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APR 26 1985

Reid Memorial Hospital  
ATTN: Barry S. MacDowell  
Executive Vice President  
1401 Chester Boulevard  
Richmond, IN 47374

Gentlemen:

We have reviewed your letter dated November 13, 1984 requesting renewal of your license and find that we will need additional information as follows:

Please clarify the location where the gas chromatograph will be used (street name, building number, etc.).

Describe your procedures for:

- a. Disposal of the foil when its use has been discontinued. If this disposal is by return to the manufacturer, please so state.
- b. Cleaning detector cells and/or removal and exchange of detector cell foil. If you follow the manufacturer's recommended procedures, please provide a copy of the procedures. If detector cells are returned to your supplier for cleaning of detector cells and/or removal and exchange of foil, please specify this.
- c. Leak testing the nickel-63 foil. If you will use a commercial leak test kit, please provide the name of the supplier and model number of the kit. If you will conduct your own leak tests, please provide descriptions of the following:
  - (1) The materials and procedures used for collecting leak test samples.
  - (2) The name of the manufacturer and model number of the measuring instrument used to analyze leak test samples.
  - (3) Your procedures for calibration of the measuring instrument including a sample calculation showing how leak test results are converted to microcuries.

Please expand your procedures for safely opening packages containing radioactive material to include a wipe test of the external surface of the final source container.

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,

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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.

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.

Item No. 18 in application dated January 1, 1979 states that solid waste will be held for decay until radiation levels (as measured with a low-level survey meter) have reached background levels. Please list what instrumentation will be used to measure radiation levels from solid waste generated by your in vitro laboratory. Also, please clarify whether you receive in vitro material in prepackaged kit form or whether you make your kits.

Please specify the individual who is responsible for overseeing inventory control of Group VI sealed sources.

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.

Please expand your laboratory rules to include the following:

Doses, when assayed in the dose calibrator, that differ by more than 10% of the prescribed dose will not be used.

Information submitted in response to this letter should state that it is additional information and not a new amendment request. If you have questions, please contact our office by dialing (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 77833.

Sincerely,

Original Signed By  
James R. Mullauer  
Materials Licensing Section

RIH

Mullauer/lid  
04/25/85