ATTACHMENT

Additional Information Required for Review of Application for Exempt-Distribution License

Question 2 –

We asked:

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.

You replied:

"Please review the definitions of these terms. The LLD and Lc are not levels at which regulatory limits apply. They refer to the properties of the detection system to detect activity above background, not a regulatory limit. The count rate that corresponds to the most restrictive of the Sch. A limits is termed the "Investigation Level" in our procedure. We have

changed the term to "Action Level" to make clearer. The LLD must be less than the Action Level for the analysis technique to be able to identify activity above the Sch. A limits adequately. See http://www.nukeworker.com/forum/index.php?topic=18295.0;imode for a short explanation of these terms.

"We believe you meant Lower Control Level in you comment rather than Lc. In that case, we agree and have reduced the Action Levels to account for the LCL."

It appears that our communications have resulted in some misunderstandings. These are addressed in reverse order in the following paragraphs.

With regard to "Lower Control Level":

- We are familiar with the use of the term "Lower Control Level" (LCL) as it applies to control charts, where upper and lower control levels are used for the purpose of checking the performance of a detection system. You appear to be using LCL differently, but we need further clarification before reaching any conclusion. Please provide additional information about your use of this term.

With regard to the LLD and Lc:

- It was not our intention to equate the LLD or the Lc with the Appendix A limits, and it is not clear to us why you reached this conclusion. However, rather than getting involved in a long and confusing discussion of exactly what was meant, it may be more productive to state our concerns in a different manner:

The main points are as follows: When you set up your counting system, you calculate Lc and use that to decide whether a given sample shows activity that is statistically significantly above the system background. To determine Lc, you choose a probability of a false positive error, usually 5%. Lc depends on this probability: if you change the probability, you change Lc. Next, you ask what level of real sample activity can be detected with sufficient reliability given the current Lc value. "Reliability" here means that if that activity is actually present, you have only a small probability that the net count from that activity will be below Lc. This is the LLD, and the probability of missing that activity (i.e. net count below Lc) is usually taken to be 5%. Missing the activity is a false negative.

To elaborate further:

Our understanding is that you will calculate a quantity that you call the action level, which is the net count rate that corresponds to the most restrictive concentration listed in Appendix A. You will then design your counting procedure to be able to detect at least that level of net count rate. The LLD for that counting system, which is independent of the action level, must be low enough to detect an action level of activity in the batch.

It appears that you have not considered that the LLD represents the mean of the distribution of count rates that the system can reliably detect. For example, suppose the LLD is 6 cpm net. A batch that contains a level of activity that corresponds to this count rate will, if counted repeatedly, result in net count rates that vary around 6 cpm in a normal distribution, with some net counts coming out above 6 and some below. When an analysis is performed (i.e., the detector is run for a specified time period), you obtain the gross count for that batch, then

subtract the background to obtain a net count. Continuing with the example, suppose the net count turns out to be 4 cpm. At first glance, this would appear to be an indication that the batch can be released. However, this is not the case, because we expect half the net count rates obtained from a batch containing the activity that corresponds to the LLD of 6 cpm to result in counts below 6 cpm.

Our request for additional details in your procedure is meant to focus on the following question: "At what net count rate would you conclude that the batch may be released?" This is the decision level, or what we are referring to as Lc, and it is much lower than the LLD. It is normally half the LLD, in this example 3 cpm. (Lc is half the LLD only when the probabilities of Type I and Type II errors are equal, which is usually the case.)

Other considerations that you should address are:

- Whether it is appropriate to assume that all gems in the batch contain the same level of activity (namely the level corresponding to the Appendix A value or lower) and what to do if this assumption is incorrect.

- How the equation used to calculate the LLD changes depending on whether the background is counted for the same time interval as the sample, for a longer time interval, or for a very long time interval.

- You indicated that you will count batches from 0.2 gm to 100 gm. You need to show that you are actually able to detect the appropriate level of activity for the smaller batches. You indicated that you will extend the counting time, but do not say to what extent. What would the longest counting time be, and at what point would this become unacceptable?

Our expectation with regard to your procedure is that you provide details of how you will decide that a batch can be released. For example, how is the background to be determined? What will decide whether the background is counted for a time period equal to that of the sample or longer? And in each case, what equation will be used to calculate the LLD? How will you decide how long to count each sample? For each possible case, what net count rate will you use to decide that the batch can be released? These details need to be worked out and clearly specified in a complete description of the method you will use to show compliance, and the procedure must be in place and approved before it is used. The procedure will need to address the following:

1. How are the batch sizes to be determined for each count?
2. What counting efficiency will be used in the calculations, and where will this number come from?
3. Knowing the batch size, what action level, and hence what LLD, is needed in order to reliably release the batch?
4. How will the background be determined and when? That is, how will you decide how long to count the background?
5. What equations will be used to determine the above levels?
6. How will you decide how long to count the sample?
7. What net count rate will you use in each case as a basis to release the batch?

Basically, what we are looking for is a technical basis manual that describes in detail how you will do your analyses, and how will decisions be made regarding the details of the procedure, such as batch size, action level, LLD, Lc, etc. You have provided a procedure that to some

extent describes how you will approach these problems, but there are too many details that are left "to be decided at the time." You should be able to establish the whole procedure in detail, given that you know what detector you will be using, what background level you can expect, and what counting efficiency to use. The procedure can describe how you will obtain exact values for these parameters at the time, i.e., given some knowledge about what background to expect, you will determine its exact value at the time in the manner that you have described in your procedure.

Question 3 (b) and (c) –

Our interpretation of your response is that you use a 4-pi efficiency in the analysis you provided because the instrument manufacturer quotes this efficiency in the instrument's specifications, but that your intent is to determine the actual efficiency for the specific geometry using a calibration source prior to performing analyses of gemstones.

- We do not see how the geometry presented in your application could be interpreted as 4-pi, therefore we request further clarification of this matter.

Section 4.2 of your April 2013 revision of "Gemstone Analysis Procedures" discusses "Action Levels" and uses the 4-pi efficiencies quoted by the manufacturer. It appears that if these efficiencies were reduced to half of the quoted values, you would still be able to detect radioactivity in samples of 10 g or larger (assuming the LLD of 6 cpm is correct as stated in Section 4.2.3 "Summary of Action Levels").

- Please review our initial RAI question, your response, and this follow-up question, and indicate whether you agree with our interpretation.