

FEB 19 1986

Docket No. 030-29020
Control No. 104630

Silliker Laboratories of New Jersey, Inc.
ATTN: Richard B. Smittle, Ph.D.
Vice President
2353 Beryllium Road
Scotch Plains, New Jersey 07076

Gentlemen:

This is in reference to your application dated November 5, 1985 for a byproduct material license. In order to continue our review, we need the following additional information:

1. In item 11 of your application, you did not provide the frequency for having your radiation detection instruments calibrated. Frequent checks of survey meters should be supplemented every 6 months with a two-point calibration on each scale of each meter. Please provide the frequency for calibrating your radiation detection instruments.
2. In item 14, "Waste Disposal", of your application, you state that short lived radioactive waste will be stored for decay, surveyed, and disposed if the radiation levels is less than two times background. Normally, waste is held for 10 half-lives and surveyed to insure the material is at background prior to releasing the material to unrestricted use. Please confirm that you will hold the waste for 10 half-lives, survey and will only discard when the levels are at background.
3. In Item 14, "Waste Disposal", of your application, you state liquid waste will be discharged into the sanitary sewage system. Please describe your methods for controlling the sewage disposal of radioactive waste in order to ensure that disposals do not exceed the limits specified in Section 20.303 of 10 CFR Part 20.
4. In item 15, "Radiation Protection Program - Health Physics Surveys", of your application you state that the RSO will conduct surveys biweekly. Please clarify the frequency of the surveys since biweekly can mean once every two weeks or twice a week.

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5. In item 15, "Radiation Protection Program - Health Physics Surveys", of your application, you state the permissible contamination levels are 100dpm per 100 cm². Please furnish the following additional information:
 - a) the instrument used to make this determination.
 - b) the lower limit of detectability for the instrument used.
 - c) the radionuclide and activity of the calibration source, and if this source is traceable to the National Bureau of Standards.
6. In item 15 Appendix A, of your application, you did not specify who assumes the responsibility for monitoring incoming isotope shipments for radiation and contamination. Please provide the name, training and experience of the individual who has this responsibility.
7. In item 15, "Radiation Protection Program-10", of your application, you do not specify the name of the instructor who teaches the radioisotope training program. Please provide the name of your instructor.
8. In item 16/17 of your application, you provide the training and experience for Dr. Smittle and Mr. Decker. It appears that Dr. Smittle has only limited experience handling millicurie quantities of carbon-14, a soft beta emitter. In addition, Dr. Smittle has not had any formal training but only on the job training. No information regarding Mr. Decker's training and experience with radioactive materials was provided. Please specify any additional information regarding the training and experience that either Dr. Smittle or Mr. Decker has obtained in order to be able to provide the necessary radiological safety expertise that 200 millicuries of phosphorus-32 for research and development requires.
9. In item HP-2 of your Radioactive Materials Manual you state that after handling material, wash hands prior to leaving the lab. Please confirm that the hands, clothing, etc. will be monitored prior to leaving the lab and if there is contamination, they will rewash and monitor prior to leaving the lab.
10. In item HP-3 of your Manual, you specify iodine-125 and hydrogen-3 (tritium); however, your application only requests phosphorus-32. Please explain this inconsistency. In addition, Section 20.203(f) of 10 CFR Part 20 requires containers to be labeled if it contains more than one microcurie of iodine-125 not 10 microcuries as you have listed. Moreover, you did not specify the quantity of phosphorus-32 which is the only isotope that you requested. Please furnish this additional information.

11. In item HP-6 of your Manual, you state that the person assigned radiation lab work will be registered with the RSO and have training orientations. This procedure is normally used by a broad scope type license and is not applicable to your program. Please modify this section of your Manual.
12. In support of your request for 200 millicuries of phosphorus-32, you should develop and submit special safety instructions to be provided to individuals using millicurie quantities of P-32. It is recommended that your procedures include, but not limited to, the following:
 - a. A mandatory radiation survey and wipe test procedure after each use.
 - b. The finger type extremity monitors for procedures that involve 1 millicurie or more.
 - c. The use of dry run prior to the 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.
 - d. The use of eye protection for procedures that involve 10 millicuries or more.
13. In your application, you did not include how you will secure licensed material (10 CFR 20.207). Please specify how you will preclude the unauthorized removal of licensed material from the place of storage.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 104630.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
Jack Davis

Jack Davis, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:

1. 10 CFR Part 20
2. Regulatory Guide 10.7