UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

February 7, 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 refers to your application, dated December 8, 2008, requesting authorization to distribute, pursuant to 10 CFR 32.11, exempt concentrations of byproduct material contained in gemstones to persons exempt from licensing pursuant to 10 CFR 30.14, and to your letter dated March 30, 2010, in response to our Request for Additional Information (RAI) of February 17, 2010.

Our RAI outlined some specific areas that you did not adequately address in your original application, and asked that you submit additional information. Your response was reviewed in combination with your original application by the original license reviewer, J. Bruce Carrico, and subsequently by a second reviewer, Richard K. Struckmeyer, who was assigned to the review in order to provide an independent assessment. This letter presents Mr. Struckmeyer's concerns, which both confirm and elaborate upon those of Mr. Carrico. Mr. Struckmeyer did not have substantial disagreements with any of Mr. Carrico's concerns.

An important reason for having a second staff member conduct an independent evaluation of your application is that staff had recommended that your application should be denied. This is not an action that frequently occurs with exempt distribution license applications and is part of the reason processing your application has taken extra time. In addition, as was mentioned in our earlier letter, some delay also resulted due to outside concerns raised regarding our licensing policy for gemstones and the evaluation and release of bulk gemstones. This issue and concern remains ongoing and we are placing special emphasis on the gemstone evaluation process.

Although we continue to have a number of concerns with your application, our principle concern relates to training and experience qualifications. We should point out that our concern with your qualifications in this area were relayed to your consultant soon after receiving your resubmitted application, and have been reiterated in telephone calls and emails. In order for us to approve an application, NRC must have a high degree of confidence in the applicant's qualifications to ensure that regulatory requirements will be complied with at the time of license issuance. When it comes to exempt concentrations in general, and gemstones in particular, we believe that the evaluation and analysis process necessary to ensure that the applicant will have the expertise to detect the very low concentrations specified in our regulations, is a sophisticated and complicated process that requires adequate training and familiarity with the radiation detection equipment to be utilized, and significant experience in conducting the analysis to be able to recognize the unknowns that likely to occur when evaluating gemstones of unknown origin.

In the following paragraphs, mention of an Item in Appendix G should be understood to refer to NUREG-1556, Volume 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses.” The following questions are numbered in accordance with those in our RAI of February 17, 2010:

Question 3

In question 3 of our RAI, we asked you to identify the specific tables, paragraphs, or sections in NUREG/CR-5883 from which you obtained the information pertaining to the guidance in Appendix G, Item B.1.g. and B.1.h. 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.

In your response, you stated that “tourmaline is produced by gamma-ray irradiation and spinel production involves no irradiation of any kind. Therefore, NUREG/CR-5883 and NUREG/CR 1717 are applicable since topaz is the only gemstone that HNJ will distribute which falls under the NRC requirements.”

Please note that Title 10, Code of Federal Regulations, Part 30, Section 30.9(a), requires that information provided to the Commission by an applicant for a license . . . shall be complete and accurate in all material respects. Therefore, we request that you explain why, in your application of 12/4/08, 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.”

Also, in our RAI, you were asked to identify the specific tables, paragraphs, or sections in NUREG/CR-5883 from which the information concerning Appendix G, Item B.1.h was obtained. You did not specifically respond to this question in your reply of March 30, 2010. Please provide this information.

Question 4

Your application of December 8, 2008, indicated that when the gemstones are received by HNJ they will already satisfy 10 CFR 30.70 requirements. You further indicated that the gemstones are cleaned “thoroughly at various stages of the pre-importation process,” you discussed Zimmerman BCS Stones experience, and you indicated that the exporter also tests for removable contamination and provides results with shipments.

It appears that you may have confused two related issues. One is removable contamination, as described in Appendix G, Item B.2.a. The other is the 10 CFR 30.70 requirement, which is concerned with radionuclide concentrations [in the gemstones], not removable contamination [on the gemstones].

In question 4 of our RAI, we referred to the guidance in Appendix G, Item B.2.a, which requests that applicants describe 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.

You stated in your application (by way of addressing item B.2.a.) that "wipe tests on five items chosen at random from the shipment will be taken to identify removable contamination." Our RAI stated that five randomly chosen stones will not be adequate. In your response to our RAI, you requested an explanation of why such sampling is not appropriate and why such sampling was acceptable for a previous application. We do not agree that the proposed sampling methods are identical. The application to which you referred included specific information concerning contamination surveys of the exterior and interior of the shipping packages. A procedure was provided as an attachment, and the description included additional details from that procedure, including the number of items to be surveyed, the types of instruments to be used, and actions to be taken if contamination is or is not found.

Your response to RAI question 4 added the following information: ". . . the interior of the shipping container will be checked for contamination." This improves upon your original statement, but does not provide the level of detail expected.

<u>Question 5</u>

In question 5 of our RAI, we asked <u>how you will assure</u> that storage of at least three weeks will pass after irradiation. You responded that Zimmerman BCS holds the irradiated stones for six months to three years after irradiation, and the University of Missouri Research Reactor Center holds them for a few months up to a few years. Please 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. (The application and the later response seem to have contradictions as to whether you will have one – or more than one – supplier.)

<u>Questions 7 and 16.</u>

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 QA program, particularly their training and experience in detection and analysis of low-levels of radioactivity. We also requested information concerning the medical physicist's (your consultant) training and experience in this area.

In your response, you identify certain radiation safety training topics that you indicate "…*will* (emphasis added) be addressed in detail as part of an initial training session…." You further indicate that Heather Johnson will be responsible for the QA Program and provide that, "Training for … the use of scalers and survey meters (items 6-10 in the training summary) *will* (emphasis added) be done as hands-on, laboratory training with the medical physicist working on-site with Heather Johnson." Your response also indicates that following this training, the medical physicist only conduct quarterly audits of your activities.

Your response does not provide any information concerning your consultant's training and experience in detection and analysis of low-levels of radioactivity as would be necessary for this type of application, and suggests that your staff has not received and, perhaps, will not receive any training prior to issuance of a license. (This perspective seems to be further supported in that your application indicates that you would not be obtaining the equipment necessary to conduct licensed activities until after the license is issued.)

This approach is not acceptable. In order for the NRC to issue the license, the individuals who will be responsible for and conducting licensed activities on a day-to-day must be qualified by training and experience at the time the license is issued. As indicated earlier, we believe that in view of the very low 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 significant experience in conducting the analysis to ensure compliance and be able to recognize the unknowns that likely to occur.

Question 8

In question 8 of our RAI, we asked you about your response to Appendix G, Item C.2.d., which states: "To comply with 10 CFR 32.11(b), the applicant will describe the initial concentration of byproduct material in the product or material."

You stated in your response that the correct value of 74 Bq/g is based on information from Zimmerman BCS, and that Zimmerman BCS does not release the irradiated gemstones until the average concentration is below 74 Bq/g. Please explain how you ensure that these concentrations are not exceeded in the gemstones from your suppliers, or provide details as to other means by which you will ensure that these limits will not be exceeded. Please clarify whether Zimmerman BCS is the only supplier of such gemstones, given that you have elsewhere made reference to the University of Missouri Research Reactor Center.

Question 9

In question 9 of our RAI, we asked you to clarify your statement with regard to the guidance in Appendix G, Item C.2.e, which requests the estimated maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing. It does not appear that you have specifically answered the question.

Our RAI stated that the approach you took in your application (where you stated that the concentration at the time of transfer will be 2 nCi/g, or 74 Bq/g) was not acceptable. In response, you stated that "Zimmerman BCS gives the maximum concentration at the time of transfer as 6-19 Bq/g." You have not addressed the issue of the concentration of the radioisotopes in the gemstones obtained from other suppliers, nor do you provide any detailed information about how you would assure that these concentrations are not exceeded, as requested by Item C.3.a. Please provide this information.

Question 10

In question 10 of our RAI, we asked you to describe your control methods to assure that no more than the specified maximum concentration is in the product at time of transfer. (Note: The text of this question is correct; however, the reference should have been to Appendix G, Item C.2.f.) You responded that “HNJ will survey all irradiated gemstones. Any shipments that do not meet the requirements of 10 CFR 30.70 will be held for physical decay until the maximum concentration requirement is satisfied.” While Item C.2.f does not specifically stipulate that you provide procedures or a description of the procedures you will follow in your process of evaluating the concentration of radioisotopes in gemstones, your application should include a description of such procedures, and/or copies of the procedures, to indicate exactly how such evaluations will be conducted.

Question 11

In question 11 of our RAI, we asked you to clarify what you meant by "radiation surveys." You responded that “The radiation survey is a measure of the radiation exposure rate. The survey will be conducted with a Ludlum Model 3 survey meter and the results will be recorded.” This response does not provide any details of your proposed survey technique. Prior to the commencement of operations, you should have complete procedures for such activities in place, and be able to demonstrate that you will be able to meet the requirements for detecting the concentrations of radioisotopes in gemstones that you plan to distribute in accordance with 10 CFR 32.11. During the application process, it will suffice to have such procedures in draft form.

Question 12

In question 12 of our RAI, we asked you to describe how you will ensure that the gemstones will meet the criterion of Appendix G, Item C.3.b. before you receive them.

In your response, you stated that no subsequent irradiation will be performed by HNJ; however, you have not provided specific information to show that you have a procedure in place for tracking the gemstones following their initial irradiation to ensure that they have not been subjected to further irradiation.

Again, as in question 8, please clarify whether Zimmerman BCS is the only supplier of such gemstones, given that you have elsewhere made reference to the University of Missouri Research Reactor Center.

Question 13

In question 13 of our RAI, we asked you to clarify your statement. The issue of concern in this question is related to Appendix G, Item C.3.c.:

“Paragraph 32.11(c) requires applicants to provide reasonable assurance of the following: Use of concentrations lower than those specified in response to Item C.2.e. are not feasible (i.e., why maximum values for a single radionuclide should not be lower; why values for multiple radionuclides should not be calculated by setting the "sum of the ratios" equal to a value less than unity).”

You addressed this item as follows in your application: "Requiring that the "sum of the ratios" is less than unity would mean a significant increase in release intervals. This would adversely affect the domestic market for irradiated gemstones. This seems unnecessary in light of the dose rates found above (C.2.e)."

Our question 13 asked HNJ to clarify to what this refers, and to completely address this item. Your subsequent response did not appear to address our concerns. You stated:

> "The irradiation facilities have studied the effects of lowering the irradiation time and report that this does not reduce the specific activity of the irradiated topaz."
>
> "As was shown in item E.2 of our application, the dose levels are well below the limits. HBM, who uses the same overseas irradiation facility as HNJ, discusses this matter in their application and concludes that 'the current limits expose unlicensed person to insignificant dose levels.'"

You stated that you saw nothing in the publicly available documents to suggest that the NRC disagreed with HBM's conclusion. The issue under consideration needs to be addressed, regardless of the NRC's evaluation of the HBM application. To this end, you should be aware that the regulations and guidance for the exempt distribution of gemstones do not directly take into consideration the dose received from their use. Please cite any available references to studies by irradiation facilities regarding the effects of lowering the irradiation time, and explain why the use of concentrations lower than those specified in response to Item C.2.e. is not feasible.

Question 14

Question 14 of our RAI asked you to provide complete, detailed information regarding your calibration program, and to describe HNJ's procedures pertaining thereto. As stated above under question 11, you should have complete procedures for your activities in place prior to the commencement of operations. A draft procedure is acceptable during the application process.

Question 15

Question 15 of our RAI refers to the guidance in Appendix G, Item D.3., which in turn refers to counting procedures within your QA program. Question 15 included nine sub-parts, roughly corresponding to the list of information (a though j) your description of counting procedures should include. Our RAI itemized the deficiencies in this part of your application. Rather than repeat these questions item-by-item, we request that you provide an evaluation that focuses on the larger objective of Item D.3. The following comments are intended to address the type of information needed to achieve this objective.

We need additional information in order to evaluate whether your proposed minimum and maximum sample sizes are adequate. Please provide an analytical basis to demonstrate why these sample sizes are appropriate. This analysis should take into consideration the various components of a radioactivity counting system, such as (but not necessarily limited to) the type of detector, geometry, background, time, statistics, and attenuation.

With regard to your observation regarding an earlier application, please note that the NRC's evaluation of an exempt-distribution license application does not necessarily depend on an applicant's response to a single question or item of guidance. While it may appear that the NRC "accepted" a particular response, it is possible that the importance of the item was overshadowed by other considerations.

Your response should include a description of how the determination of counting efficiencies will be implemented within your QA program. As stated above under question 11, you should have complete procedures for your activities in place prior to the commencement of operations. A draft procedure is acceptable during the application process.

Regarding Question 15, part 7, your description of the detection capability of a scintillation probe is incomplete. As stated above concerning sample sizes, your analysis should take into consideration the various components of a radioactivity counting system.

Regarding Question 15, part 6, you stated that HNJ will obtain the radiation detection equipment as soon as it is certain that the equipment inventory is acceptable to the NRC. We cannot evaluate the adequacy of your equipment and methods without a description of the equipment you propose to use.

Regarding Question 15, part 9, concerning procedures and/or agreements with exporters, it is not clear whether your program has adequate procedures for minimizing "false negatives." It is not appropriate to rely solely on the exporters' assessment. Please describe your method for confirming that you are able to identify individual gems with radionuclide concentrations greater than those specified in response to Item C.2.e.

<u>Question 16</u>

See question 7.

<u>Question 17</u>

In question 13 of our RAI, we asked you to describe how the use of reference sources at the beginning of each day will accomplish the goal of testing the system in the manner that would be accomplished by the introduction of "spiked" samples into the routine counting process.

We agree that the use of a known, long-lived reference source is the best way to test the constancy of the instrument. However, Appendix G, Item D.5.b. asks you to describe the methods and frequency of introducing "spiked" samples into the routine counting process, as part of your QA program, to assure identification of gems with concentrations in excess of your criteria. This is separate from the daily instrument check. Therefore, please describe how you will meet the intent of this guidance.

If we have not received a satisfactory response within 30 calendar days that addresses all of the issues in this letter and shows that you are qualified by training and experience to conduct the activities required at the time of licensing, it is our intent to deny your application. If we receive no response within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you, which will also result in the NRC's denial of your application.

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 regarding the questions raised in this letter, please contact Richard Struckmeyer of my staff at 301-415-5477, or by email at Richard.Struckmeyer@nrc.gov. For other questions, please contact either J. Bruce Carrico at 301-415-7826, or Jack Foster at 301-415-6250.

Sincerely,
/RA/
Jack W. Foster
Branch Chief, Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-37897

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).

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Sincerely,
/RA/
Jack W. Foster
Branch Chief, Licensing Branch
Division of Materials Safety and
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Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-37897

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DATE	02/7/2011	02/8/2011	02/8/2011	

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