

NMSS:CLC  
Control No. 18398

AUG 22 1985

Department of the Army  
Fitzsimons Army Medical Center and  
Medical Research and Nutrition Laboratory  
ATTN: Philip K. Russell, M.D.  
Commander  
Aurora, Colorado 80045

Gentlemen:

This refers to your application dated February 6, 1984, to renew your byproduct material license for use in nuclear medicine. We have completed review for your application and have the following comments and need for additional information.

1. Your renewal application requested that your license be upgraded to a broad scope license, and you apparently intended to include all information submitted in response to previous correspondence. However, we note that some of the information previously submitted was omitted. In particular, the present application did not include some of the information included with the application dated March 6, 1979, and the information in your letter dated June 3, 1980, in response to our letter dated May 13, 1980. Most of the items listed in the remainder of this letter summarize this required information needed to complete processing of your application for broad license.
2. With regard to your request to have your Radioisotope Committee approve users, submit the following:
  - a. Confirm that any physician authorized to use radioisotopes in or on humans will, at a minimum, meet the criteria specified in Appendix A of Regulatory Guide 10.8 dated October 1980.
  - b. Describe the criteria your Committee will follow in approving new users of byproduct material for nonhuman use. It is recommended that, as a minimum, individuals who use greater than license exempt quantities be required to meet the criteria specified in Section 33.15(b) of 10 CFR Part 33.
3. Describe the intended uses for the requested 5 curies of krypton-85 and 1.5 curies of cesium-137 in other than sealed sources.

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DISCOMMISSIONING RECORD

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4. Provide qualifications for CPT. Dunston or current Radiation Safety Officer in accordance with Item 8 of Regulatory Guide 10.8.
5. Provide information concerning use of xenon-133 and krypton-85 in accordance with Items 11 and 21 and Appendix M of Regulatory Guide 10.8.
6. Although you provided floor plans for your use areas, you did not include the information for these areas identified in Item 11 of the Regulatory Guide. Specifically, describe adjacent areas, shielding, and waste storage areas and contents.
7. Describe the various paths intended for waste disposal; e.g. decay-in-storage, sewer, transport to burial site. Also describe your waste handling procedures including segregation, packaging, surveying, and record keeping.
8. Describe your program for maintaining radiation exposures ALARA. Indicate that you will adopt Appendix O of Regulatory Guide 10.8 or provide equivalent procedures.
9. Submit procedures for the calibration of dose calibrators identifying reference sources to be used. Indicate that you will adopt Appendix D, Section 2, of Regulatory Guide 10.8 or provide equivalent procedures.
10. Appendix L of FAMC Reg. 40-604 should be updated to account for changes in Department of Transportation regulations in Title 49.
11. Identify instrumentation used for leak test sample analysis and other wipe test analysis. Identify detection limits and associated reference standards.
12. Describe personnel training program as indicated in Item 12 of Regulatory Guide 10.8.
13. Describe your bioassay procedures for tritium and radioiodine.
14. Describe special safety instructions to be provided to individuals using phosphorus-32. These instructions should include, but not be limited to, the following:
  - a. The use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum.
  - b. A mandatory radiation survey and wipe test procedure after each use.
  - c. The use of finger type extremity monitors for procedures that involve 1 millicurie or more.

- d. The use of a dry run prior to performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the Radiation Protection Officer be present during new procedures.
  - e. The use of eye protection for procedures that involve 10 millicuries or more.
15. Describe procedures and precautions for use of radioactive material in animals in accordance with Item 22 of Regulatory Guide 10.8.

These items were discussed with CPT. Dunston by telephone on August 12, 1985. We will continue our review of your application upon receipt of this information in duplicate. Please reply in duplicate and refer to Control No. 18398.

Sincerely,

Original Signed By  
C. L. Cain

C. L. Cain  
Nuclear Material Safety Section

Enclosure:  
Regulatory Guide 10.8