Weaver, Deborah

From: Herrera, Tomas
Sent: Wednesday, December 13, 2017 9:52 AM
To: stan@vici.com
Cc: Struckmeyer, Richard; Sepulveda, Lymari
Subject: NRC 2nd Request for Additional Information

Good morning Mr. Stearns,

We have reviewed Valco Instruments Company Inc.'s (Valco) response to the NRC request for additional information dated November 20, 2017, and we have identified some information that we will need in order to complete our evaluation. Please address the following questions:

1. Please resubmit the drawing in Attachment 6 "Radioactive labeling," so that is legible. We intend to use this drawing in the sealed source and device registration certificate. In addition, please provide the overall width of the TGA 3000.

2. In your letter dated November 20, 2017, in your response to A.6, you reference a drawing number 4410016. We were not able to locate a drawing with that number in the response. Please resubmit drawing number 4410016.

3. Please identify the material used in the in the construction of the frame for the TGA 3000

4. Please confirm as part of Valco's Quality Assurance program that Valco will perform a final radiation survey to verify that the radiation levels do not exceed the maximum values stated in the application prior to distribution of the product.

5. In response to Question B.9 you stated that the required analysis can be found in "Radiological Assessment of The Valco TGA 3000," Attachment 14. However, it does not appear that the requirement of Section 32.31(b) was addressed. As stated in our first RAI, Section 32.31(b) requires an applicant for a license under § 32.30 to demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

   Please provide an evaluation which demonstrates that this requirement will be met.

6. In Attachment 6, "Radiological Assessment of the Valco TGA 3000," your evaluation appears to overestimate the potential doses from the
   distribution of the TGA 3000. You stated that the quantity of Am-241 in your product is 20 µCi, which is 12.5% (20 / 160 = 0.125) of the quantity used in NUREG-1717. Also, you stated that 100 units would be distributed annually, which is 1% (100 / 10,000 = 0.01) of the number

assumed in NUREG-1717. Therefore, it appears that for "distribution and transport" the value for "Individual Annual Effective Dose Equivalent" should be (0.4)*(0.125)*(0.01) = 0.0005 mrem, and the other results should be adjusted accordingly.

7. Question B.7 of our first RAI stated that Section 32.30(b)(10) requires the applicant to submit information concerning the proposed method of labeling or marking the product and its point of sale package to satisfy the requirements of § 32.32(b). In addition to providing a new drawing for Attachment 6, "Radioactive labeling," that is more legible and includes the overall width of the device, please ensure that all of the requirements stated in question B.7 are met and are described in your reply.

If you intend to submit the information to us via email, the information should be submitted in an official company letter as an attachment to an
e-mail. Please submit the requested information within 30 calendar days of the date of this email. If we have not received the complete information within 30 days, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete new application.

Thank you,
Tomas Herrera
Sealed Source and Device Team Leader
U.S. NRC
NMSS/MSTR/MSLB
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