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Docket No. : 030-06644
License No.: 46-09750-01
Control No.: 70532

Department of Health & Human Services
Food and Drug Administration
Federal Office Building
909 1st Avenue, Room 5009
Seattle, Washington 98174

Attention: Mr. John Wiskerchen, Director
Science Branch

Gentlemen:

This is in reference to your request dated February 2, 1987 and your letter dated April 14, 1987 for amendment of your byproduct material license. This also refers to our letter to you dated March 2, 1987. In order to complete our review, we need the following additional information, as was discussed in a telephone conversation on July 13, 1987 between B. Riedlinger of our staff and Mr. Stephen D. Weagant.

1. There was a typographical error in Item 1.A. of the letter dated April 14, 1987. You should specify the year when Stephen Weagant and Charles Kaysner attended the FDA sponsored course "Principles of Immunoassay and Radiological Safety."

   Mr. Weagant stated that phosphorus 32 is being used in exempt quantities pursuant to 10 CFR 30.18. It should be noted that larger quantities of this material should not be ordered until the license is amended.

2. From the information submitted in your application and letter, it appears that a five millicurie total possession limit for phosphorus 32 would be more appropriate than the requested ten millicuries. Please state whether a five millicurie possession limit would be adequate for your program. If not, explain and specify an acceptable limit.

3. A. You should specify frequencies for conducting radiation level surveys and contamination wipe surveys in each area where phosphorus 32 is used or stored. Mr. Weagant indicated that such surveys could be conducted on a weekly basis when licensed materials are being used. Note that these surveys should also be conducted in waste storage areas. Specify the frequencies which you will use.

OFFICE	RV BJR	RV					
SURNAME	Riedlinger:ff	Thomas	8709220211 870820 REG5 LIC30 46-09750-01 PDR				
DATE	7/16/87	7/16/87					

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B. You should develop and submit procedures for conducting routine radiation level and contamination wipe surveys. You should identify the instrumentation to be used, the areas to be surveyed, the frequency of the surveys, and the action levels for decontamination and re-survey. Acceptable area survey procedures for a nuclear medicine facility are attached for your reference (Appendix I). Please note that the previous action level of 500 microcuries is too high to ensure proper contamination control. Appendix I references 200 dpm/100cm² as an acceptable action level.

4. We are not familiar with the survey instrument which you are using. You should specify its type, range, and the type(s) of probe(s) which may be used with the instrument.

5. You should submit the NRC License Number which authorizes Mr. W.F. Van Pelt to calibrate your survey instrument.

6. You should develop emergency spill procedures and submit them for review. These procedures should list the name(s) and phone number(s) of your RSO(s). Refer to Appendix H., attached.

7. Although you specified that the laboratory would be secured during non-business hours, you did not specify that areas where licensed materials are used or stored would always be locked when unattended. Refer to 10 CFR 20.207. You should submit a statement to this effect.

We will continue the review of your amendment request upon receipt of this information. In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate, and refer to Mail Control No. 70532.

Sincerely,

R. D. Thomas, Chief
Nuclear Materials Safety Section

Enclosures: Appendices H. and I.