From:	Ullrich, Elizabeth
To:	Willie Bremer
Cc:	Victor Letourneaut; Darrin John
Subject:	request for additional information July 16, 2019
Date:	Tuesday, July 16, 2019 5:23:00 PM

Up-Side Management company
LN 09-35501-02
DN 030-39124
Control No. 609627

Mr. Bremer,

1. You stated that wish to be authorized for 1000 curies of thorium-232 as coatings on optical lenses. Please note that 1000 curies of thorium-232 is equivalent to 9.1 E+6 kilograms (approximately 10,000 tons) of thorium-232. This seems excessive, particularly for optical coatings on lenses as the mass of thorium-232 does not include the glass and other components of the lenses. Provide a basis for the need for this quantity, and why this is separate line item from the quantities of source material already requested. Alternately, provide a more reasonable estimate of the amount of thorium-232 required to be authorized.

2. You stated in your October 4, 2018, response that you requested 1 curie of I-125 in sealed sources; 10 curies of I-131 as sealed sources; 90 curies of Sr-90 in any form, and 1000 curies of Th-232 as optical coatings on lenses because these quantities are similar to those on licenses you listed in your footnote 1. We have reviewed those licenses, and only one of those referenced licenses listed these materials and the license was since terminated. If you believe you still need to be authorized to possess such large quantities of these materials, please provide the following:

    a. A list of the manufacturer names and model numbers for the sealed sources and/or devices containing I-125 and/or I-131 for which you plan to provide services and commercial waste activities.
    b. Bioassay procedures for radioiodine (your current bioassay procedures do not include suitable bioassay procedures for radioiodines.
    c. Confirm that you understand that any project in which 10 curies of iodine-131 will require consideration of an emergency plan in accordance with 10 CFR 30.32(i).
    d. Procedures for handling millicurie to curie quantities of strontium-90, and bioassay procedures for Sr-90 which is retained in bone and generally released through the GI tract.
    e. Procedures for bioassay related to Th-232 which can cause very high doses in extremely small quantities.

3. In your original application, Section 10 of your application and Section 5.7 of your Radiation Protection Program referred to the contamination limits as acceptable for release for unrestricted use, and listed them in a table. These limits are the same as were formerly approved in RG 1.86. We requested that you confirm that these limits are applicable ONLY to equipment, not to building surfaces; and to commit to using meeting the Part 20, Appendix E criteria for release of buildings and outdoor areas using screening values, or site-specific values developed using the DandD

code or RESRAD, along with NUREG-1757. In your response dated October 4, 2018, you confirmed this in the "Response to Comments" table, and you altered the text on page 17 to state, "Radioactive material will be controlled in such a manner that the surface contamination for use without restriction does not exceed the levels specified in NUREG-1757 Volume 2, and DOE Order 458.1. These values may be seen in Table 2." HOWEVER, the values in Table 2 do NOT meet the Part 20, Subpart E criteria for alpha emitters and may not meet the criteria for certain beta-gamma emitters; therefore, the values on the table would not meet the NUREG-1757 Volume 2 criteria for release for unrestricted use. An additional statement "Table 2 is only applicable to materials, items, and equipment." was added to the version of the document submitted with your response dated January 16, 2019 but the prior statement still implies that these numbers meet Subpart E. Confirm that you will correct this in all documents where this table is used.

The following refer to the procedures received May 1, 2019. Confirm that these issues will be corrected and revised procedures will be issued.

a. In the radiation and contamination survey procedure, the definition of exposure is not technically correct; if you are using this definition for the purposes only of this procedure, it should so state. Section 5.2.3 states that fixed contamination levels are measured directly; however, this is not correct: only the total contamination can be measured directly but not the fixed contamination. In addition, this is different than the definition of "Fixed contamination" used in other procedures.

b. Section 2.5.1.3 of the bioassay procedure states that, if contamination is an alpha or beta emitter, a 10 milliliter sample of urine would be collected. For such alpha and beta emitters, 10 milliliters may not be a sufficient sample size, and for compounds that are not eliminated through the bladder, a fecal sample or breath sample may be required instead of urine. Confirm that you will revise your bioassay procedures to consider appropriate sample types and quantities for collection, and will distinguish between grab samples used to determine if an uptake may have occurred, and sufficient samples required to determine dose.

c. The control of radioactive material procedures require some corrections.

- contains multiple references to radiography. Your license does not authorize activities with radiography equipment. Radiography activities have specific requirements in 10 CFR Part 34 that would need to be addressed in your license application, and security requirement pursuant to 10 CFR Part 37. This should be explained or deleted.

- Section 3.2.1 defines accountable material, and uses Schedule B of 10 CFR Part 20 as quantities that do not require accounting. This should be corrected,

because the quantities in the table are specific to those manufacturers who are authorized pursuant to 10 CFR Parts 30 and 32 to distribute materials to person who do not require a specific license. Such quantities resulting from activities performed under a specific license are required to be accounted for and disposed of or transferred in accordance with NRC regulations.

- the definition of byproduct material needs to be updated to include all the byproduct material as defined in 10 CFR Part 20 and 30. The definition was revised in 2008.

- Section 6.1.2 is not sufficient for security of radiography equipment, which fall under the security requirements of 10 CFR Part 37

- the contamination limits in Table 6.2 are not current for release of facilities and therefore not acceptable, and certainly do not define radioactive material.

- Section 6.2.5 states that you will post a radiation area at 2 mR/h; the NRC requires posting at 5 mR/h. This must to be corrected.

d. The posting and access control procedures require some corrections.

- The definition of a radiation area is correct in section 3, but section 6.3.4.1 uses 2 mR/h as the criteria for posting a radiation area; the NRC used 5 mR/h. This must be corrected.

- Section 6.3.6.1 and 6.3.6.3 states that a Very High Radiation Area has a dose equivalent of 5 rem in 1 hour. The NRC defines a Very High Radiation Area to be one in excess of 500 rad (5 grays); if the quality factor is 1, this would be 500 rem, not 5 rem. Section 6.3.6.3 makes a distinction between areas that are 5 R/h to 50 R/h, and those that are greater than 50 R/h. The NRC definitions do not include this distinction. This was corrected in Revision 1 which also was submitted.

- Section 6.3.6.3 states that the posting can say “Danger, Very High Radiation Area” in areas that are 5 R/h to 50 R/h. 10 CFR 20.1902(c) requires the posting to state “Grave Danger, Very High Radiation Area” for any very high radiation area. This was corrected in Revision 1 which also was submitted..

- section 6.3.7 requires posting of airborne radioactivity areas if the airborne concentrations exceed 10% of the DAC. The NRC definition in 10 CFR 20.1002 of “airborne radioactivity area” is an area in which airborne concentrations (1) exceed a DAC, or (2) in which an individual could have an intake of 0.6 percent of the ALI (12 DAC-hours) without the use of respiratory protective equipment. Your procedure, although more restrictive than the NRC requirements, would cause over-posting of airborne radioactivity areas in the first case, and could result in lack of posting in the latter. This needs to be corrected.

e. The procedure for decontamination of tools requires some corrections.

- Section 3.2.3 refers to the use of respirators. Confirm that you will meet the requirements of 10 CFR Part 290, Subpart H, if you use respiratory protection.

- table 5.1 labeled as being regulatory limits for release based on gross alpha contamination measurements. Please provide the regulatory reference for this table.

I still do not have a response from our program office regarding the need for an environmental assessment, but will let you know when I do.

Thank you for your attention in this matter,
Betsy

Betsy Ullrich, Senior Health Physicist
USNRC Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
610-337-5040 (office)
240-704-4575 (cell)
Elizabeth.ullrich@nrc.gov