



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 7, 2005

Docket No. 03031689
Control No. 137213

License No. 19-07538-05

John M. Strong
Acting Director
Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL
OF LICENSE, CONTROL NO. 137213

Dear Mr. Strong:

This is in reference to your application dated June 10, 2005 requesting to renew Nuclear Regulatory Commission License No. 19-07538-05. In order to continue our review, we need the following additional information:

1. In your renewal application you request to add Sulfur-35 to your license but did not address the use of Sulfur-35 in many of your procedures. Please confirm that all activities applicable to Hydrogen-3 and Carbon-14 will also apply to Sulfur-35.
2. Please confirm that you would like to remove Jerry Collins as an authorized user from the license
3. In section 10.a of your renewal application, it states that the RSO will approve or decommission specific areas where radioactive materials are used and stored. Please specify your criteria for approval and decommissioning. Also note that pursuant to 10 CFR 30.35(g), licensees are required to maintain records important to decommissioning.
4. Please provide a description of the radiation monitoring instruments (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys. Appendix M of NUREG-1556 vol. 7, "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" will help to formulate your response.

J. Strong
Department of Health and Human Services

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5. Pursuant to 10 CFR 20.1501, licensees are required to make surveys of potential radiological hazards in the workplace. Please verify that you will survey and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556 Vol. 7. Section 8.10.7 of the same guidance will help to formulate your response.
6. Please confirm that sewage disposal meets the criteria set forth in Section 8.11 of NUREG -1556 Vol. 7, "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" . Refer to Appendix T of that guidance document to help you in formulating your response.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to the attention of Farrah Gaskins at the Region I Office and refer to Mail Control No. 137213. If you have any technical questions regarding this deficiency letter, please call Farrah Gaskins(610) 337-5143.

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.

Sincerely,

Original signed by Elizabeth Ullrich

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

cc:
Raymond W. Klecker, Radiation Safety Officer

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