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MAY 7 1985

Kettering Medical Center
ATTN: Robert L. Willett
President
3535 Southern Blvd.
Kettering, OH 45429

Re: Application Dated December 3, 1984 For Renewal of NRC License Number 34-13857-01

Gentlemen:

In order to complete your renewal request, it will be necessary for you to submit the following additional information:

MATERIALS

a. Specify the model number of the gadolinium-153 sealed source manufactured by Gulf Nuclear and also specify how many sources you wish to possess (e.g. source not to exceed 1 curie, 2 sources not to exceed 500 millicuries each, etc.)

b. Clarify whether or not you wish to continue your authorization for the following materials:

1. Iodine-131 as iodomethylnorcholesterol manufactured by and received from the Nuclear Pharmacy of the University of Michigan for adrenal imaging used in accordance with Notice of Claimed Investigational Exemption For a New Drug (IND) Number 12, 825 (Amendment No. 31 of your license).

2. Iodine-125 to be used for iodinating polypeptide hormones in accordance with your letter dated September 22, 1982 (AmendmentNo. 32 to your license).

c. Please be advised that we have no records on file for a Manning Research Lab strontium-90 opthalmic eye applicator as an NRC approved/registered device. Therefore, if you wish to possess this device, it will be necessary for you to respond to the pertinent items of the enclosed "Custom Reviw Guide for the Registration of Devices Containing Radioactive Materials". After review and upon approval of your request, the device may then be approved for licensure and possession by your institution.

AUTHORIZED USERS

Submit a description of the criteria that the Medical Isotope Committee will follow in approving authorized users.

a. As a minimum, the criteria specified in Appendix A of Regulatory Guide 10.8, October 1980 is acceptable for physicians using radioactive material in humans.

b. For physicians and other individuals using radioactive material for non-human use the Committee, as a minimum, should require individuals using greater than license exempt quantities to meet the criteria specified in Section 33.15(b) of 10 CFR Part 33 (enclosed).

c. Specify the methods employed for maintaining records of the Committee proceedings and evaluation of proposed users.

INSTRUMENT CALIBRATION

a. In order to check the accuracy of your dose calibrator, it is necessary for you to use appropriate reference standards as well as activity levels (for the reference standards) normally encountered in clinical use. Therefore, you will need to identify the nuclide, activity, and calibration accuracy of the intermediate energy reference standard you will use (e.g. 0.1-0.5 millicuries of barium-133)

b. Also, we recommend the activity of you low energy reference standard (cobalt-57) fall between 3 and 5 millicuries. Based on information obtained during a recent NRC inspection, the activity of your cobalt-57 reference standard is less than 1 millicurie. Modify your procedures accordingly.

TRAINING

a. Radiation workers (technologists, etc.) must receive instruction as specified in 10 CFR 19.12 (enclosed). Note that many of these items pertain to circumstances at your particular institution; therefore, you may not assume that this instruction has been adequately covered by prior occupational training, Board certification, etc. Please outline and submit your program for providing the necessary instruction. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

b. Ancillary personnel (clerical, nursing, housekeeping, security, etc.) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. Outline your method to assure that these employees receive the necessary instructions. Confirm that this instruction will be given both initially and annually thereafter on a refresher basis.

c. Please clarify the nature of training provided for individuals who will be driving the vehicles utilized for transporting of your radioactive materials. Note that their training should include all items as specified in 10 CFR 19.12. It is of particular importance that these individuals be familiar with the methods employed for handling of radioactive spills, contamination, etc. Please confirm that this instruction will be provided both initially and annually thereafter on a refresher basis.

THERAPY (UNSEALED)

Thyroid uptake can occur by breathing volatile iodine which is released when the cap is first removed from vials containing therapeutic liquid iodine-131. Personnel should be instructed to wear gloves and to open the vials in a fume hood or to take alternative precautionary measures.

A bioassay program should be established for personnel who handle therapeutic liquid iodine-131. As a minimum, thyroid counts should be obtained approximately twenty-four (24) hours after exposure. Refer to the enclosed bioassay guide.

Submit the precautionary measures and the bioassay procedures that you will follow.

THERAPY (SEALED)

a. Please clarify whether or not you wish to continue your authorization to discharge patients containing gold-198 seeds in accordance with the procedures contained in your letter dated January 17, 1984.

b. Describe your method for maintaining source accountability at all times. This should include a description of your sign-in and sign-out procedures, periodic inventory, and your method for determining that all sources are accounted for and returned to storage following treatment.

c. Describe surveys to be performed during the course of treatment and at the conclusion of treatment. You dismissal survey should be adequate to determine that all sources have been removed form the patient and from all areas that the patient occupied. Be advised that your survey program for brachytherapy patients should include adjacent areas to ensure compliance with Part 20 regulations.

PERSONNEL MONITORING

If you wish to use pocket dosimeters to monitor personnel you will need to submit the following:

a. The range of scale readings for the Dosimeter Corporation of America dosimeters you plan to use.

b. Describe your procedures for calibrating the dosimeters and also the frequency of calibration.

c. Describe your method of relating the dosimeter readings to the extremity dose received by an individual.

TRANSFER OF MATERIALS

Regarding your use of materials at Sycamore Medical Center in Miamiburg, Ohio, please proveide the following:

a. Confirmation that a physician shall be on-site at the time that radiopharmaceuticals are administered.

b. Confirmation that all doses will be assayed prior to transport, if you will not have a dose calibrator at the hospital you inten to service.

c. Confirmation that all diagnostic instrumentation transported by van shall be calibrated at Sycamore Medical Center prior to conducting nuclear medicine procedures.

d. Confirmation that a contamination survey will be performed and that all sources of licensed material and all detectable contamination will be removed after each use.

e. Confirmation that radioactive material will not be stored in the transport vehicle overnight, and that after each day's use, it will be monitored for contamination.

f. Confirmation that all radioactive materials tranposted will be received at Kettering Medical Center under the terms and conditions of your NRC License.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 77941.

Sincerely,

Original Signed By
Patricia J. Whiston
Materials Licensing Section

Enclosure: "Application for Health and Safety Review and Registration of Devices Containing Radioactive Material"

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Whiston/cm
05/02/85