

TRIP REPORT

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MEMORANDUM TO: Aptuit, LLC File

LOCATION: Aptuit, LLC
10245 Hickman Mills Drive
Kansas City, Missouri 64134

LICENSE NO.: 24-15595-01

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PARTICIPANTS: Aptuit
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U.S. Nuclear Regulatory Commission (NRC) *ml 7/10/12*
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PURPOSE: TO DISCUSS NRC RESPONSE LETTER DATED MAY 11, 2012 TITLED "NRC REVIEW OF LICENSE AMENDMENT REQUEST TO APPROVE DECOMMISSIONING PLAN FOR APTUIT, LLC (MAIL CONTROL NO. 576804)" (ML12132A374) AND LICENSE AMENDMENT REQUESTING RELEASE OF PORTIONS OF THE FACILITIES FOR UNRESTRICTED USE (MAIL CONTROL NO. 577059) (ML120590849)

BACKGROUND: In a document dated January 13, 2012 (ML12181A520), the Aptuit, LLC (licensee), requested the U.S. Nuclear Regulatory Commission (NRC) amend Byproduct Material License No. 24-15595-01 to incorporate a Decommissioning Plan (DP) for Aptuit's Scientific Operations business line of the Kansas City, Missouri facility into its license. The Amendment was tracked under Mail Control No. 576804.

In a letter dated February 27, 2012 (ML120590849), the licensee requested NRC's review and approval of a Clinical Trial Supplies (CTS) business line Final Status Survey Report (FSSR). The Amendment was tracked under Mail Control No. 577059.

During a review of the above requested license amendments, the NRC determined that the licensee was requesting two amendments to terminate License No. 24-15595-01.

The NRC initiated an acceptance review and in a letter to the licensee dated May 11, 2012 (ML12132A374) stated that NRC determined that the DP did not contain sufficient information to

allow the staff to begin a detailed technical review. Therefore, the amendment request under Mail Control No. 576804 was voided.

Due to the multiple amendment requests and NRC's determination that the DP did not contain sufficient information to allow NRC to begin a technical review, the NRC that a site visit was necessary to discuss the licensee's future decommissioning actions and tour the licensee's facility.

Discussion: The NRC staff met with the Radiation Safety Officer (RSO) and the licensee's consultant representatives and discussed the following:

1. Contained within the two amendments, the licensee submitted information to the NRC to allow unrestricted release of former radiation use and storage areas in Buildings A, B and E. The licensee had discussed that certain areas were covered by the DP, which potentially required additional remediation, and other areas the licensee had requested for immediate unrestricted use under areas denoted in the FSSR.
2. When the licensee requested incorporation of a DP into the license, the licensee was unsure of the extent of radiological contamination in certain portions of the facility. In discussions with the licensee, the RSO and the consultant's representatives informed the NRC that additional characterization may be necessary, under a DP, to determine whether remediation efforts are necessary to comply with NRC release criteria. The NRC believed that a DP may be necessary to perform an adequate characterization of the facility as the licensee does not possess specific procedures that may be necessary to perform such a characterization.
3. The licensee informed the NRC that two business lines within the facility had used licensed material and that the managers had decided the NRC amendments would be sent to NRC, one for each business line. Thus the two amendment requests.
4. The inspector discussed the contents of the letter dated May 11, 2012 and the reasons NRC decided that an insufficient amount of information was available for a technical review of the DP. Specifically, a significant amount of time focused around additional characterization of the facility and the procedures necessary to perform that characterization to determine if the site could be releasable for unrestricted use under NRC regulations.

During the meeting, NRC staff outlined NRC decommissioning and license termination requirements. The NRC staff discussed the need for the licensee to submit information associated with an adequate characterization, which may require a DP, prior to NRC approval of remediation activities, which also may require a DP. The licensee also recognized the difficulty in submitting two amendments for a termination request of a single license as a termination of the license could not be granted by the NRC until the entire facility met the conditions of NRC unrestricted release criteria.

Conclusion: The licensee agreed to the following:

1. Discuss with appropriate licensee managers of both business lines to determine if a single amendment could be sent to the NRC rather than two amendments for unrestricted release of the facility within 30 days of this memo.

2. Determine whether additional characterization would be necessary to determine if all areas could be released for unrestricted use. To perform such a characterization, the licensee may be required to submit a DP with procedures to sure public health and safety are protected from such characterization work. Remediation efforts would be contingent on the results of the characterization results within 60 days of this memo.

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