



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

November 30, 2012

Idaho State University
Technical Safety Office
ATTN: Peter C. Farina
Radiation Safety Officer
921 South 8th Avenue, Stop 8106
Pocatello, Idaho 83209-8106

SUBJECT: VOIDANCE OF NEW LICENSE APPLICATION

The Nuclear Regulatory Commission (NRC) has completed the review of Idaho State University letter dated November 10, 2012, providing a response to the NRC request for additional information letter dated October 11, 2012. The response letter did not include sufficient information for the NRC to make a determination that the proposed activity will be conducted in an adequate manner since the automated transfer system is still in the design phase. Other deficiencies were identified and these are listed below. Therefore, Idaho State University application for a license for the production of accelerator-produced radionuclides has been voided without prejudice. This action is without prejudice to the resubmission of an application.

1. The license application dated August 14, 2012, was submitted with an incorrect fee category. The correct license application fee category for production of accelerator-produced radionuclides is 3S (program code 03210) in the amount of \$6,500.
2. The response letter dated November 10, 2012, states that the intent of the license application dated August 14, 2012, is to distribute licensed material to Idaho State University authorized users as well as external entities. Page 3 of the license application, states in "Item 1, License Action Type" that the application is for the production of radioactive materials using an accelerator. There is no reference to distribution of licensed material to outside entities.
 - A. Distribution of licensed material to external entities will require a separate NRC distribution license. Licensing guidance for the distribution of radionuclides is provided in NUREG-1556, Volume 12. The license application fee for a Broad Scope Type A distribution license (program code 03211, fee code 3.A.) is \$12,800.
3. The response letter dated November 10, 2012, providing mathematical calculation demonstrating that unsealed radioactive material authorized in Broad Scope license 11-27380-01, and unsealed radioactive material listed in the new license application for production of accelerator-produced radionuclides, will result in quantities less than 10^5 times the applicable limits in Appendix B of 10 CFR Part 30, has several errors. These errors are described in the enclosures, and in items 3.A. and 3.B.
 - A. The mathematical calculation needs to account only for the material that will be authorized in the accelerator production license, excluding the material authorized under Broad Scope license 11-27380-01.

- B. A separate decommissioning financial assurance Statement of Intent letter with the corresponding amount for the proposed accelerator production license is needed.
4. The response letter dated November 10, 2012, did not provide detailed description of the following.
 - A. Transfer of the irradiated material from the irradiation room to the authorized users,
 - B. How the “automated transfer system” and the “shielded target container” work, and
 - C. If applicable, how radioactive material in liquid form is transferred through the delivery lines and distributed to authorized users.
 5. The response letter dated November 10, 2012, did not provide procedures describing the radiation safety precautions that the workers will follow for the following activities.
 - A. Entering the room after the target is irradiated,
 - B. Handling and cutting the irradiated target, and
 - C. Distribution of the irradiated targets to the authorized users.
 6. The response letter dated November 10, 2012, did not provide procedures describing the testing frequency and methods for testing the door interlocks and radiation alarms inside and outside the irradiation room.
 7. The response letter dated November 10, 2012, shows that only a portion of the table found in Page L-1 of NUREG-1556, Volume 21, was incorporated into the operating and emergency procedures, and not the table in its entirety.
 8. The Radiation Safety Program Manual and Radiation Safety Training Program needs to be revised to state that staff from the Technical Safety Office/Radiation Safety Office will have unfettered and unrestricted access to any university facility using licensed radioactive material, including the Idaho Accelerator Center, to conduct unannounced radiation safety reviews, audits, radiation surveys and monitoring, and any other radiation safety duties.
 9. The Radiation Safety Program Manual and description of the duties of Radiation Safety Committee members needs to be revised to state that the committee must ensure that appropriate university policies and procedures incorporate elements of the NRC’s Safety Culture Policy Statement. The revision should include the following.
 - A. A written commitment from the university stating that it will perform a written evaluation comparing the university’s policies against NRC’s Safety Culture Policy as described in NRC’s Regulatory Issue Summary (RIS) 2012-01 dated January 17, 2012, and NUREG/BR-0500 dated June 2011. RIS 2012-01 can be found at: <http://pbadupws.nrc.gov/docs/ML1129/ML112940226.pdf>. NUREG/BR-0500 can be found at: <http://pbadupws.nrc.gov/docs/ML1116/ML11165A021.pdf>. The university must describe the time frame by which this evaluation will be conducted and the radiation safety manual must allow for periodic re-evaluations.

- B. A written commitment from the university stating that it will identify to its workers (including contractors) who are engaged in NRC licensed activities the different options that individuals can use to raise radiation safety concerns. This should include a way for workers and contractors to raise concerns anonymously.
 - C. A written commitment from the university stating that it will perform a written evaluation comparing the university's safety conscious work environment policies against NRC's Regulatory Issue Summary (RIS) 2005-18 dated August 25, 2005, "Guidance for Establishing and Maintaining a Safety Conscious Work Environment." This RIS can be found at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200518.pdf>. The university must describe the time frame by which this evaluation will be conducted and the radiation safety manual must allow for periodic re-evaluations.
10. The Radiation Safety Program Manual needs to be revised to include procedures describing the type of training and the frequency of the training that staff and managers will receive on 10 CFR 30.7, "Employee Protection," and NRC's Safety Culture Policy Statement. 10 CFR 30.7 prohibits discrimination against an employee for engaging in certain protected activities. The procedures should include the following.
- A. A discussion about worker's rights to raise radiation safety concerns without being retaliated against.
 - B. A discussion of the university's policies on safety culture.
 - C. A discussion of the university's policies on safety conscious work environment. Training to managers should include how to respond to workers who raise safety concerns.
 - D. A discussion of the university's process for prioritizing and evaluating radiation safety concerns, including providing feedback to the individual who raised the concern.
 - E. A discussion of the options that individuals have for raising safety concerns, including the option to raise concerns anonymously or to the NRC.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-38577

Control: 579117

Enclosures: As stated