

JUN 19 1985

Veterans Administration Medical Center
ATTN: J. L. Warnock, Medical Center Director
1500 E. Woodrow Wilson Blvd.
Jackson, MS 39216

Gentlemen:

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING A MATERIAL LICENSE
APPLICATION (REFERENCE: 18578; 030-02261)

This refers to your application dated January 15, 1985, concerning renewal of your license number 23-08786-01. Additional information and clarifications in the following areas are needed in support of your application:

1. Under Item 10 (Calibration of Instruments) for survey instruments, Appendix D to Regulatory Guide 10.8 was referred to; however, no information was given on the calibration sources used, i.e., manufacturer, model number, activity or exposure rate, accuracy, and traceability to a primary standard. Please provide this information.
2. Under Item 12 (Personnel Training Program) the training to ancillary personnel was unclear. They should be informed about radiation hazards, appropriate precautions and recognition of radiation warning signs and labels. Also, it was unclear whether the training for radiation workers included personnel working in research labs.
3. Under Item 15 it was unclear whether the "Regulations for Nuclear Medicine Personnel" and "General Safety Rules" are also used by personnel in research and development. If different procedures are used in research, please submit. Also, if nuclear medicine personnel are involved in dosing patients for therapy they should be instructed in the importance of verifying the patient's name, the radionuclide, the chemical form, and the activity vs. the physician's written orders prior to dosing the patient.
4. For both therapy applications and research, bioassays may be required or should be considered for personnel working with millicurie quantities of H-3, I-125, or I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the form, procedures or equipment used make it likely that the material could be inhaled, ingested, or absorbed into the body. Please show that the need for bioassays has been thoroughly considered. Enclosed is Regulatory Guide 8.20 which gives guidance on bioassay programs for I-125 and I-131.

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Our review of your application will continue upon receipt of the above information. If you should have any questions, do not hesitate to contact me at FTS 242-2675.

Sincerely,

Carol A. Connell
Radiation Specialist
Nuclear Materials Safety Section

Enclosure:
Regulatory Guide 8.20

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