ATTACHMENT

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

Various statements in your application indicate that no activation occurs as a result of irradiation of diamonds by 1 MeV electrons. The purpose of obtaining an exempt-distribution license in accordance with 10 CFR Part 32.11 is to authorize the introduction of byproduct material into a "product or material" owned by or in the possession of the licensee (in this case, diamonds) and the transfer of ownership or possession of the diamonds containing the byproduct material. In order for the NRC to issue such a license, it is assumed that the diamonds will contain byproduct material in the form of activation products. As part of the licensing process, it is necessary for the NRC to consider the possibility that the assumed conditions of irradiation (i.e., 1 MeV electrons) may not always be met, and therefore that you may, through no fault of your own, occasionally receive diamonds that have been irradiated at a higher energy or by a different process. Thus, the burden is on the licensee to demonstrate that the concentrations of any and all such byproduct material in the diamonds do not exceed the limits specified in 10 CFR Part 30, Section 30.70 (Schedule A).

The item numbers below correspond to those in the attachment to our letter of April 24, 2012.

Item B.1.d. – You stated "…the diamonds are irradiated in two locations…," but you named only one location. Please provide the additional location.

Item B.1.f. – The response to this item cannot be "not applicable" without further explanation. The NRC does not have knowledge of any data (i.e., results of scientific studies) to indicate that no activation occurs as a result of irradiation of diamonds by 1 MeV electrons. Therefore, you must state how gems are handled to ensure grouping according to geologic origin of gems and type(s) of irradiation or treatment to which gems have been exposed (significant variations in induced radionuclides may result from differences in gems' origin and type(s) of irradiation or treatment received). Given that you intend to use only one type of irradiation, you may state that "type of irradiation" is not a cause of variation. If you have reason to believe that geologic origin does not introduce any variation in induced radionuclides, please state your reasons and provide any applicable references. You may supply additional information such as an explanation of what occurs when diamonds are irradiated by 1 MeV electrons; i.e., what is the mechanism by which color enhancement occurs, and why you claim that no activation occurs.

Item B.1.g. – You stated "…no radionuclides are expected, as there is no activation of the gems due to low energy beam irradiation." Please provide references to any data or scientific studies that support the supposition that no activation of the gems occurs. If no such studies exist, then it must be assumed that the diamonds will contain byproduct material in the form of activation products; consequently the burden is on the licensee to demonstrate that the concentrations of any and all such byproduct material in the diamonds does not exceed the limits specified in 10 CFR Part 30, Section 30.70 (Schedule A). (Applies also to item C.2.c. and item C.2.f.)

Item B.1.i. – (Your item 2). You stated "No radioactive materials are expected; and we anticipate having less than 1 microcurie of activity in the diamonds at any time, including natural activity." However, because the NRC has no knowledge of studies to prove that no activation occurs, an estimate must be made. Therefore, please provide the requested possession limit determined by multiplying the maximum number of gems to be possessed at one time by the maximum total activity anticipated in any one gem.

Item B.2.a. – You stated "Since a low energy linear accelerator is used, there will be no radioactive contamination, and therefore there is no specific check for removable contamination." However, because the NRC has no knowledge of studies to prove that no activation occurs, and because of the possibility of the activation of surface contaminants, you must describe your procedures used to ensure that each irradiated gem is free of removable contamination.

Item C.2.a. – You stated "Diamonds will be irradiated and since the energy of the electron beam is low (1.0 MeV), no radioactivity will be induced." However, because the NRC has no knowledge of studies to prove that no activation occurs, you should instead state that byproduct material may be introduced, unless you can provide reference to scientific studies that prove otherwise.

Item C.2.c. – You stated "The method of introduction of byproduct material is by electron beam irradiation; however, as previously stated, no activity is expected to be introduced." See item B.1.g.

Item C.2.f. – You stated "…primary method is use of a low energy accelerator that does not add radioactivity to the gems." See item B.1.g.

Item D. – You stated that the QA program for laboratory analysis will be contracted to a commercial laboratory, and that laboratories to be used include CoPhysics Corporation or any NELAP accredited laboratory. This is unacceptable. In order to obtain a license for exempt-distribution of irradiated gemstones, an applicant must demonstrate, as a minimum, that the company (1) has, and will continue to maintain, the necessary analytical capabilities over the duration of its license; (2) utilizes individuals who, at the time the license is issued, are qualified by training and experience to conduct licensed activities on a day-to-day basis; and (3) possesses complete quality assurance and quality control (QA/QC) procedures that fully address the detection of very low level activity associated with exempt concentrations of byproduct material.

The applicant must provide assurance that its analytical capabilities are sufficient to detect concentrations of radionuclides at and below the levels specified in 10 CFR 30.70 Schedule A. Your application and the procedure you provided as Attachment 4 do not contain sufficient information to provide this assurance. Please submit procedure(s) and results of analyses that demonstrate that your analytical capabilities are sufficient for this purpose.

Item D.3.a. – You stated that selection of samples will be as provided from Prism USA Inc. by lot. Please expand upon this statement to include the criteria by which samples are selected. In particular, please define "by lot," and indicate what, if any, pre-screening of diamonds occurs during the selection process.

Item D.3.d. – Please state how the length of time for sample analysis may vary depending upon other factors such as sample size, geometry, etc, and how the time is determined. The procedure you provided as Attachment 4 contained very little information about this.

Item D.3.e. – With regard to counting geometry, please state how you will account for and minimize potential problems of shielding (shielding of radioactivity from some diamonds by others in a sample) and self-shielding (shielding that occurs within a given diamond). Geometries routinely used by the laboratory may not be suitable for the purpose of analyzing irradiated diamonds, particularly when the concentrations of byproduct material are expected to be very small.

Item D.3.g. – It appears that you have used the terms lower limit of detection (LLD) and minimum detectable activity (MDA) interchangeably. Please clarify your definitions of these terms. Note: Your clarification should be provided in the context of your (i.e., the licensee's) overall laboratory analytical program capability and associated quality control and quality assurance (QA/QC) program. As a minimum, your clarification should provide these definitions and indicate where they are found in your QA/QC program.

Item D.3.h. – You stated "The statistical methods are performed by commercial software manufactured by instrument vendors such as Canberra, Ortec and PGT. The results of calculations are deemed accurate via review of standard, spike, duplicate and other QA checks." Please demonstrate that the "review of standard, spike, duplicate and other QA checks," which are normally performed at much higher activity levels than that found in gemstones, are adequate to ensure the capability of the detection instruments that are proposed for use. Also, because of this difference in activity levels, your laboratory personnel must have sufficient understanding of, and expertise in, statistical methods for analyzing data, calculating background and lower level of detection, and determining confidence levels, and must not simply rely on information generated by commercial software programs.

Item D.3.i. – With regard to procedures for minimizing "false negatives," you stated "False negatives are kept to a minimum by ensuring that the MDAs of the analysis are less than 1/5 of the values shown in 10 CFR 30.70, Schedule A." Please state how you will ensure that the MDAs of the analysis are less than 1/5 of the values shown in 10 CFR 30.70, Schedule A.

Item D.3.j. – With regard to sample calculations, you stated "Gamma spectroscopy calculations are performed by commercial software manufactured by instrument vendors such as Canberra, Ortec and PGT. The results of calculations are deemed accurate via review of standard, spike, duplicate and other QA checks." Our concerns related to Item D.3.h. also apply to this item.

Item D.3.k. – With regard to the adequacy of measurements to identify all induced radionuclides, you stated "Since the energy of the electron beam is 1.0 MeV and no activation is expected at this low energy, no induced beta emitting or gamma emitting radionuclides are expected. Nevertheless, gamma analysis is performed on the diamonds, and if no significant activity is detected (i.e., all gamma-emitting

nuclides are < 25% of 10 CFR 30.70 Schedule A limits), then it is assumed that no significant activation has taken place, and there is no need to analyze for pure beta emitters." Please explain why analysis for beta emitting radionuclides is unnecessary when all gamma-emitting nuclides are < 25% of 10 CFR 30.70 Schedule A limits; in particular, explain what is significant about the 25% cutoff.

Item D.3.l. – With regard to ensuring that the concentrations listed in 10 CFR 30.70, Schedule A are not exceeded, you stated "All gems will be evaluated in lots by gamma spectroscopy. The total activity will include any detected radionuclides, and where the results indicate no detection above the MDA, then the MDA value will be used in the "sum of the ratios" calculation." Our concerns related to Item D.3.a. also apply to this item. If you intend to analyze gems in batches, rather than individually, you must demonstrate how you will ensure that you account for and minimize potential problems of shielding and self-shielding (as described in item D.3.e.).

Item D.3.m. – With regard to demonstrating that there is only 1 chance in 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value, you stated "A qualitative response is provided as follows: since the low energy electron accelerator does not induce radioactivity, then there is an extremely low probability of any gem reaching the 10 CFR 30.70 maximum values." This item is intended to address a situation in which the activity is <u>not</u> quantitatively measured in each gem individually. Your response may be adequate if you have the capability to make quantitative measurements to demonstrate that the concentrations of any and all such byproduct material in each diamond (as opposed to groups of diamonds) does not exceed the limits specified in 10 CFR Part 30, Section 30.70 (Schedule A). Therefore, if you intend to analyze gems in batches, rather than individually, you must demonstrate how you will ensure that there is only 1 chance in 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value.