

August 4, 2011

HNJ Inc.  
Attn: Kristen Holcomb  
5525 N. MacArthur Blvd. Suite 160  
Irving, TX 75038

Mail Control No. 022794

SUBJECT: APPLICATION FOR A LICENSE TO DISTRIBUTE GEMSTONES PURSUANT TO 10 CFR 32.11 TO EXEMPT PERSONS

Dear Ms. Holcomb:

This letter refers to your application, dated December 8, 2008, requesting U.S. Nuclear Regulatory Commission (NRC) authorization to distribute, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 32.11, exempt concentrations of byproduct material contained in gemstones to persons exempt from licensing under 10 CFR 30.14, your letter dated March 30, 2010, in response to our Request for Additional Information (RAI) of February 17, 2010 (1<sup>st</sup> RAI); and your e-mail sent April 8, 2011, responding to our February 7, 2011, RAI (2<sup>nd</sup> RAI).

In our 2<sup>nd</sup> RAI, we informed you that we had a second staff member conduct an independent evaluation of your application because staff had recommended that your application be denied. We also informed you that while we continued to have a number of concerns with your application, our principle concern related to training and experience qualifications. As explained in our letter, in order for the NRC to approve an application, the NRC must have reasonable assurance of the applicant's qualifications to ensure that regulatory requirements will be complied with at the time of license issuance. The NRC's regulations at 10 CFR 30.33(a)(3) require that the applicant be "qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property." When it comes to exempt concentrations in general, and gemstones in particular, the evaluation and analysis process necessary to detect the very low radionuclide concentrations specified in the NRC's regulations is sophisticated and complicated and requires an applicant to have adequate training and familiarity with the radiation detection equipment to be utilized, and experience in conducting the analysis so that the applicant will be able to recognize and respond to the unknowns that may occur when evaluating gemstones of unknown origin.

Our 2<sup>nd</sup> RAI also notified you of our intent to deny your application if we did not receive a satisfactory response from you within 30 calendar days that addressed all of the issues identified in the 2<sup>nd</sup> RAI and showed that you are qualified by training and experience to conduct the activities required at the time of licensing. It further informed you that if you failed to respond within 30 calendar days from the date of the 2<sup>nd</sup> RAI, the NRC would consider your application to have been abandoned, which would also result in the NRC's denial of the application. By way of a telephone call and an email received March 2, 2011, you requested, and were granted, an additional 30 days to respond. On April 8, 2011, you submitted a partial response to our 2<sup>nd</sup> RAI that did not address all of our concerns.

Our 2<sup>nd</sup> RAI requested information regarding 14 different items. (The items were not sequentially numbered as they were taken from our 1<sup>st</sup> RAI.) Our evaluation of the partial response you provided to our questions follows:

### Question 3

Section 32.11(b) of the NRC's regulations requires, in part, that an applicant provide specific information regarding the nature, quantity, and concentration of byproduct material that the applicant intends to use. NUREG-1556, Vol. 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," dated September 1998, is available to provide guidance and assistance to applicants preparing license applications. The information contained in NUREG-1556, Vol. 8 describes one or more methods acceptable to the NRC that may be used by an applicant to establish compliance with NRC regulations.

In question 3 of our 2<sup>nd</sup> RAI, we asked you to identify the specific tables, paragraphs, or sections in NUREG/CR-5883, "Health Risk Assessment of Irradiated Topaz," dated January 1993, from which you obtained the information pertaining to the identification and classification of all radionuclides with physical half-lives greater than 2 hours induced in gems (NUREG 1556, Vol. 8, Appendix G, Item B.1.g. and B.1.h.) which you plan to distribute. We noted that NUREG/CR-5883 generally applies to topaz and that your application indicated that you intend to also distribute irradiated tourmaline and spinel, and asked you to clarify how the information you provide in the table would apply to these gemstones. You did not specifically respond to this question in your reply of March 30, 2010.

We also requested that you explain why, in your application of December 4, 2008, tourmaline and spinel were listed on Form 313, item 5.b, and, by way of addressing the guidance in Appendix G, C.2.a., you stated "other gems such as tourmaline and spinel." In your April 8, 2011, response you indicate that in the initial application of December 4, 2008, you listed tourmaline and spinel after review of the Gemstone Irradiation and Radioactivity article by Charles E. Ashbaugh.<sup>1</sup> You also noted that while these stones are not a typical request for your core customers, you wanted to include any and all gems that would possibly fall under the NRC jurisdiction and that you believed at that time that these stones would. You further clarified that spinel is generally treated with heat only and tourmaline is treated with gamma ray irradiation, and that neither of these stones have been considered for customer presentation since the time of your application.

Based on this information, it is our understanding that you are withdrawing your request to distribute tourmaline and spinel that may have been treated through neutron or accelerator irradiation.

### Question 4

In our 1<sup>st</sup> RAI, we asked that you clarify a statement contained in your application, namely, that the gemstones HNJ will receive will already satisfy the requirements of 10 CFR 30.70. In your

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<sup>1</sup> Ashbaugh, III, C.E., "Gemstone Irradiation and Radioactivity." *Gems & Gemology*, Vol. 24, No. 4, pp. 1996-213, 1988.

March 30, 2010, response you indicated that the gemstones are cleaned at various stages of the pre-importation process and that tests for removable contamination are performed by the exporter. Our 2<sup>nd</sup> RAI noted that you may have confused two related issues. One is removable contamination, as described in NUREG-1556, Vol. 8, Appendix G, Item B.2.a. The other is the 10 CFR 30.70 requirement, which, in the case of your application, is concerned with radionuclide concentrations [in the gemstones], not removable contamination [on the gemstones].

NUREG-1556, Vol. 8, Appendix G, Item B.2.a, provides that applicants may satisfy NRC concern that public health and safety will not be adversely affected due to removable contamination remaining on the stones by describing procedures used to ensure that each irradiated gem is free of removable contamination, including a description of sampling, monitoring, counting, and statistical techniques used, specification of the criteria used to determine when gems are essentially "free of removable contamination," and a description of what will happen to gems exceeding the specified criteria.

Your application provided for wipe tests on five items randomly chosen from the shipment to identify removable contamination which we informed you would not be adequate. In your response to our 1<sup>st</sup> RAI, you requested an explanation why such sampling was acceptable for a previous application. In our 2<sup>nd</sup> RAI, we noted that the purposes for the proposed sampling were not identical. The application to which you referred included specific information concerning contamination surveys of the exterior and interior of the shipping packages. In that case, the applicant committed to conduct this package survey in addition to, but not as a substitute for, a survey of all stones for removable contamination.

In your most recent response you state, "[m]ore detail should have been given as to our specific procedures in the receiving and handling of packages." Again, this RAI is not asking for procedures regarding package contamination, but instead, procedures for determining if there may be removable contamination on the stones themselves. All stones must be tested for removable contamination; increasing the number of pieces as you indicate, "to five percent or no less than ten pieces," is not acceptable to satisfy NRC's public health and safety concerns regarding removable contamination. Your response also states, "I have attached a copy of the procedures and a copy of the quote sheet on the equipment we intend to purchase..." However, there is only a copy of a quote sheet attached.

Your April 8, 2011, response further specifies that you sell finished pieces of jewelry and discusses the manufacturing process done in your facility in China. You mention that jewelry pieces are cast with stones in the pieces and that the pieces then go through various stages of cleaning, filing, polishing, etc. before being shipped to the U.S. You indicate that the stones are received cut and polished ready to be set in your factory from the supplier and that you purchase your stones as "finished polished goods from the largest and most reputable suppliers in the industry." You indicate you previously received confirmation that Zimmermann BCS Stones GmbH (Zimmermann) is the main supplier of irradiated topaz in the finished goods industry and that you would be willing to supply documentation that irradiated *rough* topaz came from this source and further mention that you visited with Zimmerman at the Tucson show this year with one of your stone suppliers that has their *rough* irradiated by them.

This is somewhat confusing. As you are aware, Zimmermann is associated with a current NRC licensee, HBM Virginia LLC USA, who is authorized to distribute processed topaz gemstones pursuant to 10 CFR 32.11. It would appear that if your “finished polished goods” were passing through this licensee there would be no need for you to have a license. However, the fact that you discuss that your suppliers are having *rough* topaz irradiated by Zimmermann suggests that there must be further filing, shaping, etc. of the stones that is likely to result in surface contamination. If you conduct activities at your China facility to clean the stones and confirm the stones are free of removable contamination, you certainly should have described this procedure as part of your application.

#### Question 5

In question 5 of our 1<sup>st</sup> RAI, we asked how you will assure that storage of at least three weeks will pass after irradiation. You responded with information concerning the amount of time Zimmerman and the University of Missouri Research Reactor Center holds gemstones prior to release. However, your application suggests that you may have multiple suppliers and that the gemstones may be irradiated by others. Therefore in our 2<sup>nd</sup> RAI, we asked you to explain how you ensure that your suppliers are adhering to these holding times, or provide details as to other means by which the minimum storage time of three weeks will be met.

Your April 8, 2011, response confirms that there often is more than one supplier for basic gemstones such as blue topaz, and you indicate that the suppliers you deal with are large reputable suppliers that have rough gemstones irradiated at the largest and most reputable facilities for yield, consistency and such. You further state that you would be able to request and provide documentation as to the holding time due various business arrangements.

If you can obtain “official” documentation that confirms the length of time the gemstones are held after irradiation, this certainly should have been included as a commitment in your procedures. However, staff would have liked to have seen an example of the documentation. We are familiar with Zimmerman and the University of Missouri’s procedures (through the company International Isotopes Inc.); however, as specified in NUREG-1556, Vol. 8, Appendix G, Item B.1.d., you should have also identified, in order to satisfy NRC’s public health and safety concerns regarding excessive radiation levels that may occur with freshly irradiated stones, any other person who make be actually irradiating, via reactor or accelerator, the gemstones you are importing.<sup>2</sup>

#### Questions 7 and 16

In questions 7 and 16, we asked that you provide additional details regarding training and experience that the individuals who will be responsible for handling, evaluating, and controlling the release of irradiated gems and for the quality assurance (QA) program, particularly their training and experience in detection and analysis of low-levels of radioactivity. 10 CFR 30.33(a)(3) and 32.11(a) requires that the applicant “be qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property.”

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<sup>2</sup> Note this applies to both reactor or accelerator irradiation - the Energy Policy Act of 2005 gave NRC regulatory authority over certain accelerator produced radioactive materials.

In your March 30, 2010, response, you identified certain radiation safety training topics that you indicate “*will* be addressed in detail as part of an initial training session...” (emphasis added). You further indicate that Heather Johnson will be responsible for the QA program and provide that, “[t]raining for ... the use of scalers and survey meters (items 6-10 in the training summary) *will* be done as hands-on, laboratory training with the medical physicist working on-site with Heather Johnson” (emphasis added). We noted that your response suggests that your staff has not received and, perhaps, will not receive any training prior to issuance of a license and that your application indicates that you would not be obtaining the equipment necessary to conduct licensed activities until after the license is issued.

The NRC staff previously informed you in the 2<sup>nd</sup> RAI that this approach was not acceptable and that in order for the NRC to issue the requested license, the individuals who will be responsible for conducting licensed activities on a day-to-day basis, must be qualified by training and experience at the time the license is issued.

In your April 8, 2011, response, you again indicate that Ms. Johnson is the designated Radiation Safety Officer and that she has completed Basic Radiation Safety and a Certificate of training was presented on August 10, 2007. However, you did not include the certificate for our review. You further indicate that Ms. Johnson and Veronica Mathies also completed the DOT, IATA and NRC Requirements for Shipping Limited Quantity Radioactive Materials with Radiation Fundamentals with Certificates of Training presented on August 11, 2008. Again, no certificates were submitted for our review.

As stated previously, the individuals who will be responsible for conducting licensed activities on a day-to-day basis must be qualified by training and experience at the time the license is issued. Because of the very low radionuclide concentrations specified in our regulations, the gemstone evaluation and analysis process is a sophisticated and complicated process that requires adequate training and familiarity with the radiation detection equipment to be utilized and experience in conducting the analysis to ensure compliance and be able to recognize the unknowns that are likely to occur.

As previously mentioned, our 2<sup>nd</sup> RAI requested information regarding 14 different items. You only provided a partial response addressing four of the items, including a response to Question 15, part 6 by providing a “quote by Ludlum Measurements with the outline of the equipment to be purchased upon approval by the NRC.” You also indicate “[t]he rest will come in a separate email...;” however, no additional information has been forthcoming.

The NRC staff finds that, despite its repeated requests, you have failed to provide a detailed description of your program including: where and by whom each irradiation or other treatment is performed; how you will receive gemstones; how you will monitor them to identify and remove “hot” stones; how you will identify and quantify all radionuclides; how you will determine the concentration of each identified radionuclide; a description of procedures used to ensure that each irradiated gem is free of removable contamination; and how you will determine that stones may be released in accordance with the criteria in 10 CFR 30.70 and when they may be released. You have also failed to provide full and complete information on the QA program you will implement to ensure that your counting equipment is calibrated properly and continues to function within defined limits; the operating procedures your personnel follow on a day-to-day basis; and identify an individual responsible for and conducting licensed activities on a

day-to-day who is qualified by training and experience. This information is necessary so that the NRC may understand the scope and intent of your proposed activities, and determine whether the proposed activities satisfy the NRC's regulations in 10 CFR 30.33 and 32.11 within the timeframe specified in the request.

In your correspondence, you have indicated that for some items, such as training, you would "add much more training upon completion of the NRC licensing," and that purchase of equipment would also wait "...upon approval by the NRC." You have also indicated that information regarding other issues, such as specific QA procedures, equipment calibrations procedures, etc. for which you have not provided complete information, "...will come in a separate email..." which has not been received. Responses such as these do not provide the staff with the type of information needed to make the findings required by 10 CFR 30.33.

Therefore, in accordance with 10 CFR 2.108, your application for a new license is hereby denied for failure to provide that information requested and required by the staff to make the findings required by 10 CFR 30.33(a) and 32.11.

Further, in accordance with 10 CFR 2.103, your request is hereby denied as HNJ has not identified an individual who is qualified by training and experience to ensure compliance of NRC's regulatory requirements for the purpose requested. To receive such a license, you must be qualified pursuant to 10 CFR 30.33(a)(3). Additionally, as discussed above, you have failed to provide information required by 10 CFR 32.11(b) and (c), including, but not limited to, reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in 10 CFR 30.70, and an adequate description of the product or material into which the byproduct material will be introduced and the method of introduction, the initial concentration of the byproduct material in the product or material, the control methods to assure that no more than the specified concentration is introduced into the product or material, and the estimated time interval between introduction and transfer of the product or material.

This denial will not adversely affect NRC's consideration of any application you may file in the future. Should you resubmit your application with complete and adequate information as required, you should reference this letter and Mail Control 022794. Note that you have up to one year from the date of this letter to resubmit your application without the need for an additional application fee.

As provided in 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days of the date of this letter by submitting a request, in writing, to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, with a copy to the Associate General Counsel for Hearings, Enforcement, and Administration, Office of the General Counsel, at the same address. Refer to 10 CFR 2.302 for additional filing options and instructions. If submitting via private courier (e.g., FedEx, UPS), send your request to 11555 Rockville Pike, Rockville, Maryland, 20852, instead of using the Washington, DC, address.

HNJ, Inc.

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Should you have any questions, please contact Bruce Carrico at (301) 415-7826 or [jbruce.carrico@nrc.gov](mailto:jbruce.carrico@nrc.gov).

Sincerely,

*/RA/*

James G. Luehman, Deputy Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

HNJ, Inc.

-7-

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Sincerely,

*/RA/*

James G. Luehman, Deputy Director  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

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