UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 6, 2014

Docket Nos. 03005596 License Nos. 32-12358-01

Control Nos. 582714
582711

William P. Fitzgerald, Jr., C.H.P.
Radiation Safety Officer
U.S. Department of Health and Human Services
National Institute of Environmental Health Sciences
P.O. Box 12233, MD F0-07
Research Triangle Park, NC 27709

SUBJECT: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NOS. 582714 AND 582711

Dear Dr. Fitzgerald:

This is in reference to your applications dated December 9, 2013 requesting to renew Nuclear Regulatory Commission License Nos. 32-12358-01 and update your decommissioning funding plan. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than the Radiation Safety Officer. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

2. Thank you for submitting the Statement of Intent dated November 20, 2013. However, the Certification of Financial Assurance that was dated November 20, 2013 was signed by the Radiation Safety Officer. Please re-submit the Certification of Financial Assurance with a signature from the Director of your institution.

3. On page 2 of your application dated December 9, 2013, you have requested a possession limit of 10 Curies for hydrogen-3 but on the following page you have submitted the Certification of Financial Assurance for 1 Curie of hydrogen-3. Please rectify the difference between your license possession request and Certification of Financial Assurance for hydrogen-3.

4. In the Certification of Financial Assurance that was submitted with your application, you indicate that you will “further restrict the possession of unsealed byproduct material or readily dispersible source material to quantities less than 10^5 of the applicable limits in

Appendix B of 10 CFR 30 as specified in 10 CFR 30.35(d)." Please describe how you plan to verify that this restriction will not be exceeded.

5. On page 5 of your application you indicate that radioactive material will be used for metabolic and distribution research studies. You also indicated that you do not plan to use radioactive material for the internal or external administration of byproduct materials to human beings or the radiation exposure to human beings. Please confirm that you also do not plan to add byproduct material to any food, beverage, drug, or other product designed for ingestion or inhalation by or application to, a human being and then transfer that material to another licensee for administration to human subjects to support a metabolic and distribution research study.

6. On page 8 of your application you have described the criteria that the Radiation Safety Committee will use for approving new principle users and radiation safety workers. Please submit for review the criteria the Radiation Safety Committee will use to approve uses of radioactive material.

7. In Section 10.1 of your application you indicated that the RSO or his staff health physicists will perform unannounced audits of each principal user's laboratories about once per year. These types of audits are essential to gauge the effectiveness of your radiation safety program. Please confirm that the audits will be completed once per year. In addition, please describe how you plan to review the entire radiation safety program content annually in accordance with 10 CFR 20.1101.

8. On page 13 of your application you indicate that the Radiation Safety Officer will make approximately monthly surveys of all laboratories using radioactive material. On page 23 of your application you commit to surveying your facility and maintaining contamination levels in accordance with Appendix S of NUREG – 1556, Volume 11 which may require some laboratories to be surveyed weekly and require all your radioactive material labs to be surveyed at a minimum on a monthly basis. Please confirm that personnel at your facility, either the radiation safety staff and/or the scientific staff, will collectively perform surveys and maintain contamination levels in accordance with Appendix S of NUREG – 1556.

9. You plan to use radioactive material *in-vivo*. Will these procedures involve survival experiments in which the animals are returned to ancillary animal caregivers or will your experiments be non-survival experiments such that the animals containing radioactive material are only handled by the authorized users? If ancillary animal caregivers will be required to handle animals containing radioactive material, please submit the procedures they will follow and describe the training that they will receive.

10. In item 6 of page 27, you indicated that radioactive waste held for decay-in-storage will be held for a minimum of ten half-lives of the longest-lived radioisotope in the container. Please be aware that the condition in your renewed license that will authorize using decay-in-storage as a method of waste disposal will not stipulate the number of half-lives needed to decay the waste. The authorization will only require that the waste be decayed to levels that are indistinguishable from background when monitored with an appropriate survey instrument. Please advise if you wish to commit to a minimum of ten

half-lives of the longest-lived radioisotope in the container as a required minimum decaying period for decay-in-storage waste.

11. Please be advised that the standard license condition that is currently used for licensee's that are granted authorization to incinerate radioactive waste and dispose of the ash as ordinary waste must meet the following criterion:

    "Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver 108-m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies."

    Note that release criteria for hydrogen-3 and carbon-14 will be ten times more restrictive then the authorization that is currently in your license.

    In Item 8. on page 31, you indicate that "in most cases the isotope in the ash is assumed to be S-35, which is the isotope with the longest half-life of those that would be in the ash after incineration." Carbon-14 has a longer half-life than sulfur-35 and a more restrictive release criterion than sulfur-35. It has also been detected in incinerator ash at other incinerators that are used to combust research generated radioactive waste.

    Licensees may assume that 5 percent of the carbon-14 contained in the incinerator feed remains in the ash, and compliance may be shown by calculation of the expected ash content based on activity in the feed. However, because the oxidation of carbon-14 is to some extent dependent on the proper operation of the combustion chambers, you should perform initial and periodic quality control tests of your ash to verify the validity of the 5 percent assumption. Annual tests will be sufficient.

    Please respond to the following questions:

    a. Describe how you assure that your ash sample is "composite" and that a 0.1 gram sample is representative of a 30 or 55 gallon drum of ash. How many samples do you analyze per drum of ash.

    b. You indicated that the MDA for sulfur-35 is 12 dpm (5.45×10^{-6} uCi). Since carbon-14 has nearly the same beta energy as sulfur-35, the MDA for carbon-14 would also be approximately 5.45×10^{-6} uCi. For a 0.1 gram sample, your MDA for sulfur-35 and carbon-14 on a per gram basis would be 5.45×10^{-5} uCi/g.

        - Please submit your complete calculation of the MDA for sulfur-35/carbon-14.

        - Tell us if you plan to sample all your potential radioactive ash for carbon-

14 or if you plan to use the 5 percent assumption with initial and annual quality control checks. Regardless of which method you choose, the release criterion for carbon-14 is $3x10^{-6}$ uCi/g for ash to be released as general waste which is less than your MDA. Please describe how you plan to sample and assay the ash for carbon-14 to assure that ash released as general waste meets the release criteria.

- Since sulfur-35 and carbon-14 are indistinguishable from each other using liquid scintillation counting techniques and they have significantly different release criteria, describe how you plan to differentiate your ash sample analysis between sulfur-35 and carbon-14.

c. Counting an ash sample in a liquid scintillation vial will result in a significantly quenched sample. Please describe how you plan to address sample quench in analyzing your results.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control Nos. 582714, and 582711. If you have any technical questions regarding this deficiency letter, please call John Miller at (610) 337-5089.

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

Sincerely,

Original signed by Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

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