OCT 24 1984

FCML:CFM
030-02658
(18127)

Veterans Administration Hospital
ATTN: Edward Silberstein, M.D.
Professor of Radiology and Medicine
32 Vine Street
Cincinnati, Ohio 45220

Gentlemen:

This is in reference to the telephone conversation on October 11, 1984 between myself and Mr. Kenneth Fritz, regarding your amendment request dated July 31, 1984. As discussed in our conversation on that date, the following additional information will need to be submitted to continue our review:

1. In regard to the move to your nuclear medicine department facilities, Rooms C213 and C204 respectively, please describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, and measurement of radioactive material.

   Submit a detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

   a. Use and storage of Tc-99m generators.

   b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, described how the material will be secured. Confirm that this area will be surveyed at least weekly.)

   d. Preparation and dispensing of Group III kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

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DATE ▶							

In regard to your use of xenon-133, submit a version of your facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where xenon-133 will be used or stored. This information is necessary in order to determine that the vents are properly located and that use and storage areas are under negative pressure. (See Figure M-1 of Appendix M, Regulatory Guide 10.8, for an example of the type of diagram to be submitted.)

2. In order to approve your request to conduct xenon-133 ventilation studies and cerebral blood flow studies in your new nuclear medicine department facility, the following must be submitted:

   a. Please provide calculations to show that the air concentration of xenon-133 in your restricted area, averaged over a year, does not exceed the required 1×10^{-5} microcuries per milliliter (see example in Item 5 of Appendix M).

   b. In regard to the use of a trapping system as your method of disposal, utilizing charcoal filters. Note that a difficulty with this approach is that charcoal is not 100 percent efficient for trapping xenon-133, therefore exhaust from your trapping system may be vented to the outdoors of other unrestricted areas. Describe how you will handle the problem of leakage from this trapping device by submitting calculations to show that air concentrations of xenon-133, averaged over 1 year, does not exceed 3×10^{-7} microcuries per milliliter (see example in Item 6.a. of Appendix M).

   c. Confirm that the frequency of periodic measurements that you will make to determine that airflow rates are maintained are performed at least semi-annually.

   d. In reference to the use of the NOVO system as a method to administer xenon-133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)

3. Submit your Notice Of Claimed Investigational Exemption for a New Drug (IND) Number, which has been accepted by the Food and Drug Administration (FDA), for the radiopharmaceutical xenon-133 in saline for cerebral, muscle, and skin flow studies.

4. In reference to the movement of your nuclear medicine department, I am enclosing the Nuclear Regulatory Commission's (NRC) guidelines for decontamination of facilities and equipment. A copy of your survey report must be filed with the Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, D. C. 20555, and also the Administrator of the NRC Regional Office (Region III). The survey report should:

   a. Identify the premises.
   b. Show that reasonable effort has been made to eliminate residual contamination.

c. Describe the scope of the survey and general procedures followed.
d. State the findings of the survey in units specified in the instructions.

We will continue review of your letter upon receipt of the requested information. Please reply in duplicate and reference Mail Control No. 18127.

Sincerely,

Cassandra F. McDonald
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:

1. Regulatory Guide 10.8
2. 10 CFR Part 20

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DATE	10/23/84	10/23/84					

Medical Center
3200 Vine Street
Cincinnati, OH 45220

Veterans Administration

August 30, 1984

In Reply Refer To: 539/115

Ms. Helen Malaskiewicz
Nuclear Medicine Service (115)
Department of Medicine and Surgery
Veterans Administration Central Office
Washington, D.C. 20420

SUBJ: NRC License Amendment

I hereby approve the enclosed corrections.

Donald L. Ziegenhorn

DONALD L. ZIEGENHORN
Medical Center Director

Encl.

'84 SEP 12 A9:00

for Helen Malaskiewicz

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

9/7/84

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