

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

December 20, 2018

Ideal Source Quality Assurance ATTN: William B. Yelon, Ph.D., RSO 1309 Overhill Ct. Columbia, MO 65203

# SUBJECT: IDEAL SOURCE QUALITY ASSURANCE REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Yelon:

This letter is in response to your application dated October 8, 2018, requesting a new exempt distribution license.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Control Number 610271.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

W. Yelon

2

If you have any questions, please contact me at (301) 415-5477, or by e-mail at <u>Richard.Struckmeyer@nrc.gov</u>.

Sincerely,

### /RA/

Richard K. Struckmeyer Materials Safety Licensing Branch Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards

Docket No. 030-39136

Enclosure: Request for Additional Information

# W. Yelon

# IDEAL SOURCE QUALITY ASSURANCE REQUEST FOR ADDITIONAL INFORMATION DATED DECEMBER 20, 2018

### ML18296A009 (pkg)

#### ML18353A235 (Letter)

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OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	RStruckmeyer	DWeaver	RStruckmeyer
DATE	12/20/2018	12/20/2018	12/20/2018

## Ideal Source Quality Assurance Application dated October 8, 2018 Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Ideal Source Quality Assurance application for a new exempt distribution license dated October 8, 2018, and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, Chapter 32 (10 CFR 32), Sections 32.11 and is described in the relevant guidance document NUREG-1556, Volume 8, Rev. 1, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/).

- On page 3, under "1. c. Irradiation," and page 35, under "j. Diamond testing," you indicated that no activation of diamonds is expected because they are subjected only to low energy electron irradiation. However, the following elements or isotopes apparently have low thresholds for activation by electron irradiation (due to photoneutron reactions resulting from bremsstrahlung): beryllium 1.67 MeV, <sup>6</sup>Li around 5.5 MeV, and <sup>238</sup>U around 6 MeV. How do you verify that the diamonds to be tested contain none of these?
- 2. On page 5, under "How information in part g was obtained," you stated that the contribution of the <sup>32</sup>P to the total activity can be calculated based solely on the fluence and decay time. Please describe how the contribution of the <sup>32</sup>P to the total activity is calculated based solely on the fluence and decay time.
- 3. Also in the same section on page 5, you stated, "...every packet is subjected to high resolution germanium counting...each packet is treated as unique, and release is based on the specific results of the Ge counting and not the generic impurity distribution." This statement appears to imply that every packet is counted, but information provided later in the application seems to suggest otherwise. Please clarify.
- 4. On page 6, under "Documentation," the following statement is unclear: "A unique certificate will accompany each sale of approved will detail (at least) size, shape and quantity." Please restate this (the above) sentence to make its meaning clear.
- 5. On page 11, under "e. Estimated maximum concentration of the radioisotopes at the time of exempt release," you stated, "The Quality Assurance (QA) program described in Appendix A provides that the average activity in each lot of stones is less than or equal to the exempt limit, based on the sum of ratios criterion." Does this sentence refer to the QA program that was in effect under the previous license, or that will be followed under the new license? Please provide an estimate or assumptions regarding the maximum activity of a stone that might be released, and how this estimate or these assumptions were determined.
- 6. Also on page 11, under "Control method," you stated, "Quality assurance (QA) procedures, described in detail in Appendix have been developed to guarantee that the average activity in the stones is less than or equal to the exempt limit based on the sum-of-ratios criterion. Selection of stones after irradiation to guarantee that not more than one stone per 1000 has

activity equal to or greater than twice the exempt limit (for medium and large stones) is described in the appendix, but will be employed only in special circumstances." A similar statement is made on page 18, under "D. The Quality Assurance Program." Please describe the special circumstances that would apply.

- 7. On page 13, under "D. Information on the Quality Assurance Program," you stated, "The exporter (irradiator) maintains the following equipment ... Nal(TI) detectors for selection (and removal) of stones with activities exceeding twice the exempt limit ... This facility will test stones on a one by one basis after they have been cut from rough according to customer demands. Please explain why the selection (and removal) of stones with activities exceeding twice the exempt limit applies here but apparently not elsewhere in the application.
- 8. On page 18, under "D. The Quality Assurance Program," you stated, "The QA program at the import facility consists of verification of the isotope distribution and average activity, and qualitative evaluation of the activity distribution. An essential ingredient in the QA program is the requirement that the results reported by the importer and the exporter must agree, for all tested lots, before the entire shipment is qualified for release." Please provide the definition of "tested lots," and indicate what proportion of lots is tested.
- 9. On page 23, under "b.iii. Background calibration," you stated, "Inasmuch as our original method employs sorting for outliers <u>before</u> the average activity has decreased to the exempt limit, the Ge counting was performed <u>after</u> the Nal(TI) counting, on the reassembled packet, excluding the outliers identified in the Nal(TI) sort." This statement appears to lack context, in particular as to how it relates to background calibration. Please provide additional information regarding how this statement relates to the rest of subsection b.iii.
- 10. On page 23, under "D.3. Counting Procedures: Introduction," you stated, "It must be recognized, however, that no method can guarantee that very small stones are free of outliers, even when single stone counting is applied." This statement does not seem to be intuitively obvious. Please provide further information to explain this statement.
- 11. Also on page 23, under "D.3. Counting Procedures: Introduction," you stated, "However, the doses associated with batch release of stones based on the NRC limits are negligible compared to permitted doses for large stone satisfying the exempt limits." Please clarify whether "the NRC limits" refers to concentration limits or dose limits. (This is similar to the comment on page 28, under "d. Counting times").
- 12. On page 28, under "b. Maximum and minimum sample sizes," you stated, "Stones of different sizes and shapes will not be mixed in a test volume, except as they constitute an existing inventory of previously identified "outliers", that have been stored in bins designated for their accurately determined dates of release. <u>This</u> [emphasis added] is based on their specific activities and sum-of-ratios from the single stone counting that has accompanied the binary sorting of outliers procedure previously in use." Does *this* refer to the dates of release? If not, please clarify.
- 13. On page 28, under "c. Counting efficiency," you stated, "The efficiency for the Nal(TI) detectors is estimated to be approximately 40% for the high energy gamma rays from <sup>182</sup>Ta. Because the mass of the samples undergoing testing will be relatively large (200 gm) the

background will be negligible, and it can be assumed that all counts are from the stones. Even using small samples (10 gm) we have found that the system reliably reports the specific activities and sum-of-ratios for those samples." However, in other parts of the application, the Ge (germanium) detector was described as being used for individual nuclide detection. If this is correct, how does the Nal(TI) system report the specific activities and sum-of-ratios? (Examples are on pages 5 and 13. Page 5: "In addition to the historical data used to estimate the generic distribution of isotopes in stones of differing origins, every packet is subjected to high resolution germanium counting. These data are, in turn, used to establish the average distribution and concentration of isotopes. Page 13: "High resolution gamma detector (Ge) for identification of isotopes and determination of average activity. Nal(TI) detectors for selection (and removal) of stones with activities exceeding twice the exempt limit").

- 14. On page 28, under "d. Counting times," you stated, "The counting time for each test sample will typically be 30-60 seconds, but will be increased if the uncertainty in the result (2-sigma) exceeds the NRC exempt limit. The program is designed to allow a re-measurement with the statistical error to be reevaluated from the combination of the measurements." Please clarify whether "NRC exempt limit" refers to concentration limits or dose limits. (This is similar to the comment on page 23, under "D.3. Counting Procedures").
- 15. On page 29, under "h. Statistical methods for analyzing data, calculating background and lower level of detection and data confidence levels," please provide clarification for the following:
  - a) "Nevertheless, the data contained here applies to the proposed license and demonstrates our thorough knowledge of the activity distribution in topaz." It is unclear as to whether this means that ONLY the data applies to the proposed license, and if so, what data?
  - b) "This allows us to set a conservative threshold for triggering the "alarm" requiring a sorting of the group to identify a potential outlier." Will sorting be done as part the methodology you are proposing?
  - c) "The procedure uses the conservative assumption that all stones, except a <u>single</u> <u>outlier</u> have average activity given by the weighted average of the activities of the distribution up to twice the mean activity (the distribution average)." Please clarify why it is conservative to assume that the distribution contains a single outlier. What if the batch has more than one outlier? Also, please explain what is meant by the "weighted average" and the "distribution average."
  - d) "The 'alarm' level is set at the average activity of that group plus the activity of a minimum outlier, i.e. one whose activity would result in stone with twice the exempt limit at T<sub>r</sub>, <u>minus 10%</u>. The counting time would be set such that a group containing such an outlier would not be detected would be at least 4 standard deviations from the alarm limit." Please provide additional clarification of this section. The second sentence, in particular, is difficult to follow. It appears to mean that the probability of not detecting the outlier is low, but it is not clear as to how this is accomplished. Is this similar to a determination that the average activity plus one (or two) standard deviation is less than or equal to the exempt limit?

- e) "If the limit is exceeded, the group is divided in two and each half tested using the same procedure. The outlier can be uniquely identified by successive division of the group and re-measurement. The detection system automatically records the mass of each parcel and records the specific activity of each smaller group, with the same threshold preserved." This method appears to be what was described elsewhere in the application (including in the next paragraph) as the previously used method. Please clarify whether the quoted portion of this paragraph is relevant to the proposed methodology for this application.
- 16. On page 31, under "i. Sample calculations" (begins on page 30), you stated, "Assume that the <sup>182</sup>Ta distribution average (defined in h. above)...." Section h does not appear to contain such a definition. Although it may not be relevant to the current application, please clarify where the <sup>182</sup>Ta distribution average is defined.
- 17. On page 33, under "a. selection of samples" (begins on page 32), you stated, "We propose that 5% of the parcels be verified at the importer's facility, with not fewer than 5 parcels per (intended) shipment." Please define what you mean by "intended."
- 18. On page 33, under "b. Maximum and Minimum sample size," you stated, "Typical lots selected by the applicant for verification will contain 1 kg or less of gemstones of a single size, shape, geologic origin and irradiation history. These will be measured on the importer's Nal(TI) system, using the equipment employed at the irradiator's facility." Please clarify what is meant by "using the equipment employed at the irradiator's facility." Should this say using equipment similar to that (or identical to that) employed at the irradiator's facility?
- 19. Also on page 33, under "b. Maximum and Minimum sample size," you stated, "As with the exporter, verification will be carried out only on single packets of stones (with the exception noted above for mixed, decayed outliers) with masses up to 1000 gm. Sample sizes will not exceed 200 gm, but in cases of small packets, may be considerably smaller." Please clarify the following two points: (a) Is a "sample" a packet, or an individual stone; and (b) If sample sizes will not exceed 200 gm, how would it be possible to carry out verification on single packets of stones with masses up to 1000 gm?