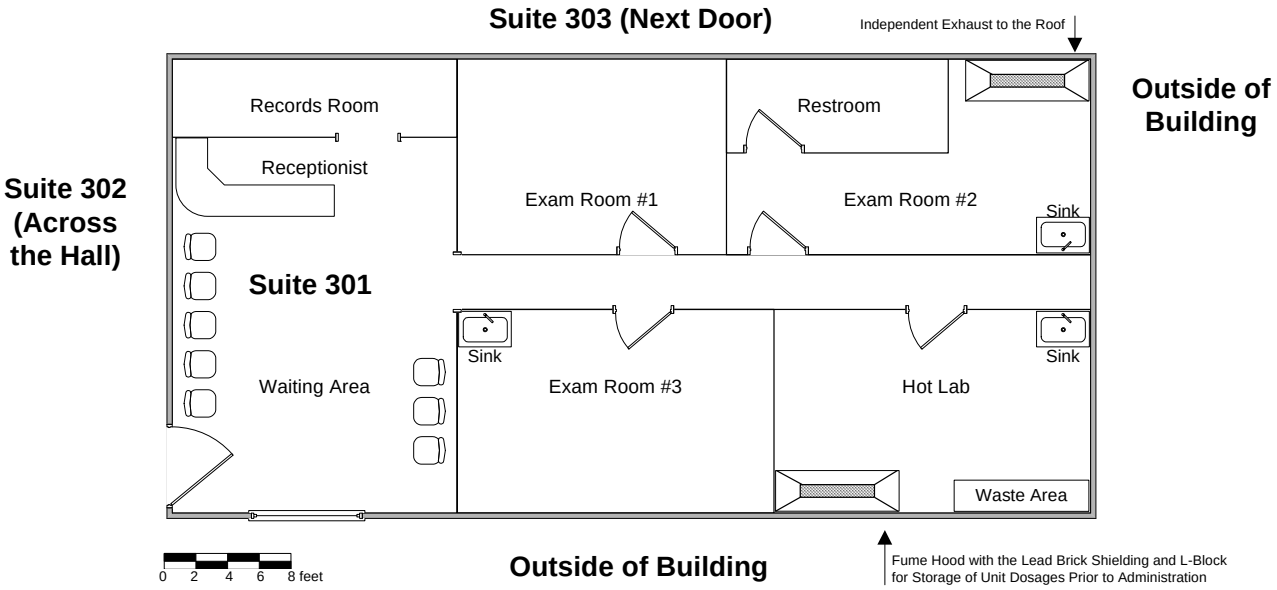
APPENDIX J

FACILITIES AND EQUIPMENT

Applicants must completely describe the proposed facilities and equipment as required by RH-8010. The facility diagram, as shown in Figure 16.1, should include the room or rooms and adjacent areas where radioactive 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.



- 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.

Figure 16.1 Facility Diagram for an Example Nuclear Medicine Suite

Special Requirements Related to the Type of Radioactive Material

Additionally, the following special requirements, which are dependent on the types of radioactive material and the specific use of the material, must be addressed in the facility description.

A. For **Uptake, Dilution, or Excretion Studies** permitted by RH-8500 and RH-8530, Applicants must provide room numbers for areas in which radioactive 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.

B. For use of **Unsealed Radioactive Material-Written Directive Required** permitted by RH-8550 and **Sealed Sources** permitted by RH-8600, Applicants must provide the above information and in addition, they must provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under RH-8420. The discussion must include a description of shielding, if applicable. Regulatory requirements, the ALARA principle, good medical care, and access control must be considered when determining the location of the therapy patient's room or a therapy treatment room.

   The applicant must describe additional facilities and equipment for the radiopharmaceutical therapy program to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood). Also note, there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium radioiodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

C. For use of **Sealed Source for Diagnosis** permitted by RH-8620, the applicant must provide the room numbers of use.

D. For use of **Photon Remote Afterloader Units, Teletherapy Units,or Gamma Stereotactic Radiosurgery Units** permitted by RH-8630, the Applicant must provide all of the information discussed above and the shielding calculations for the facility as described in the diagram.

   For **teletherapy**, **GSR**, and **HDR facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of RH-8634 is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

   Paragraph RH-8634 requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system)

will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. Paragraph RH-8634, in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of **PDR remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;

- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;

- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:

    - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;

    - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;

- The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;

- The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and

- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees shall prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant must describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

E. For **Other Medical Uses of Radioactive Material or Radiation** under RH-8670, Applicants must review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

The applicant must demonstrate that the limits specified in RH-1208 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 Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv) and demonstrating that the requirements of RH-1208 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 RH-1208. A program to assess and control dose within the 0.5 rem (5 mSv) annual limit and procedures to be followed to maintain the dose ALARA (RH-1004) must be developed (see RH-1208).

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they must describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by Department. If applicants elect to use portable shielding, they shall 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, along with a written description of the changes, must be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided.

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).

The following References are provided to assist the Applicants

- 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)",
  - Report 40, "Protection Against Radiation from Brachytherapy Sources,"
  - Report 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities".
- NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy",
- NUREG/CR-6324, "Quality Assurance for Gamma Knives".

Note: The NUREGs may be outdated because the revised Rules and Regulations for Control of Sources of Ionizing Radiation were amended after these documents were published.