



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

September 27, 2013

Docket No. 030-38333
EA-13-168

License No. 06-00183-08

Stephanie S. Spangler, M.D.
Deputy Provost for Health Affairs and Academic Integrity
Yale University
Environmental Health and Safety
135 College Street, First Floor Suite 100
New Haven, CT 06510

SUBJECT: NRC INSPECTION REPORT NO. 030-38333/2013-001 AND NOTICE OF VIOLATION, YALE UNIVERSITY AND RESPONSE TO YOUR LETTER DATED JULY 25, 2013

Dear Dr. Spangler:

This responds to your July 25, 2013, letter to the U.S. Nuclear Regulatory Commission (NRC) letter and Notice of Violation (Notice) dated June 28, 2013, [ML13182A057]. The NRC Notice described one Severity Level IV violation identified during an inspection conducted at your PET Research Center, New Haven, Connecticut on May 14, 2013, and continued with the review of additional information provided by electronic mail and telephone on May 23, June 5, and June 25, 2013. This violation cited the failure to restrict the possession of unsealed byproduct materials with half-lives greater than 120 days to the quantities for which a prescribed amount of financial assurance was provided. In your July 25, 2013, letter, you provided clarifying information and contested the violation because you believed the NRC provided you information that indicated incidentally activated products in removable cyclotron components were not part of the licensed materials for which financial assurance is required.

Our letter dated July 31, 2013, [ML13212A133] indicated that the NRC was evaluating the merits of your dispute of the violation. Based on the NRC staff's review of the points raised in your letter dated July 25, 2013, the violation has been determined to remain valid, as described in the Enclosure.

We also reviewed your corrective actions for this violation, as described in your July 25, 2013, correspondence. These actions included the submission of a Decommissioning Funding Plan (DFP) and other documents in support of the financial assurance requirements for this license and License No. 06-00183-03 (Type A license of broad scope). The financial assurance documents were submitted separately as a licensing action related to the financial assurance, under Control No. 580868, and will be reviewed by licensing staff members. Based on your submission of these documents in the licensing process, we consider your corrective actions acceptable and no further information is required regarding this violation.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available

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electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response you choose to provide should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. 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 contact Judith Joustra at 610-337-5355 if you have any questions regarding this matter.

Sincerely,

/RA/

James W. Clifford, Director
Division of Nuclear Materials Safety

Enclosure:
NRC Staff Review of July 25, 2013 Letter

cc w/Enclosure:
Tammy Stemen, Radiation Safety Officer
State of Connecticut

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/RA/

James W. Clifford, Director
Division of Nuclear Materials Safety

Enclosure:
NRC Staff Review of July 25, 2013 Letter

cc w/Enclosure:
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OFFICIAL RECORD COPY

NRC Staff Review of July 25, 2013, Letter

In your letter dated July 25, 2013, you disputed the violation on the basis that the NRC failed to provide Yale University with fair notice of its interpretation that incidentally activated products in removable cyclotron components be included in the financial assurance unity rule calculation. A summary of your points and the NRC's responses are as follows:

Yale University Issue 1

You stated that, during the review of the new license application, the NRC provided concurrence that it was appropriate to exclude from the financial assurance calculation those incidentally activated products in removable components, and the NRC has consistently reaffirmed this interpretation.

NRC Response

The NRC was not able to identify any records that demonstrated the agency provided concurrence that it was appropriate to exclude the removable components from the financial assurance calculations. The NRC did not find, in any of the related licensing correspondence from the NRC, a statement that the NRC concurred or reaffirmed that long-lived materials in incidentally activated removable components did not need to be considered. Furthermore, we note that 10 CFR 30.35 requires financial assurance to be provided for certain quantities of licensed materials with half-lives greater than 120 days, therefore an exemption from the regulations would be necessary in order to omit long-lived materials in incidentally activated removable components from financial assurance. An exemption had not been granted.

Yale University Issue 2

You stated that NRC written guidance for the preparation of accelerator production licenses in NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Material Using an Accelerator" (NUREG-1556, Vol. 21) did not contain any discussion on how to determine the appropriate possession levels for byproduct material activation products.

NRC Response

The NRC agrees that the NUREG-1556, Vol. 21 guidance does not contain a discussion of how to determine the appropriate possession quantities for incidentally activated materials. The NRC understands that the inventory of incidentally activated materials will vary for each licensee, according to a variety of factors such as: the type of accelerator used; the types of components used in the accelerator; the materials comprising the accelerator, its components and the facility it is housed in; and the operating time of the accelerator. The NRC expects that the licensee operating the accelerator to have the best knowledge of their facility and enabling them best to determine the expected inventory of incidentally activated materials.

We note that NUREG-1556, Vol. 21, Section 8.5.2 does discuss the financial assurance requirements. It states, in part, that "Most accelerator production facilities will be required to comply with the financial assurance requirements because of the activation materials that are

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produced during operation.” In addition, incidentally activated materials are shown as line items on the Sample License in NUREG-1556, Vol. 21, Appendix D, without specifying whether they are in fixed or removable components, and in quantities greater than those you requested. Most accelerator production facilities are commercial businesses which require higher license limits than you requested.

In addition, NUREG-1556, Vol. 21, Section 8.5.1 includes the following paragraph:

“The anticipated possession limit in becquerel (Bq) or curie (Ci) for each radionuclide should also be specified. Possession limits must include the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radionuclide with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2, Financial Assurance and Recordkeeping for Decommissioning.”

The NRC believes this paragraph clearly indicates that all material with half-lives greater than 120 days, in all forms possessed under the license, must be included in the license limits and that financial assurance must be provided for these materials.

Yale University Issue 3

You stated that Yale University considered only the activation in fixed components in the information provided to the NRC regarding financial assurance, and provided as Attachment 2 to your July 25, 2013, letter, Section 5.2 of your license application. You further stated that the NRC approved this approach.

NRC Response

The NRC acknowledges that Section 5.2 of your application included calculations of long-lived activation materials only for the fixed parts and concrete. However, statements made earlier in this section refer to long-lived activation materials in both removable and fixed components. Furthermore, although Section 5.2 states that the fixed components would be the main object of future decommissioning, this section does not state that long-lived materials in removable components would not be considered in determining financial assurance needs. The NRC notes that Item 4 of your response letter dated October 8, 2010, specifically discusses the long-lived materials in removable components such as Havar foils, and proposed a limit of 25 millicuries for the those materials. The quantity requested for the removable components was the same as that for the fixed components. Given your unity rule calculation results of 0.5019 for the fixed components, and your explanation that removable components were expected to be disposed of periodically, the NRC believed that you would be able to manage the actual inventory of material in both fixed and removable components such that the prescribed amount of \$225,000 you provided for financial assurance could be accepted.

Enclosure

The NRC further notes that, in the Certification of Financial Assurance that you provided with the letter dated October 26, 2010, the listing of long-lived radionuclides under License No. 06-00183-08 includes "Any byproduct material with atomic numbers 1 through 83 and half-life greater than 120 days in activation products, 50 millicuries total." The NRC understood this line item to include the 25 millicuries in removable components plus the 25 millicuries in fixed components; therefore, the NRC believes that you were providing financial assurance for both removable and fixed components.

The NRC acknowledges that the new license issued on October 27, 2010, was missing the license condition limiting your total inventory to the quantities for which the prescribed amount was provided. The license condition was included in the Corrected Copy issued March 21, 2011 (and further revised in the Corrected Copy issued April 26, 2011) to constrain the inventory to those quantities for which the first prescribed level of \$225,000 financial assurance was provided. The NRC notes that this license condition is listed as a constraining limit for four line items on the license (8.G, 8.H, 8.I, and 8.J), including long-lived activation materials in both removable components and in fixed components.

Yale University Issue 4

You stated that the NRC Safety Inspection Report and Compliance Inspection dated September 27, 2011, did not identify any violations, which you believe indicates that the financial assurance was fully compliant with NRC regulatory requirements.

NRC Response

The NRC's regulatory oversight program includes inspections of only selected aspects of a licensee's program and is conducted on a sampling basis. Each inspection, therefore, is not a comprehensive inspection of all aspects of a licensee's program for every inspection. Consistent with this approach, the NRC "Safety Inspection Report and Compliance Report" form states that the inspection "...consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector." Based on the items selected by the inspector for review during the September 27, 2011, the inspector did not identify any violations. Based on the items selected for review during the most recent inspection that began at your facility on May 14, 2013, and continued with the information provided to the inspector on May 23, 2013, a violation of the financial assurance requirements was identified.

Yale University Issue 5

You stated that, based on your current understanding, you do not believe that the NRC should approve any accelerator production facility at the \$225,000 prescribed amount of financial assurance. You stated that the NRC regulations and guidance do not reflect the relative hazards of materials that came under NRC jurisdiction as a result of the Energy Policy Act of 2005, thereby imposing more stringent requirements for some radionuclides such as cobalt-57 which is an incidental activation material from accelerator production activities. You further stated that, as activation materials are neither purchased materials nor created intentionally,

and are not desired by the licensee, you do not understand why the NRC requires these materials to be included in the financial assurance calculation.

NRC Response

The NRC agrees that, under the current regulations, it is unlikely that most accelerator production facilities can maintain the inventory of materials below the quantities limited by the \$225,000 prescribed financial assurance level. However, licensees that operate accelerators infrequently, or for short durations, may be able to demonstrate that they can meet those quantity constraints. The NRC agrees that the current regulations are not yet revised to consider the relative hazards of some of the materials that came under NRC jurisdiction as a result of the Energy Policy Act of 2005. Until such time as the regulations change, licensees are required to comply with current regulations. Activation materials with half-lives greater than 120 days have always been required to be considered for decommissioning financial assurance, but prior to the Energy Policy Act of 2005, only materials licensees who operated nuclear reactors, or received materials activated in a nuclear reactor, were familiar with this issue. Because these materials are not wanted, and because these activation products can be costly to remove and dispose of when it comes time to decommission a facility, it is very important that financial assurance be provided for the decommissioning of facilities that have incidental activation of materials.