



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001

October 29, 2007

HBM Virginia LLC  
ATTN: Mr. Martin Zimmerman  
854 Beartooth Falls Court  
Henderson, NV 89502

Mail Control No. 022621

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

Dear Mr. Zimmerman:

This refers to your Application for Material License, NRC Form 313, dated August 17, 2007. We do not have sufficient information to complete the review of your application. In order to continue our review we ask that you provide the following additional information:

1. Page 3, Item B.1.d, last paragraph: Please define "service certification."
2. Page 4, Item B.1.f, first paragraph: Please define "geologic origin of gems." Specify whether this is the country of origin, the type of geologic formation, or something else.
3. Page 4, Item B.1.f, fourth paragraph: Please clarify the statement "Lots are formed based on irradiation batch." This could be done by reference to another part of the application.
4. Page 5, Item B.1.g, first paragraph on this page: Please explain why 0.2 is the cutoff between major and minor radionuclides.
5. Page 5, Item B.1.g, second and third paragraphs on this page: Cs-134 is shown as a major isotope in the second paragraph, but is stated to be "seldom detected in sub-lots" in the third paragraph. Please clarify this, or provide a correction if one of these statements is in error.
6. Page 5, Item B.1.g, third paragraph on this page: Please clarify the statement ". . . they may however play a dominant role . . ." and indicate whether the quantity ( $\mu + \sigma$ ) enters into this determination.
7. Page 5, Item B.1.g, fourth paragraph on this page: Please define, or provide examples of, "increased vigilance."
8. Page 6, Item B.1.h, second paragraph: Item B.1.h asks the applicant to describe how NRC can be assured that [the provided] information is representative of gems imported in the future. Please provide sufficient information about the mix of radionuclides from other partner reactors to provide such assurance.

9. Page 9, middle of page (paragraph beginning "HBM Virginia will audit . . ."): Please provide additional details regarding audit procedures, including how HBM Virginia will assure independence of the audit process.
10. Page 13, Item C.2.f. (middle of page): Please clarify how " . . . it will be possible to track the respective gamma spectroscopy analysis throughout the complete remainder of the production and import process." Does this imply that a record of the analysis is kept with each lot? If so, what happens to this record when the lot is divided into sub-lots?
11. Pages 12, Item C.2.f.: Please clarify the definitions on page 12, particularly as to how these relate to the steps described on pages 13 and 14.
12. Page 15, Item C.2.f. (first full paragraph): Please provide additional details to expand upon the statement " . . . gemstones sorted in bin 2 or 3 are expected to be compliant with 10 CFR 30.70 after storage for one half-life of the dominant isotope found in bin 4."
13. Page 19, Item D.3.g: Please indicate whether the quantity measured is lower limit of detection (LLD), minimum detectable activity (MDA), or other quantity as defined within the context of current usage in counting statistics.
14. Page 19, Item D.3.g: The quantity  $N_p(LD)$  is defined as  $?N_p(bkgd)^{1/2}$  multiplied by "3." The multiplier normally encountered is "4.65." Please provide additional information to show how the equation was developed.
15. Page 20, Item D.3.h: The last sentence states that "Peak areas are given . . . at the 1 $\sigma$  level, hence at the 68% confidence level." Please provide additional details to explain how this relates to the determination of the peak areas measured in gamma spectroscopy analysis, and how this is related to the quantities discussed in question 13 and 14.
16. Page 21, Item D.3.h (first full paragraph on this page): Please clarify the sources of "systematic uncertainty." Also note that NIST recommends that the term "systematic uncertainty" be avoided, and that "systematic error" is more appropriate. See: <http://physics.nist.gov/Pubs/guidelines/appd.1.html>
17. Page 21, Item D.3.i: Please clarify what is meant by "audited regularly."
18. Page 21, Item D.3.b: The reference to "C.1.f." should be "C.2.f."
19. Page 21, Item D.4. states "Specify who will be responsible for the QA program, and describe this individual's training and experience in detection and analysis of low-levels of radioactivity." It does not appear that sufficient information has been provided here or in the response to C.1.b.
20. Page 22, Item D.5.a: The response to this item is given as "Please refer to item C.2.f.;" however, C.2.f does not appear to address the QA program per se. Please clarify this by indicating where the aspects of the QA program are addressed in your application.

21. Page 22, Item D.5.b: The response to this item indicates that you would not use "spiked" samples. Please clarify the nature of the "samples" used in the second line of this paragraph.

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 renewal. This action would be without prejudice to the resubmission of another application with the required information. Voiding active control of your renewal would require you to discontinue distribution of your exempt licensed products.

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 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: [rks@nrc.gov](mailto:rks@nrc.gov).

Sincerely,

**/RA/**

Richard K. Struckmeyer  
State Agreements & Industrial Safety Branch  
Division of Materials Safety and  
State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

Docket No. 030-37531  
Mail Control No. 022621

21. Page 22, Item D.5.b: The response to this item indicates that you would not use "spiked" samples. Please clarify the nature of the "samples" used in the second line of this paragraph.

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 renewal. This action would be without prejudice to the resubmission of another application with the required information. Voiding active control of your renewal would require you to discontinue distribution of your exempt licensed products.

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 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: [rks@nrc.gov](mailto:rks@nrc.gov).

Sincerely,

**/RA/**

Richard K. Struckmeyer  
State Agreements & Industrial Safety Branch  
Division of Materials Safety and  
State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

Docket No. 030-37531  
Mail Control No. 022621

DWhite            Region 1/DNMS/LAS            MMoriarty            TKime            BBrown  
                         LEusebio

<b>OFFICE</b>	FSME/DMSSA/SAISB
<b>NAME</b>	Richard Struckmeyer
<b>DATE</b>	October 29, 2007