



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001

March 21, 2013

Prism (U.S.A.), Inc.  
ATTN: Alpesh Jiwani  
22 West 48th Street, Suite 1201  
New York, NY 10036

Mail Control No. 579934

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION - APPLICATION FOR EXEMPT  
DISTRIBUTION LICENSE

Dear Mr. Jiwani:

This refers to your Application for Material License, NRC Form 313, dated January 15, 2013, and letter dated January 14, 2013. We do not have sufficient information to complete the review of your application. In order to continue our review we ask that you provide additional information as described below:

1. In Attachment 1, Section 4.1, your application provides the following statement: "The Investigation Level is based on the count rate expected from a single 1-carat gemstone having a concentration at 2 times the 10 CFR 30.70, Schedule A limit for the most restrictive of the expected nuclides (Ce-144 or C-14)." However, you are required to be able to detect a gemstone containing activity at or greater than the concentration specified in Schedule A. Using twice the Schedule A value to set the LLD level is less restrictive than using the Schedule A value. An applicant needs to show that his analytical method can detect the Schedule A levels as well as meet the probability requirement. You should investigate the possibility that if you use the standard 5% probabilities of false positive and false negative, you would also meet the 1 in 1000 criterion. Please show that your system is capable of achieving this level of sensitivity.
2. Your application describes, in various places, how to calculate the LLD, and it shows that your detection system is capable of meeting that requirement. However, it does not discuss the procedure you will use to ensure that the LLD is met. Your procedure should describe how you will determine that the concentration of radionuclides in a given batch is below the Appendix A limits. To accomplish this, the procedure should specify the net counts at which you will conclude that the activity in a gemstone exceeds Appendix A limits. This level is the decision level ( $L_C$ ) and not the LLD as you appear to indicate in your document. As an approximation, the decision level is about one half the LLD. Therefore, if the required LLD is (for example) 100 cpm, then  $L_C$  would be about 50 cpm, and this would be the level at which the Appendix A limits would be exceeded.

At a minimum, the following additional details should be provided:

- Specify how the counting time is determined, including factors that may cause this to change under various conditions.

- Specify how the background is determined. (The background will be subtracted from the sample count in order to determine the net count.)
- Specify how you will determine the net count so as to determine whether the radionuclide concentration in the sample exceeds Appendix A limits.

Without the above information, specifying the LLD is not sufficient. Use of the LLD as the decision level (i.e., whether the sample does or does not exceed the Appendix A limits) is not valid.

In summary, you should describe to us, step by step, in detail, how a batch is checked for the concentration radioactivity in the gemstones it contains. One possible approach would be to provide a procedure that would be used by the analyst that includes how background is to be determined, how often, how long a count time, how long will the batches be counted, how the net count is to be determined, and what will be the decision level.

3. In Attachment 1, Section 4.2, your application provides calculations for the Ce-144 and for the C-14 investigation levels. We request additional clarification of how the counting efficiencies for these conditions were obtained.
  - (a) The equation for Ce-144 uses a value of "0.17," while the value of 0.14 appears in the list of factors below the equation. Please indicate which value is correct.
  - (b) The efficiencies for the Ludlum detector are quoted as being 4-pi efficiencies, whereas your counting geometry appears to be less than 2-pi. Please explain this apparent discrepancy. Is it necessary to adjust the efficiencies given by the manufacturer?
  - (c) If the 2-pi (or less) geometry, rather than the 4-pi geometry, is correct, please provide a revised analysis of how the counting efficiencies used in the LLD calculations were (or should be) obtained.
  - (d) Please provide the basis for the counting efficiency of 0.050 used in the equation for C-14.
4. In Attachment 1, Section 5.2.2, your application describes calibration procedures wherein the photon counting efficiency is to be determined using a Cs-137 source; however the gamma emissions from Ce-144 are below about 150 keV. Please provide data to show that the counting efficiency for counting the emissions from Ce-144 is the same as that measured using Cs-137. Alternatively, please provide data to show that the counting efficiency is constant across the energy range from about 0.7 MeV down to 0.1 MeV.
5. In Attachment 1, Section 5, your application describes background counting and how the background count rate is used in calculations, but the procedure does not make clear how such background count rates are to be determined. Please indicate:
  - Whether the background count rate for the system been determined officially.
  - How this was done and how it will be done and checked during operation. Specifically indicate whether the background is determined, and then periodically checked, by doing a long background count (i.e., much longer than the sample counting time).

- How long the background will be counted, and how long the samples will be counted.
  - How frequently the background will be checked during operation.
6. In Attachment 1, Section 6, your application describes general QA/QC procedures, but it does not specify how you will verify the low-level counting capability of the system. The high level counts and the confidence intervals are used to check drift, calibration, etc., but not the low-level counting capability. Please state how the low-level counting capability of the system is to be verified and periodically checked. Please state how you will demonstrate that the theoretical assessment of that capability is in fact valid.

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 and void the active control for your exempt distribution license application. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Any correspondence regarding your amendment application should reference the control number specified above.

If you have any questions, please feel free to contact me at (301) 415-5477 or electronic mail: [richard.struckmeyer@nrc.gov](mailto:richard.struckmeyer@nrc.gov).

Sincerely,

**/RA/**

Richard K. Struckmeyer

Licensing Branch

Division of Materials Safety and  
State Agreements

Office of Federal and State Materials and  
Environmental Management Programs

Docket No. 03038614

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Sincerely,  
**/RA/**  
 Richard K. Struckmeyer  
 Licensing Branch  
 Division of Materials Safety and  
 State Agreements  
 Office of Federal and State Materials and  
 Environmental Management Programs

Docket No. 03038614

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