



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

August 29, 2012

Docket No. 030-12630
Control No. 577800

License No. 01-00126-16

James B. Johnson
Executive Director
US Army Test, Measurement and Diagnostic Equipment Activity
Department of the Army
US Army Aviation and Missile Command
US Army TMDE Activity
AMSAM-TMD-SR, Building 5417
Redstone Arsenal, AL 35898-5000

SUBJECT: US ARMY TEST, MEASUREMENT AND DIAGNOSTIC EQUIPMENT ACTIVITY,
REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION
FOR AMENDMENT TO LICENSE, CONTROL NO. 577800

Dear Mr. Johnson:

This is in reference to your letter dated June 25, 2012 requesting to amend Nuclear Regulatory Commission License No. 01-00126-16. In order to continue our review, we need the following additional information:

1. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; or contain the information identified in 10 CFR 32.210(c). Please provide this information for all the sealed source(s) requested in your application.

Please note that a final rule for "Requirements for Distribution of Byproduct Material" contains changes to 10 CFR 30.32(g) requirements. This rule is effective October 23, 2012. The rule may be found in the Federal Register, Volume 77, Number 143 published Wednesday, July 25, 2012. If you wish to provide alternate information as described in the final rule, we could review that information but would not issue the renewal until after rule becomes effective.

2. Item 7, section 3 of your application states that you have attached an organizational chart of USATA. The chart was not included. In accordance with Section 8.7.1, NUREG-1556, Volume 11, "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Licenses of Broad Scope," it recommends that an applicant submit an organizational chart. Please submit an organizational chart.
3. 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).

4. Describe criteria your RSC will use to review and approve facilities and equipment. Your description will need to include your method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme. Also describe your procedures for control, review, and approval of significant facilities or equipment modifications.
5. In item 7, section 5 of your application, you stated your procedures for greater flexibility. Although the NRC will provide even greater flexibility to Type A Broad Scope licensees to make program 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, your application was missing some of the needed statements. If you would like authorization for this flexibility, please provide the following commitments.
 - 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. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.
 - 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.
6. Your application requests that David Walsh, Corey Sedgwick, William Harris Jr., Steven Rogers, and Richard McGeorge be named on your license as an alternate Radiation Safety Officer (RSO). The NRC does not place alternate or assistant RSOs on the license. The individual listed on an NRC license as the RSO is the individual responsible for overseeing the radiation safety program. However, the RSO may delegate certain tasks to other qualified individuals. The RSO must confirm that those delegated tasks were performed as required and in compliance with NRC regulations and your NRC license. No response is required for this item.
7. 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.

8. Provide a statement delineating the Radiation Safety Officer (RSO) duties and responsibilities for carrying out the radiation safety program. Section 8.7.3 of NUREG-1556, Volume 11 discusses the duties and responsibilities of the RSO and may be helpful in developing your response.
9. In item 8, section 5 of your application described the training of irradiator operators, but did not describe the annual safety review and performance evaluations of irradiator operators. Section 8.8.2 of NUREG-1556, Volume 5, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About 10 CFR 36 irradiator Licenses," requires the applicant to describe the program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e). Please describe the program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e).
10. In item 9, section 5 of your application described the irradiator facility. The following information needs to be provided about the irradiator facility:
 - a. Section 8.9.1 of NUREG-1556, Volume 6 states to describe the irradiator including drawings, diagrams, sketches, and photographs as appropriate, show locations of safety-related equipment and features as required in 10 CFR Part 36. Please provide a diagram of the irradiator facility along with locations of major safety equipment, shielding, and block diagram of irradiator safety-related controls.
 - b. Section 8.9.2 of NUREG-1556, Volume 6 states to submit information describing the access control system and how it works that demonstrates compliance with the requirements of 10 CFR 36.23. In addition describe the irradiator alarm system and the lock and key system for controlling source movement and how it meets 10 CFR 36.31(a).
 - c. Section 8.9.3 of NUREG-1556, Volume 6 states to describe the shielding used and its composition. Submit a diagram showing the configuration of shielding including walls, the ceiling, and indicate the thickness of each and penetrations in the shielding.
 - d. Section 8.9.4 of NUREG-1556, Volume 6 states to describe the type and location of the heat and smoke detectors to be used to detect a fire in the radiation room, the alarms to alert personnel trained to summon assistance, how the sources will automatically become fully shielded if a fire is detected.
 - e. Section 8.9.5 of NUREG-1556, Volume 6 states to describe the location and type of radiation monitors that will be used to meet the requirements of 10 CFR 36.23(c). Describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used,

as appropriate. Discuss the alarm set-points or the methods for establishing the alarm set-points.

- f. Section 8.9.8 of NUREG-1556, Volume 6 states to describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds and how it will affect the lock on the doors in the radiation room.
 - g. Section 8.10.6 of NUREG-1556, Volume 6 states for routine operations to provide an outline that specifically states the radiation safety aspects of the written operating procedures of the irradiator, including entering and leaving the radiation room. The description should be detailed enough to show how the licensee will comply with 10 CFR 36.67. Describe how the applicant will prevent access to keys by individuals who have not been qualified to be operators as required by 10 CFR 36.31(a). Describe how the applicant will address the required presence of a person who is trained to respond to alarms must be onsite.
 - h. Section 8.10.6 of NUREG-1556, Volume 6 states for non-routine operations, give a statement that: "The irradiator manufacturer or other person authorized by NRC or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, clearing stuck source racks, investigating/remediating removable contamination/leaking sources, (re)installing source cables, and other critical operations requiring special skills or the potential for radiation overexposures," or give the information listed in Appendix I supporting a request to perform this work "in-house."
 - i. Section 8.10.8 of NUREG-1556, Volume 6 states to provide an outline of the radiation safety aspects of the written emergency procedures which address the procedures listed in 10 CFR 36.53(b).
11. License Condition No. 16 is an exemption to the requirements of 10 CFR 36.23(a). During a renewal the applicant needs to reiterate that they either need, or no longer need, this exemption.
12. In item 10, section 3 of your application, your material accountability procedures did not include a statement to prevent exceeding financial assurance limiting conditions. Limiting Condition No. 13 must be reviewed during inventory and purchasing processes to ensure you do not possess quantities for which financial assurance is required. Confirm that you will establish procedures to ensure that the possession of unsealed byproduct material will not exceed quantities less than or equal to 10^4 of the applicable limits in Appendix B of 10 CFR Part 30 as specified in 10 CFR 30.35(d); and special nuclear material to quantities less than 10^4 of the applicable limits in Appendix B of 10 CFR Part 30 as specified in 10 CFR 70.25(d). Note that, at this time, the maximum quantities of source material requested do not require financial assurance.
13. In item 10, section 7, you did not provide enough specifics about the frequency of your survey program. As stated in section 8.10.7, please submit procedures to evaluate radiological hazards, both external and internal. 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.

14. Your application included a new Certification of Financial Assurance. The Certification did not include the limiting conditions statement that allows you to use the prescribed values. This limiting condition is currently License Condition No. 13 on your license. Please add this condition to the Certification of Financial Assurance. Please note that your license does not have enough authorization of source material to require financial assurance and thus that portion of License Condition No. 13 will be removed and does not need to be included on your certification. Additionally, sealed sources do not need to be included on the certification as the maximum quantities of material authorized as sealed sources do not require financial assurance.
15. Currently License Condition No. 26 allows neutron activation in limited quantities. This would appear to be a limited authorization for research and development. If you desire authorization for research and development, please specifically request authorization for research and development. This license condition will be removed from the license. Performance of any neutron activation will be reviewed as part of inspection to ensure the activities are authorized under the license and performed within regulatory requirements.
16. The maximum limit requested for the material requested in item 8.N. is confusing.. Please change the request to the limit the maximum amount of materials as “ xx microcuries per radionuclide and yy microcuries total activity” similar to item 8.B. Please note that this will affect the Certification of Financial Assurance, so a new Certification of Financial Assurance must be submitted.

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).

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

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.

J. Johnson

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We will continue our review upon receipt of the information requested in the numbered paragraphs above. Please reply to my attention at the Region I Office and refer to Mail Control No. 577800. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040, Dennis Lawyer at (610) 377-5366 or Farrah Gaskins at (610) 337-5143..

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

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

cc:
Stephen V. Howard, C.H.P., Radiation Safety Officer

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