



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

April 12, 2006

Docket No. 03004675
Control No. 138288

License No. 20-08361-01

Edmond J. Baratta
Radiation Safety Officer
Department of Health & Human Services
Public Health Service
US Food & Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL
OF LICENSE, CONTROL NO. 138288

Dear Mr. Baratta:

This is in reference to your application dated January 20, 2006 requesting to renew Nuclear Regulatory Commission License No. 20-08361-01. The guidance for broad scope license application is contained in NUREG 1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope." The following paragraphs refer to sections in this manual unless otherwise stated. In order to continue our review, we need the following additional information:

1. Confirm that the Radiation Safety Manual is submitted as part of your license application, and that any changes in the Manual information and procedures shall be submitted to the NRC and approved by amendment of your license prior to implementing the changes. Alternatively, you may submit the Radiation Safety Manual as a reference for specific procedures referred to in Items of your license application; in this case only changes made in the referenced procedures would require amendment of the license. You may also minimize the need for frequent amendments if you specify those sections of your manual which are administrative in nature and/or do not reduce the level of safety. Such areas might include: modifications required by NRC rule changes; revision of internal management forms; selection of authorized contractors for dosimetry, waste disposal, calibration, and other similar services; references to specific manufacturers and/or models of equipment.
2. NRC will provide even greater flexibility to Type A Broad Scope licensees to make programs changes and changes to procedures specifically identified in documents which were previously approved by the Commission and incorporated into the license, without prior Commission approval. If you would like authorization for this flexibility, please provide the following statements.
 - a. Changes to your program and procedures will be limited to the following areas: training; audit program; radiation monitoring instruments; material receipt and

accountability; safe use of radionuclides and emergency procedures; and radiation surveys. In addition, state that you will apply for, and receive an amendment to your license prior to implementing any other programmatic or procedural changes.

- b. The proposed revision will be documented, reviewed, and approved by the your Radiation Safety Committee in accordance with established procedures prior to implementation.
 - c. The revised program will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
 - d. Your staff will be trained in the revised procedures prior to implementation.
 - e. Your audit program will evaluate the effectiveness of the change and its implementation.
3. You have requested for use at temporary job sites in item 5 of your application. As written in section 8.3 of NUREG-1556, Volume 11, please describe the scope of the activities being performed at temporary job sites and the method of controlling licensed material at those sites.
 4. Item 5 of your application, requests for sealed sources. Per our guidance, section 8.5.1, please submit the manufacturer and model numbers as registered in the Sealed Source and Device (SSD) Registration Certificate. This request would be applicable to the radionuclides identified as item 5 O, EE, FF, and GG.
 5. Item 5 of your application places material authorization limits at satellite locations of use. This authorization is normally controlled by the Radiation Safety Committee. If you wish to not limit your material type authorization, please remove this request. However, removing the material types would cause these locations to be added when considering financial assurance requirements.
 6. 10 CFR 30.35 requires that licensees authorized to possess and use unsealed licensed material with a half-life greater than 120 days in quantities greater than those described in 10 CFR 30.35(a) must submit decommissioning funding plan (DFP) in any new or renewal application. This plan must include an actual estimate of the costs for decommissioning your facility and a description of the methods of assuring funds in accordance with 10 CFR 30.35(e). The appropriate level of detail for the cost estimate is discussed in Appendix A.3 to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance." The submitted DFP and cost estimate is greater than the 3 year requirement for updating the DFP. Please submit an updated cost estimate. If the DFP cost estimate is greater than your current certification of financial assurance, you must submit a revised financial assurance instrument in the prescribed amount of the cost estimate. Please follow closely the recommended wording for financial assurance mechanisms found Appendix A to Volume 3 of NUREG-1757.

7. As required in section 8.5.2 of NUREG-1556, Volume 11, please submit a Certification of Financial Assurance. A Certification of Financial Assurance is part of an updated Decommissioning Funding Plan (DFP). The guidance and requirement may be found in NUREG-1757, Volume 3, "Financial Assurance, Recordkeeping, and Timeliness," section A.2.5 on page A-24.
8. Item 6 of your application lists the purposes for each type of radioactive material. These purposes do not align with the current license and is missing a purpose for radionuclides identified as item 5 DD through II. Additionally, the radionuclides do not align with the submitted Decommissioning Funding Plan written as page A-28. Please submit purpose of licensed material again.
9. Describe the criteria your Radiation Safety Committee (RSC) will use to approve authorized users and uses for activities utilizing licensed material. These criteria should specify the minimum acceptable standards for training and experience of the users, facilities and equipment, the operating or handling procedures, the types of surveys or monitoring and the survey frequency requirements. Your application must provide sufficient detail to assure that the RSC evaluations are sufficient in scope and depth to satisfy 10 CFR 33.13(c)(3). In addition, you may wish to correlate the survey frequency for research laboratories to the hazard using a scheme such as that found in Appendix K of NUREG-1556, Volume 11, "Program Specific Guidance About Licenses of Broad Scope."
10. Provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material. Appendix J of NUREG-1556, Volume 11 contains a model delegation of authority and may be helpful to you in developing your response.
11. As requested in section 8.8 of the NUREG-1556, Volume 11, please submit the qualification of the training program instructors, method of assessing the success of the training. Additionally, components of dosimetry requirements and waste handling requirements seemed to be missing from the listed topics. Please confirm that users of licensed material will obtain training in those areas.
12. The application did not discuss criteria that the RSC will use to approve new facilities. As requested in section 8.9 of the NUREG-1556, Volume 11, please describe the criteria your RSC will use to review and approve facilities and equipment beyond room 121, 121A, and 121B. Additionally, describe your procedures for control, review, and approval of significant facilities or equipment modifications.
13. As requested in section 8.10.2 of NUREG-1556 Volume 11, please provide the criteria used by your RSC to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities.

14. As requested in section 8.10.2 of NUREG-1556 Volume 11, please submit procedures for instrument calibration or state that instruments will be calibrated by a vendor who is licensed by NRC or an Agreement State to perform instrument calibrations.
15. Your application did not discuss frequency of ambient radiation level surveys. As requested in section 8.10.7 of NUREG-1556 Volume 11, please submit procedures to evaluate external radiological hazards. If you wish, you may state, "we will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, volume 11, 'Program-Specific Guidance about licenses of Broad Scope.'"
16. As requested in section 8.10.7 of NUREG-1556 Volume 11, please submit your leak test procedures. As an alternative you may state, "we will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, 'Program-Specific Guidance about licenses of Broad Scope.'"
17. 10 CFR 20.2003(a)(1) requires that a licensee may discharge licensed material into sanitary sewerage if the material is readily soluble (or is readily dispersible biological material). Information Notice 94-07 (<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1994/in94007.html>) provides methods for determining compliance with this requirement which are acceptable to the U.S. Nuclear Regulatory Commission.

Please review this Information Notice and provide specific information as to how you will assure that your releases to the sanitary sewerage system will meet the solubility criteria in 10 CFR 20.2003(a)(1). If you wish, you may indicate that you will use one of the methods described in Information Notice 94-07. Otherwise, describe your alternative methodology including the models, calculations, analytical techniques, and quality control measurements as well as the records that will be maintained.

In addition, provide calculations to show compliance with 10 CFR 20.2003(a)(2)(3)(4) and confirm that records will be maintained of all disposals made into the sanitary sewerage system.

18. In your application you have requested to clean ionizing smoke detectors per RSM Attachment D. Please provide the manufacturer and model number of each sealed source in these smoke detectors. Please provide manufacturers instructions or recommendations associated with each model of smoke detector.

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).

E. Baratta
Department of Health & Human Services

5

We will continue our review upon receipt of this information. Please reply to Dennis Lawyer's attention at the Region I Office and refer to Mail Control No. 138288. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5366.

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

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

cc:
Martin J. Finkelson, Center Director

DOCUMENT NAME: E:\Filenet\ML061080593.wpd

SISP Review Complete: DLawyer

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	C	DNMS/RI	N	DNMS/RI			
NAME	DLawyer /DRL1/		EUllrich /BU/					
DATE	04/12/06		4/12/06					

OFFICIAL RECORD COPY