UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

December 5, 2017

Brian Baker, Director
Departmernt of Health and Human Services
Food and Drug Administration
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890-1197

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 592468

Dear Mr. Baker,

By letter dated July 21, 2017, the Department of Health and Human Services, Food and Drug Administration (FDA), submitted a decommissioning plan (DP), Environmental Report, and Statement of Intent (Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML17215A951) to the U.S. Nuclear Regulatory Commission (NRC) for the Winchester Engineering and Analytical Center (WEAC) located at 109 Holton Street, Winchester, Massachusetts. The FDA proposes a partial site release of soil areas at the WEAC to comply with the requirements of 10 CFR 30.36(g) and enable the construction of new buildings on the site in the future.

The NRC staff performed an acceptance review (ADAMS Accession No. ML17275A831) in accordance with the guidance provided in NUREG-1757, Consolidated Decommissioning Guidance, Volume 1, Revision 2 and determined the application was acceptable to begin its detailed technical review. While conducting its detailed technical review the staff determined that additional information is required to complete its review. Please provide the following additional information:

1. The provisions of 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), and 10 CFR 70.38(g)(4)(v) require that licensees provide "a plan for assuring the availability of adequate funds for completion of decommissioning. "Section A.13 of NUREG-1757, Vol. 3, Rev. 1, provides general guidance on preparing the financial assurance demonstration in a DP under 10 CFR 30.36, 10 CFR 40.42, and 10 CFR 70.38. Section A.13.1.4 specifies that "in general, the cost estimate should be adjusted to account for completed decommissioning activities, for inflation and other changes in the prices of goods and services (e.g., waste disposal cost increases), for changes in facility conditions, and for changes in decommissioning procedures."

   The FDA DP does not include a description of the means the licensee will employ to adjust the cost estimate and associated funding level to assure the availability of adequate funds for completion of decommissioning. To ensure compliance with the

regulatory requirement and that adequate funding is available if needed, describe the means to adjust the cost estimate and associated funding level.

2. The provisions of 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), and 10 CFR 70.38(g)(4)(v) require that licensees provide "an updated detailed cost estimate for decommissioning" when submitting the DP. Section A.13.1.1 of NUREG-1757, Vol. 3, Rev. 1, states that "Cost estimates should be updated to reflect completed decommissioning activities, current contamination levels, inflation, changes in waste."

   The required soil remediation work is described in Section 8.3 of the DP. In Section 8.3, FDA states that "all disposables (mostly personal protective equipment) will be placed into Rad-Bags and disposed of with site soils in B-25 boxes. North Wind anticipates generating between two and four boxes (approximately 85 cubic feet net volume each)." Appendix E to FDA's DP contains the details of the decommissioning cost estimate, as prepared by North Wind Group, the third-party contractor. North Wind's price quote is broken into two separate tables: (1) decommissioning costs exclusive of a deep soil remediation option, and (2) decommissioning costs associated with a deep soil remediation option. The first table contains the costs of packaging (i.e., labor, one roll of Rad-Bags, two B-25 boxes, and other equipment), shipping, and disposal. The second table, which covers a deep soil remediation option, does not appear to include soil packaging, shipment, or disposal costs.

   To ensure that adequate funding is available include these costs or provide a justification for excluding soil packaging, shipment, and disposal costs from the deep soil remediation cost estimate.

3. The provisions of 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), and 10 CFR 70.38(g)(4)(v) require that a decommissioning plan contain a comparison of the decommissioning cost estimate "with present funds set aside for decommissioning." Section A.13.1.3 in NUREG-1757, Vol 3, Rev 1 states that "the Decommissioning Funding Plan (DFP) must include a comparison of the amount of the updated cost estimate for decommissioning to the amount of coverage provided by the licensee's financial assurance mechanism(s). If the cost estimate exceeds the financial assurance coverage, the licensee must increase the amount of coverage to at least the amount of the cost estimate."

   The total Decommissioning Cost Estimate (DCE) identified in Section 15.1 of the DP is $572,807.84. The submission includes a contract awarded by the FDA to a third-party contractor in charge of the decommissioning activities in the amount of $432,752.73, with optional funding of $25,493.54 for deeper soil remediation (if needed). The difference between the contract and the DCE (i.e., the amount of required financial assurance) is $114,561.57. However, the financial assurance mechanism included in the DP is a statement of intent for $114,500. The financial assurance mechanism, therefore, is $61.57 short. To ensure compliance with the regulatory requirement and that adequate funding is available increase the financial assurance to cover the full decommissioning cost estimate.

4. The provisions of 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), and 10 CFR 70.38(g)(4)(v) require that a decommissioning plan contain "a plan for assuring the availability of adequate funds for completion of decommissioning."

The FDA's submission includes a contract awarded by the FDA to a third-party contractor in charge of the decommissioning activities in the amount of $432,752.73, with optional funding of $25,493.54 for deeper soil remediation (if needed). The difference between the contract and the DCE will determine the amount of required financial assurance. The contract submitted with the DP, however, is not fully-executed (i.e., boxes 30a, 30b, and 30c in the SF144 are not completed). In addition, the contract document does not contain a description of the full scope of work covered by the contract. To ensure compliance with the regulatory requirement and that adequate funding is available: (1) confirm the contract has now been executed, funding has been obligated, and the contractor agrees to the full terms of the contract, and (2) provide the contract's scope of work in order to confirm the contract covers all activities identified in the DP.

5. The provisions of 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), and 10 CFR 70.38(g)(4)(v) require that a decommissioning plan contain "a plan for assuring the availability of adequate funds for completion of decommissioning." Section A.11 in NUREG-1757, Vol 3, Rev. 1 states that "A statement of intent should demonstrate that a government licensee can request special funding from its funding body when necessary. This is different from a guarantee or commitment of a licensee's own funds. Therefore, it is not satisfactory for a licensee to demonstrate that it is authorized to enter into contracts and guarantees committing its own funds or to promise to allocate funds from its operating budget, from other general appropriations (either current or future), or from other internal resources."

   The FDA's statement of intent is executed by the FDA's Deputy Commissioner for Operations/COO. Attached to the statement of intent is an excerpt from a Staff Manual Guide, which indicates that the Deputy Commissioner for Operations/COO has the authority to perform all delegable functions of the Commissioner. The documentation does not state that the authority to request and obtain funding is one of the delegable functions. A statement of intent should demonstrate that a government licensee can request funding from its funding body when necessary. To ensure compliance with the regulatory requirement and that adequate funding is available, provide additional detail confirming that the Deputy Commissioner for Operations/COO has authority to request funding from the FDA's external funding body (i.e., the Congress of the United States of America, through the U.S. Department of Health and Human Services and the Office of Management and Budget).

6. The provisions of 10 CFR 51.45(b) and (c) require, in part, that an environmental report contain a description of the proposed action, the impacts of the proposed action on the environment, any adverse impacts that cannot be avoided, and an analysis that considers and balances the impacts of the proposed action and any alternatives. In the Executive Summary and in sections 2.1.2 and 5.0 of the Environmental Report, the FDA states that "suitable" or "an approved" fill material will be used to backfill excavation areas prior to the areas being returned to original grade. The source and anticipated volume of this fill material is not identified.

   Please provide the source and anticipated volume of fill material to be used in backfilling excavated areas. The NRC requests this additional information to inform its assessment of transportation impacts pursuant to its preparation of an Environmental Assessment per 10 CFR 51.21.

7. As required by 10 CFR 40.42(g)(4)(i), the licensee needs to provide sufficient site groundwater characterization data to allow NRC staff to determine the radiological status of the groundwater at the facility. The status of groundwater presence beneath the site appears confusing. The DP states that the depth to groundwater in this region is greater than 6 feet below ground surface (bgs), and the groundwater was not measured in overburden soil or in soil investigative borings advanced to depths of up to 26 feet bgs at the site based on an environmental site assessment report (Sanborn Head, 2016) (Sec. 3.5.2). The statement above provides the impression that groundwater was observed at the site. However, Sect. 4.4 states that groundwater has not been encountered in historical borings down to 26 feet bgs.

   Please clarify the groundwater status at the site, which may be found in the following two references, along with the associated boring logs and field notes:

   1) Sanborn Head. 2016. Phase I Environmental Site Assessment with Limited Subsurface Investigation 109 Holton Street Woburn and Winchester, Massachusetts; Sanborn Head; April 6, 2016.

   2) GW A. 1994. Environmental Assessment: US FDA WEAC; Groundwater Associates, November 1994.

8. The regulation in 10 CFR 20.1501 requires adequate surveys to determine the quantities and concentration of residual radioactivity.

   The DP identifies the primary contaminants to be those associated with uranium ore. Because this has the potential to be collocated with thorium ore, what evaluation was performed for natural thorium in the samples previously collected (i.e., Th-232 + decay chain)? Also, because the site has operated under a variety of licenses in the past, the methods of evaluating just U-238/U-234, Th-230, and Ra-226, may create a situation where another contaminant is present at significant levels is not considered. Explain how you plan to analyze samples to check for the presence of radionuclides other than those noted for natural uranium and its decay chain.

9. The regulation in 10 CFR 20.1204 states, in part, that the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

   The DP states you are primarily looking for uranium ore but that it is possible that uranium by-product or chemically separated uranium may also be present. The sample analyses provided in Figure 13 would seem to indicate the ratios of the radionuclides may fluctuate a fair amount. However, when establishing the air monitoring and effluent monitoring, you assume equal activity contributions from each of the major radionuclides. Provide the justification for this assumption.

10. The decommissioning criteria in 10 CFR 20.1402 states, in part, that a site will be considered acceptable for unrestricted release if residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year. As such licensees must consider residual radioactivity in all media (soil, groundwater, surfaces) in the area being addressed if such apply.

In multiple places in the DP it is stated that the DP is not applicable to structures or equipment in the impacted area. However, it also states that some surfaces (concrete pads, asphalt, etc.) will be considered in the final status survey. It further states that the criteria in *Policy and Guidance Directive FC 83-23: Termination of Byproduct, Source, and Special Nuclear Material Licenses* (NRC 1987), will be used to survey any surfaces to be left in the impacted area. The release criteria for decommissioning is dose based as opposed to the criteria in FC 83-23. Please provide a dose based criteria for surface activity as well as the methods that will be used to consider both the remaining surface activity in the impacted areas as well as remaining activity in soil when comparing to the dose criteria in 10 CFR 20.1402. You may note that the NRC staff is differentiating between materials clearance criteria (i.e., materials being released from the site under license) vs. decommissioning criteria (i.e., materials that will remain on site after license termination).

11. The regulation in 10 CFR 20.1501 requires adequate surveys to determine the quantities and concentration of residual radioactivity. The DP further states that it is following MARSSIM methodology for the final status survey.

    In the Final Status Survey (section 14) it states that 16 gridded/random sample locations are specified initially for each survey unit (Figure 21). Elsewhere it states that 14-16 sample locations are anticipated per survey unit. Provide the justification for the number of sample locations planned in the survey units.

12. The regulation in 10 CFR 20.1501 requires adequate surveys, including subsurface, to determine the quantities and concentration of residual radioactivity.

    Provide the time frame for when the asphalt was placed in the impacted area. This will help staff consider whether there may be soil contamination beneath the asphalt since only small segments of asphalt are planned to be removed.

13. The decommissioning criteria in 10 CFR 20.1402 states, in part, that a site will be considered acceptable for unrestricted release if residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year. Staff understand that the licensee anticipates a partial site release but it is unclear exactly what portions of the site the DP is addressing and which are being requested to be released from the license. It is also unclear whether structures must be considered in the DP.

    Section 4.1 of the DP states that the DP does not address buildings/structures. Considering that the purpose of the decommissioning effort is presumably to clear land and release property so that a structure can be built, staff presume this means all significant structures and ground coverings in the northern section of the site will be removed prior to the decommissioning effort (assuming this is allowed by license) leaving only soil and possibly debris in the soil to be considered. The DP then goes on to discuss the ground beneath the existing structures which will require concrete boring and possibly moving concrete pads. In Figure 21, the DP discusses Survey Unit 4 which contains the main building on the site and which staff previously were not considering part of the decommissioning effort. However, in section 14.2.1, it states soil under the main plant and adjoining structures will not be addressed whereas soil under structures in the northern plant section are addressed (staff note that Building 13 is omitted from

the discussion).

Clarify the intent to decommission/remove structures and ground coverings such as asphalt or concrete pads in the partial area that is planned to be decommissioned. Also clarify exactly what areas of the site are being addressed by the DP and the FSSP.

In order to continue prompt review of your application, we request that you submit your response to this letter within 60 calendar days from the date of this letter.

If you have any questions regarding this request for additional information, please contact Varughese Kurian, Project Manager, at 301-415-7426.

Thank you for your cooperation.

Sincerely,

Stephen Hammann, Senior Health Physicist
Decommissioning, ISFSI, and Reactor HP Branch
Division of Nuclear Materials Safety
Region I

License No. 20-08361-01
Docket No. 03004675
Mail Control No. 592468

cc: Edmond Baratta, Radiation Safety Officer
Elon Malkin, Decommissioning Project Manager

the discussion).

Clarify the intent to decommission/remove structures and ground coverings such as asphalt or concrete pads in the partial area that is planned to be decommissioned. Also clarify exactly what areas of the site are being addressed by the DP and the FSSP.

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Thank you for your cooperation.

Sincerely,

Stephen Hammann, Senior Health Physicist
Decommissioning, ISFSI, and Reactor HP Branch
Division of Nuclear Materials Safety
Region I

License No. 20-08361-01
Docket No. 03004675
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cc: Edmond Baratta, Radiation Safety Officer
Elon Malkin, Decommissioning Project Manager

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