

April 18, 2013

Mr. Clinton J. Gregg
Radiation Safety Officer
Aptuit, LLC
10245 Hickman Mills Drive
Kansas City, Missouri 64134-0708

SUBJECT: NRC REVIEW OF LICENSE AMENDMENT REQUEST REGARDING
DECOMMISSIONING PLAN AND REQUEST FOR ADDITIONAL INFORMATION –
APTUIT, LLC (MAIL CONTROL NO. 579062)

Dear Mr. Gregg:

This refers to your letter dated August 30, 2012 (ML12248A095) requesting approval of a Decommissioning Plan (DP) for the Active Pharmaceutical Ingredients (API) (i.e. radiosynthesis) laboratories and systems, including legacy ductwork and a spill area in an analytical laboratory (B3-298), as required by Title 10 of the Code of Federal Regulations (CFR) 30.36(g)(1). The licensee submitted a complete revision of the DP on February 28, 2013 (ML13053A398) as part of their response to NRC's letter requesting additional information dated February 7, 2013, (ML13038A630).

Our review of the DP identified issues with potential contamination of building sink and floor drains which may need to be addressed as part of the DP associated with sink drains, floor drains and the pH treatment building. Specifically during NRC's technical review of the DP, the NRC noted that your facility had historically disposed of liquid effluent containing licensed material via the sanitary sewerage system, as documented in NRC Inspection Reports No. 030-09415/1996-001, 030-09415/1991-001 and 030-09415/1985-001.

On page 19 of the resubmitted DP dated February 28, 2013, the licensee stated "Water from sink drains and floor drains in the API laboratories goes to an on-site pH treatment building, where it is adjusted if necessary prior to disposal to the city sewage system. There are no holding tanks between the drains and the pH treatment building. Drain disposal of radioactive materials was not allowed." In addition, the licensee also stated "However, contamination in the API laboratory sinks is found during the weekly routine surveys, and some of the highest results from the scoping survey conducted on December 15, 2011 were in the sinks, indicating the potential for contamination in the drains."

Based upon the information submitted in the DP, the NRC does not believe that a sufficient amount of information has been provided to properly characterize and document whether a DP is necessary as a result from previous potential residual contamination in sink drains, floor

drains and the pH treatment building. In a letter dated July 26, 2012 (ML12209A411), the licensee stated, in part, the DP will be used as part of the license termination request. If that is your intention, then the DP should address the remediation of all buildings, structures and components associated with historical site operations, including liquid effluent to demonstrate compliance with 10 CFR 30.36 (g)(1).

In telephonic discussions with Mr. Michael LaFranzo, of my staff, on April 10, 2013, you indicated that evaluations of the liquid effluent residual contamination within the drainage and sewer pipe system at the facility was performed. However, bear in mind that the outcome of this evaluation was not provided to the NRC. Therefore, the NRC cannot make a determination on whether residual contamination resulting from liquid effluent disposal through the sanitary sewer system could significantly impact a potential dose to a member of the public, or, in conjunction with other residual contamination at the facility, would be less than the regulatory limits as permitted by 10 CFR 20.1402 and, by extension, support license termination.

In making the above determination, the licensee is requested to review its Historical Site Assessment to ensure all drain pathways to the sewerage system have been identified and evaluated both within API area, the pH treatment building and any other location controlled by the licensee. Failure to completely identify and evaluate any and all areas concerning residual contamination within the pathways to the sewage system could result in additional delays in NRC approval of the DP.

The licensee is requested to provide NRC information associated with its plans to address the drain and sewer pipe system within 30 days from the date of this letter.

In addition, the NRC requests that the licensee provide NRC with your proposed procedures necessary to ensure proper characterization of radioactive waste as will be used in the waste manifest. The procedures should include, but not limited to survey techniques and assumptions used to determine total activity for each radionuclide.

The NRC will continue its technical review of the DP and will inform the licensee when the review is complete. NRC's review will be complete when all pertinent information from the licensee is received and the NRC has completed its independent evaluation of the information to ensure compliance with all applicable regulations.

If you have any questions concerning the enclosed information, please contact Michael LaFranzo of my staff at 630-829-9865.

C. Gregg

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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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA by Wayne J. Slawinski Acting for/

Christine A. Lipa, Chief
Materials Control, ISFSI and
Decommissioning Branch
Division of Nuclear Materials Safety

Docket No. 030-09415
License No. 24-15595-01
Mail Control No. 579062

cc: Kevin Duffield
State of Missouri

C. Gregg

- 3 -

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