

Mr. David R. Smith
 Radiation Safety Officer
 Shieldalloy Metallurgical Corporation
 P.O. Box 768
 Newfield, New Jersey 08344

January 28, 1998

SUBJECT: REVIEW OF BIOASSAY PROGRAM (TAC NO. L30921)

Dear Mr. Smith:

This refers to your letter dated June 5, 1997, transmitting a draft copy of Procedure No. RSP-010, "Exposure Control - Newfield Facility." This procedure addresses various requirements for the indirect bioassay of potentially exposed individuals. You indicated that this procedure was not submitted for NRC review and approval. Instead, it was submitted as supporting information to assist the NRC in determining if indirect bioassay is an appropriate method to evaluate exposures at your Newfield facility.

Our examination of RSP-010 has identified concerns that need to be addressed to ensure that you are able to meet the requirements of 10 CFR Part 20 using indirect bioassay. To demonstrate compliance with these requirements, please provide the information specified in Part II of the enclosure. This information should be submitted to the NRC within 30 days of the date of this letter.

The NRC staff expects that your procedures will be modified as necessary to address the concerns outlined in Parts I and II of the enclosure. However, it is not necessary to resubmit the procedures. We will examine your bioassay program at a future NRC inspection.

Please reference the above TAC No. in future correspondence related to this request. If you have any questions on this matter, please contact me at (301) 415-5819.

Sincerely,
 Original signed by:
 Heather Astwood
 Licensing Section 2
 Licensing Branch
 Division of Fuel Cycle Safety
 and Safeguards, NMSS

Docket 40-7102
 License SMB-743

Enclosure: As stated

Distribution: w/encl. (Control No. 130S) [PARTIAL]

Docket 40-7102 File Center PUBLIC NMSS R/F
 FCSS R/F FCLB R/F Region I JKinneman, RI

1/1
 N/F-03

[c:\chotoo\shieldal\note.bio]

OFC	FCLB	E	FCLB	E	FCLB	E	FCLB	E	FCLB	E
NAME	SChotoo	SC	SSoong	SS	HAstwood	AA	PShea		MAGalloway	
DATE	1/22/98		1/22/98		1/26/98		1/28/98		1/28/98	

9802240112 980128
 PDR ADDCK 04007102
 C PDR





UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 28, 1998

Mr. David R. Smith
Radiation Safety Officer
Shieldalloy Metallurgical Corporation
P.O. Box 768
Newfield, New Jersey 08344

SUBJECT: REVIEW OF BIOASSAY PROGRAM (TAC NO. L30921)

Dear Mr. Smith:

This refers to your letter dated June 5, 1997, transmitting a draft copy of Procedure No. RSP-010, "Exposure Control - Newfield Facility." This procedure addresses various requirements for the indirect bioassay of potentially exposed individuals. You indicated that this procedure was not submitted for NRC review and approval. Instead, it was submitted as supporting information to assist the NRC in determining if indirect bioassay is an appropriate method to evaluate exposures at your Newfield facility.

Our examination of RSP-010 has identified concerns that need to be addressed to ensure that you are able to meet the requirements of 10 CFR Part 20 using indirect bioassay. To demonstrate compliance with these requirements, please provide the information specified in Part II of the enclosure. This information should be submitted to the NRC within 30 days of the date of this letter.

The NRC staff expects that your procedures will be modified as necessary to address the concerns outlined in Parts I and II of the enclosure. However, it is not necessary to resubmit the procedures. We will examine your bioassay program at a future NRC inspection.

Please reference the above TAC No. in future correspondence related to this request. If you have any questions on this matter, please contact me at (301) 415-5819.

Sincerely,

A handwritten signature in cursive script that reads "Heather Astwood".

Heather Astwood
Licensing Section 2
Licensing Branch
Division of Fuel Cycle Safety
and Safeguards, NMSS

Docket 40-7102
License SMB-743

Enclosure: As stated

Shieldalloy Metallurgical Corporation
Docket 40-7102

PART I

1. Procedure RSP-010 includes Attachment 4, "Technical Basis for the Routine Monitoring Frequency." In this attachment, the monitoring frequency for urine bioassay is determined by postulating a scenario where a worker intakes an amount of thorium-232 (^{232}Th) equal to the ^{232}Th ALI specified in 10 CFR Part 20 Appendix B, Table 1, Column 2, adjusted for particle size. Since the ratio of ^{232}Th to uranium-238 (^{238}U) in ores processed by Shieldalloy Metallurgical Corporation (SMC) is known, and since there is no mechanism known by SMC whereby uranium and thorium are separated prior to intake, assessment of the monitoring frequency is based on detection of ^{238}U in urine. The monitoring frequency is chosen as the number of days after the intake at which the concentration of ^{238}U in urine is expected to be at the minimum detectable concentration (MDC). SMC stated an MDC of 0.03 pCi/L for ^{238}U .
- a. Because SMC ores contain natural uranium, thorium, and daughter radionuclides, an intake of ^{232}Th is accompanied by an intake of all of the other radionuclides present. Because of the dose contribution from the other radionuclides in the mixture, an intake of ^{232}Th at the ^{232}Th ALI (stochastic) would result in a committed effective dose equivalent (CEDE) that is greater than the dose limit of 5 rem.

The value of I_0 in the calculation for the urinalysis monitoring frequency (on page 28 of Attachment 4) should be reduced to 10% of the maximum intake of ^{238}U , as recommended by Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." To determine the maximum intake of ^{238}U , the percentage of ^{238}U in the mixture should be multiplied by the ALI for the mixture or, alternatively, by the most restrictive ALI, which is the ^{232}Th ALI specified in 10 CFR 20, Appendix B, Table 1.

The ALI for the mixture should be determined using the sum-of-fractions technique, as follows:

$$\frac{1}{ALI_{mix}} = \sum \frac{f_i}{ALI_i}$$

Where, ALI_{mix} is the ALI for the mixture, f_i is the activity fraction of radionuclide i , and ALI_i is the ALI of radionuclide i specified in 10 CFR 20 Appendix B, Table 1, Column 2 (or for ^{238}U and ^{232}Th as adjusted for a 2 μm particle size).

For example, if the activity ratio of ^{232}Th to ^{238}U equals 1.6, the ALI_{mix} is 0.024 μCi , and ^{238}U is 6.9 % (by activity) of the mixture. Therefore, the maximum intake of ^{238}U is 0.024 $\mu\text{Ci} \times 0.069 = 0.0017 \mu\text{Ci}$. The bioassay measurement frequency should then be

ENCLOSURE

- based on not more than 10% of this maximum intake ($0.0017 \mu\text{Ci} \times 0.1 = 1.7 \times 10^{-4} \mu\text{Ci}$).
- b. It is not clear that the $^{232}\text{Th}/^{238}\text{U}$ activity ratio equals 4.5. Some references in RSP-010 state "Th/U = 4.5." This implies a ratio of total thorium (Th-227, 228, 230, 231, 232, 234) to total uranium (U-234, 235, 238). In addition, other submittals (for example, letter dated September 26, 1997 from Mr. Smith of SMC to Mr. Weber of NRC) indicate $^{232}\text{Th}/^{238}\text{U}$ ratios of 1.25 ± 0.33 . This should be clarified.
 - c. The urinalysis monitoring frequency specified in the attachment is based on a ^{232}Th to ^{238}U ratio of 4.5. However, as indicated in footnote 3 of the Attachment, the Th/U (assumed $^{232}\text{Th}/^{238}\text{U}$) ratio of SMC ores is variable and can be characterized as 4.5 ± 1.4 . For ores that have a $^{232}\text{Th}/^{238}\text{U}$ ratio greater than 4.5, the sampling frequency would have to be increased to detect ^{238}U in urine at the specified level. Either the most conservative case should be used to establish the monitoring frequency, or procedures should be modified to include adjusted of the monitoring frequency based on a determination of the actual $^{232}\text{Th}/^{238}\text{U}$ airborne ratio for each batch processed at SMC.
 - d. Success of the bioassay program is highly dependent on the minimum detectable concentration (MDC) that can be achieved by the laboratory analyzing the samples. SMC should have procedures to monitor the laboratory's MDC to ensure it remains consistently at 0.03 pCi/L for ^{238}U . Based on the laboratory's performance, it may be necessary to adjust the indirect bioassay monitoring frequency or use air monitoring data instead of indirect bioassay to characterize dose.
 - e. SMC should establish an action level of no greater than 50% of the ALI for the mixture, which will trigger investigation and corrective actions as necessary to ensure that a worker does not receive a dose in excess of the limits specified in 10 CFR 20. These actions may include taking additional bioassay samples to accurately assess the dose.
2. Attachment 4 states that "a sampling frequency of once within 18 days of the *last work experience* with licensed materials...will meet the objective of the monitoring program" [emphasis added]. In addition, 5.7.5.2.1 of Procedure RSP-010 states that routine bioassay measurements will be done "once within 14 calendar days of the *last work experience*" [emphasis added]. The sampling frequency should be correlated to the first day of work with licensed materials in the event that processing extends beyond current work-periods of approximately 4 days.
 3. Regarding Procedure RSP-010, it is not clear that each radionuclide in the mixture (not just ^{238}U and ^{232}Th) is being considered in the dose assessment. This should be clarified.
 4. There is an error in the reported ALI for ^{238}U in Section 5.7.7.1.3 of Procedure RSP-010. The ALI, as approved in your renewed license, is 7×10^4 pCi not 4×10^8 pCi.

- 5. - When indirect bioassay measurements indicate results less than the minimum detectable concentration for the analysis, these values should not be recorded as zero, but should be recorded as the actual number.

PART II

1. Commit to an urinalysis monitoring frequency based on the NRC staff's comments in Part I. Provide a justification for all parameters used to derive the frequency.
2. Commit to an action level of at most 50% of the ALI for the mixture, which will trigger investigation and corrective actions as necessary to ensure that a worker does not receive a dose in excess of the limits specified in 10 CFR 20 Appendix B.
3. Commit to the establishment of procedures to monitor laboratory capabilities to ensure that MDC's remain at or below 0.03 pCi/L for ²³⁸U and to adjust the bioassay program as necessary.
4. Commit to the revision of Section 5.7.5.2.2 of RSP-010 to state "at least once every year if fecal bioassay is used."