UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 2019

Brian Baker
Center Director
U.S. Food and Drug Administration
Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MA 01890

SUBJECT: THE WINCHESTER ENGINEERING AND ANALYTICAL CENTER – LETTER INDICATING THAT REMEDIATED AREAS MEET THE REQUIREMENTS OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*, 20.1402 FOR UNRESTRICTED RELEASE

Dear Mr. Baker:

By letter dated September 13, 2018, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18215A047), the Nuclear Regulatory Commission (NRC) responded to the Food and Drug Administration (FDA) submission of a Decommissioning Plan (DP), Environmental Report, and Statement of Intent Package (ADAMS Accession No. ML17215A951) to the NRC for the Winchester Engineering and Analytical Center (WEAC) located at 109 Holton Street, Winchester, Massachusetts.

The NRC staff evaluated the appropriate regulatory process to address the identified contamination which resulted from past Atomic Energy Commission activities and is not associated with current licensed activities. The NRC staff notes that the U.S. Department of Energy previously eliminated the site from consideration for inclusion in the Formerly Utilized Sites Remedial Action Program (FUSRAP) (ADAMS Accession Nos. ML18215A059, ML18215A057). Nonetheless, recognizing the FDA's efforts to remediate the area and as part of our oversight function in the interest of public health and safety, the NRC staff arranged for an independent confirmatory survey to verify that the residual radioactivity met the current radiological criteria for unrestricted use of a site under title 10 of the *Code of Federal Regulations (10 CFR)*, 20.1402 (the residual radioactivity is less than the Derived Concentration Guideline Levels (DCGLs) proposed in the submitted DP)[1]. Also, to facilitate proposed construction at the site and upon satisfactory completion of an independent confirmatory survey, the NRC staff stated it would provide a letter stating that the remediated areas meet the requirements of 10 CFR 20.1402 for unrestricted use.

In its September 2018 letter, the NRC staff indicated that the final status surveys conducted by FDA, dated August 16, 2018, appeared to indicate that the residual radioactivity levels had been reduced below the established DCGLs (ADAMS Accession No. ML18232A458). Further, the

[1] The NRC staff notes that the DP also included As Low As Reasonably Achievable (ALARA) Concentration Guidelines (ALARA CGs); however, NUREG-1757, Volume 2, Appendix N states that an ALARA assessment is generally not necessary for remediating soil by disposal at a licensed waste facility for unrestricted release due to the high costs involved. Therefore, the NRC did not consider the ALARA CGs when evaluating the site against the unrestricted release DCGLs.

analyses, remediation, and surveys submitted to the NRC appear to have been performed consistent with NRC guidance for decommissioning found in NUREG 1757, Volume 2, Revision 1. Subsequently, the NRC staff arranged for an independent confirmatory survey to verify that the residual radioactivity met the radiological criteria for unrestricted use of a site under 10 CFR 20.1402. Our contractor, Oak Ridge Institute for Science and Education (ORISE), conducted that independent confirmatory survey during the period of October 9–11, 2018. This confirmatory survey identified several hotspots requiring further remediation and/or consideration with respect to meeting the criteria for unrestricted use. FDA then instructed Northwind Solutions, its contractor, to perform additional remediation of the elevations and resample to demonstrate the elevations were adequately remediated.

Following remediation of the hotspots and subsequent soil grab sampling, the NRC took possession of select split samples from the remediated areas and provided them to our contractor, U. S. Department of Energy – Idaho Operations Office, Radiological and Environmental Sciences Laboratory (RESL), to be independently analyzed. The results of the select split sample analysis are reported in the ORISE finalized report (Adams Accession Number ML19074A144). FDA also submitted, to the NRC, a supplemental survey report (ADAMS Accession Number ML19073A209). As such, based on both the FDA's survey reports and the ORISE confirmatory survey report, the NRC now has reasonable confidence that the remediated areas, identified as survey units 1, 2, and 3, meet the requirements of 10 CFR 20.1402 for unrestricted use.

As you are aware, survey unit 4, which was included in the FDA DP, is not addressed by this letter. ORISE identified an anomaly in this survey unit such that some, or all, of the survey unit could be considered a Class 1 survey unit. However, it is the NRC staff's understanding that the anomaly is not located in a generally accessed area and that proposed construction activities at the site will not disturb the area. Also, the FDA has indicated it will address the suspect area in the future. As such, the NRC staff finds it adequate that FDA simply restrict ground disturbing activities in the immediate area of the anomaly until such time as it is adequately assessed or remediated, as needed.

The NRC staff does not plan to amend the FDA's license to release the remediated areas for unrestricted use given the FDA's plans to continue licensed activities in the subject area. Accordingly, the NRC staff recommends that upon receipt of this confirmatory letter, the FDA withdraw its license amendment request for a partial site release.

We continue to recommend that the FDA work with the U.S. Army Corps of Engineers responsible for the FUSRAP program to determine whether additional FUSRAP material exists on the site or on adjacent properties.

Should you have any questions concerning this request for additional information, please contact James Smith, Project Manager at 301-415-6103 or the undersigned at 301-415-6631.

Sincerely,

/RA/

Stephen Koenick, Chief
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-04675
License No.: 20-08361-01
Control No.: 592468

cc: E. Malkin, FDA/WEAC

SUBJECT: THE WINCHESTER ENGINEERING AND ANALYTICAL CENTER– LETTER INDICATING THAT REMEDIATED AREAS MEET THE REQUIREMENTS OF 10 CFR 20.1402 FOR UNRESTRICTED RELEASE **DATE March 20, 2019**

DISTRIBUTION:
ASchwartzman, NMSS GChapman, NMSS MRoberts, RI
SHamman, RI

ADAMS Accession No.: ML19073A063 ***via email**

OFFICE	DUWP	DUWP	DUWP	OGC
NAME	JASmith	SAchten*	SKoenick	IIrvin*
DATE	3/14/19	3/15/19	3/20/19	3/20/19

OFFICIAL RECORD COPY