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030-33128
29-30031-01

August 18, 1993

Sheri Ann Arredondo
Nuclear Materials safety Branch
Division of Radiation Safety
and Safeguards
US Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Arredondo:

As per our telephone conversation this morning, I am changing the following answers to meet the NRC's requirements. For convenience, I will bold changed areas, so that you can rapidly note the changes and expedite our NRC Isotope License application (NRC Docket No. 030-33128, Control No. 117911).

11. Describe procedures for measuring iodine or tritium released into unrestricted areas: **Iodine release is monitored by checking the charcoal filter(s) before an iodination with the hand held survey Geiger counter (to determine a background level), and after an iodination with the hand held survey Geiger counter, and counting of the charcoal filter(s) or the charcoal in the gamma counter. Additionally, the researcher's thyroid will be checked (contract service) within 72 hours after an iodination. If we were to detect any significant amount of iodine release (> 5 times over back ground in the hood charcoal filter), we would check procedures for technical errors and the chemical fume hood for problems.** As discussed in Enzon's Radioisotope Safety Manual section 8.1.3, page 40, there is a fixed procedure for monitoring release during an iodination procedure.

Since we do not plan to work with any volatile H^3 products, we do not anticipate any problems. If, however, we were working with a volatile organic or substance, we would try to trap or contain the gases via chemical traps and counting trapped samples for released radioactivity. The Radiation Safety Officer would be responsible for performing such monitoring, documenting the results and keeping records of any problems.

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12. Submit a bioassay program for employees handling tritium and carbon in quantities larger than 10 mCi: If an employee were to use >10 mCi of an isotope, the reaction must be performed in the chemical fume hood. **If a researcher were to use > 100 mCi of [H^3] or any isotope, a urine test would be performed before (for a base line) and after the experiment.** If post experimental wipes, or any indication of a spilled reaction occurred, then whole body exposure to volatile H^3 and C^{14} would have to be performed (outside contractor). We would have them trap and count exhaled gases (water and CO_2) from the exposed researcher. Additionally, we would examine the urine for radioactivity. The Radiation Safety Officer would then make a determination as to the degree and severity of the release, and if necessary, would notify the proper authorities.

14. List procedures for working with radioactive iodine: There are specific procedures for working with radioactive iodine. They are listed in Enzon's Isotope Safety Manual in section 8.1, pages 40-43. **Changes include the following:**

    *** Charcoal filters are counted via hand held survey Geiger counter.**
    *** All laboratory areas are monitored via swipe test after iodinations.**
    *** All laboratory procedures are performed with safety goggles and use of lead or plexiglass shields is mandatory.**

15. List procedures for the handling of P^{32}: Special handling procedures for using P^{32} are discussed in section 8.2, pages 44-45 in Enzon's Radioisotope Safety Manual. Additionally, after discussions with the Radiation Safety Officer, Corporate Safety Officer and several of the researchers, we feel that 200 mCi of P^{32} is excessive, and we would like to amend our application Supplement A to 100 mCi of P^{32} on hand. **Changes include the following:**

    *** All laboratory procedures are performed with safety goggles (especially if isotope quanties are > 10 mCi) and use of plexiglass shields is mandatory for all experimental labeling procedures.**

23. Describe package receiving procedures: As discussed in question 21, the receiving procedures are detailed in Enzon's Radioisotope Safety Manual in section 3.2, pages 11-12. All receiving personnel receive additional training in safety and emergency procedures for handling broken or leaking radioactive packages. Additionally, safety equipment, **including disposable latex gloves, a plexiglass container, and a monitoring Geiger counter kept will be in the receiving area for handling of radiolabeled packages.**

27. Describe decay-in-storage procedures: **We will keep radioactive waste for at least 10 half-lives or until it decays to a non-detectable/background level. Before it is disposed via regular waste procedures, the container will be checked to ensure that the radioactivity is at background levels. These procedures are detailed in Enzon's Radioisotope Safety Manual in section 5.8, page 28.**

29. Supplement B: **We will withdraw Dr. Richard Greenwald's name from the list of principal isotope users until such time that he has the experience to work with the given isotope.**

Additionally, as you suggested, we would like **to ammend our application Supplement A to 70 mCi of C^{14}** on hand to ensure that we do not have to carry extra liability insurance.

I will also change/ammend those sections of Enzon's Isotope Safety Manual that need to be changed.

To summarize, the major changes in our Radioisotope License Application are the following:

Amend Supplement A by reducing the P^{32} level from 200 mCi to 100 mCi.
Amend Supplement A by reducing the C^{14} level from 100 mCi to 70 mCi.
Correct wording in supplement F Item 2
Supplement B Add Drs. Masih Hashim, and Mel Silberklang, and withdraw Dr. Richard Greenwald.

I believe that this takes care of all the questions raised this morning. If there are additional questions, please feel free to call me at 908-980-4902. I thank you for helping us get this isotope application processed.

Sincerely yours,

Carl Walter Gilbert

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Attachment
cc: Robert G.L. Shorr, Ph.D.
Jack McLaughlin, C.S.O.