



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

J-6

April 17, 2013

Docket No. 03006923

License No. 19-00915-06

Control No. 580279 (Ref.) RLJ

John T. Jensen  
Chief, Radiation Safety Division  
U.S. Department of Agriculture  
Office of Homeland Security and Emergency Coordination  
Radiation Safety Staff  
5601 Sunnyside Avenue, Mailstop 5510  
Beltsville, MD 20705

SUBJECT: U.S. DEPARTMENT OF AGRICULTURE, REQUEST FOR ADDITIONAL  
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO  
LICENSE, CONTROL NO. 580279

Dear Mr. Jensen:

This is in reference to your letter dated March 22, 2013 requesting to amend Nuclear Regulatory Commission License No. 19-00915-06. In order to continue our review, we need the following additional information:

1. Since the irradiator you wish to modify is not in the sealed source and device registry please submit the information as required in 10 CFR 30.32(g)(2): For sources or devices manufactured before October 23, 2012, that are not registered with the Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application must include: (i) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

10 CFR32.210(c) states: The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

2. Please provide the qualifications of the service vendor that you will be using to show

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they are qualified to perform the modification on the irradiator.

- 3. You have requested the removal of the Gainesville, Florida location. Please provide a copy of the most recent leak tests from the device(s) that were located at that facility since having licensed material at this location.

- 4. You have requested a number of location nomenclature changes to this license. This affects your financial assurance. Currently your Statement of Intent includes a different license commitment which had been revised. Locations of your facility are not on the Statement of Intent as stated in the guidance. The current Certification of Financial Assurance also includes certification of material from a different license which has been amended, causing the Certification of Financial Assurance to be inaccurate. 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(d) must submit certification for financial assurance or a decommissioning funding plan (DFP) in any new or renewal application. A DFP must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the Plan. 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." Submit certification for financial assurance in the prescribed amount using one or more of the approved financial assurance mechanisms provided in Chapter 4 to Volume 3 of NUREG-1757. Please follow closely the recommended wording for financial assurance mechanisms found in Appendix A to Volume 3 of NUREG-1757.

- 5. Please confirm that you wish to change your licensee name (Item 1 of your license) to U.S. Department of Agriculture, Office of Homeland Security and Emergency Coordination, Radiation Safety Staff.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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 No. 580279. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

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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 Dennis R. Lawyer***

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety