UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

February 17, 2010

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

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. We apologize for the delay in responding to application; however, as you are aware, we have had previous conversations with your consultant, Todd Anderson, who we informed of certain concerns we have regarding the application, and that there have also been some outside concerns raised regarding our licensing policy for gemstones and our licensees current approach to evaluating and releasing bulk gemstones. While we are still in the process of evaluating these additional concerns, we wanted to continue with processing your application and at least have you address the apparent concerns we have noted.

We find that we will need the following additional information to continue review of your application: (Note that each of the following Items cited refer to Appendix G of NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses" unless otherwise noted.)

1. Item B.1.d requests that you identify where and by whom each irradiation or other treatment is performed and that you identify foreign reactors by name and country.

   Your application indicates that the gemstones will be subjected to both reactor and accelerator irradiation. However, in your response to this item, you only indicate that the gemstones will be treated by overseas facilities, "such as Zimmerman BCS Stones" of Germany. It our understanding that if fact you may be importing gemstones that have been irradiated by other facilities.

   Please clarify and provide specific information to identify any other facilities that may be irradiating the stones you will import and/or further discuss exactly how and from whom generally you anticipate receiving the gemstones you plan to evaluate. We note that you refer to exporters from whom you anticipate receiving gemstones – please clarify.

2. Item B.1.f requests information concerning how gems are handled to ensure grouping according to geologic origin and type(s) of irradiation and note that

significant variations in induced radioisotopes may result from differences in the gems' origin and type(s) of irradiation.

Your application indicates that “The grouping by gemstone type accounts for grouping by type of irradiation” and “…information on the geologic origin of the gems is not available to HNJ.” Your statement regarding maintaining a record of the mass and activity per lot does seem relevant to this question.

Please clarify how the grouping by gemstone type will account for type of irradiation and why information regarding geologic origin is unavailable to HNJ. Please describe any effort you will make to obtain this information from your suppliers.

3. Item B.1.g requests that you Identify of all radioisotopes with physical half-lives greater than 2 hours and classify each as either a "major" or "minor" radionuclide depending on its contribution to total activity in gems to be distributed. Item B.1.h asks how the preceding information was obtained and if this information should be representative of gems imported in the future.

   Your response to item g provides a table, and in the response to item h you indicate that this information was obtained from NUREG/CR-5883.

   Please identify the specific tables, paragraphs, or sections in NUREG/CR-5883 from which obtained this information. Noting that the NUREG/CR-5883 generally applies to Topaz and that your application indicated that you intend to also distribute irradiated tourmaline and spinal, please clarify how the information you provide in the table would apply to these gemstones.

4. Item B.2.a requests that you 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.

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

   Please clarify why you would assume the gemstones already satisfy 10 CFR 30.70 requirements when received by HNJ. Again, it is our understanding that you may be importing gemstones that have been irradiated by other facilities so it cannot be assured Zimmerman BCS Stones’ procedures may be followed in all situations. If you are uncertain of who in fact may be irradiating the gemstones, then you will need to describe procedures as requested in this item. Each gemstone will need to be tested, five randomly chosen stones will not be adequate. Also please note that your procedures should describe the equipment, monitoring, counting, and statistical techniques used.

5. In item B.2.b of your application you indicate that sorted gems will be stored for at least three weeks after irradiation to allow for decay of short-lived activation products.

   Please clarify how you will assure that storage of at least three weeks will pass after irradiation.

6. In item B.2.d of your application you indicate that gemstones exceeding the criteria in your item C.2.e will be held for decay. However, please note that the limit you cite in C.2.e, 2 nCi/g (74 Bq/g) is not an acceptable limit. The radionuclide concentrations in the gemstones must meet the limits specified in 10 CFR 30.70 at time of distribution. Please clarify.

7. Item C.1.b requests that you identify the individuals who will be responsible for handling, irradiation, storing, counting, evaluating, and controlling the release of irradiated gems and describe their training and experience.

   In your response, you identify two individuals who will be responsible for handling the gemstones. You further indicate that these individuals, and any others, will receive training in general radiation safety and handling and shipping hazardous materials.

   However, the information you provide needs to show that the responsible individuals, and others, have, or will receive, adequate training and experience in analyzing gemstones, identifying the radioisotopes present and their concentrations, and in using the radiation detection instrumentation that will be needed to conduct these assessments and assure that the gemstone comply with regulatory requirements. Please clarify and provide detailed information to show that the individuals conducting these activities have or will receive adequate training prior to conducting such activities without supervision.

8. In your response to Item C.2.d, you state, “The maximum activity levels observed in irradiated gemstones, analyzed for release has been as high as 20 nCi/g (740 Bq/g).”

   Please clarify how you reached this conclusion, and when you performed such analysis. Please specifically address this item for the tourmaline and spinal gemstones.

9. Item C.2.e asks you to estimate the maximum concentration of the radioisotopes in the gemstones at the time of transfer to persons exempt from licensing.

   In your response you indicate that the concentration at time of transfer will be 2 nCi/g (74 Bq/g).

   Please note that while this level seems to be a commonly referenced criteria within the industry, it is not acceptable. The individual and collective radioisotope concentration at the time of transfer must not exceed the concentrations and limits specified in 10 CFR 30.70. Please clarify.

10. Item C.2.e asks you to describe your control methods to assure that no more than the specified maximum concentration is in the product at time of transfer.

Your response discusses some exporter not releasing gemstones until they are below 74 Bq/g or an average concentration of 70 Bq/g.

This item asks you to describe your procedures. Again my understanding is that you will not know how the gemstones were processed or analyzed prior to you receiving them and so you must assure 10 CFR 30.70 requirements will be met. Please clarify.

11. In item 3.a of your application you indicate that HNJ will conduct radiation surveys to ensure that the byproduct material concentrations do not exceed exempt concentrations prior to transfer. Please clarify what you mean by “radiation surveys.”

12. In item 3.b of your application, regarding reconcentration, you state, “Shipments of irradiated gemstones must meet the requirements of 10 CFR 30.70 before they are sent to HNJ.” Please describe how you will ensure that the gemstones will meet this criteria before you receive them.

13. In your response to Item 3.c, the last sentence states, “This seems unnecessary in light of the dose rates found above (C.2.e). Please clarify what this sentence refers to – please completely address this item.

14. Item D.2 requests that you specify the frequency, standards (including radionuclide, activity, and accuracy), and procedures used to calibrate your radiation detection equipment.

    In your response you state, “All survey meters will be calibrated annually by a licensed facility. HNJ will use NIST-traceable reference sources to test for constancy, efficiency, and energy resolution for the Ludlum Model 2000 scaler.”

    Please provide complete, detailed information regarding your calibration program as requested in this item. You should identify the licensed facility which will calibrate your survey instruments, describe NHJ’s procedures, and identify who will conduct these activities and describe their applicable training and experience.

15. You need to provide more complete and detailed information in your response to Item D.3. As specified in D.3, you need to provide detailed Quality Assurance (QA) Program procedures that HNJ will be expected to implement and individuals follow to in measuring gemstones to ensure, as described in the Appendix, that:

    a. After each irradiation, measurements performed on gems are adequate to identify all induced radionuclides

    b. Before release to unlicensed persons, gems are analyzed to ensure that the concentrations listed in 10 CFR 30.70 are not exceeded; because multiple radionuclides will normally be present, the "sum of the ratios" does not exceed unity. (In lieu of use of the "sum of the ratios," it would be acceptable to assure that (1) induced beta and/or gamma emitting byproduct material has a physical half-life less than 3 years and (2) concentration does not exceed 1 x 10-6 µCi/gm.

c. If the activity is not quantitatively measured in each gem individually (i.e., if quantitative measurements are made on groups of gems), there is only 1 chance in a 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value (for single or multiple radionuclides).

The following are some items from your application that need further clarification regarding this item (please note this list is not meant to be all inclusive):

1. Specifically describe what you intend by each type of jewelry and type of irradiated gemstone in a.
2. Please provide more detailed information concerning selection of samples and sample size. You should describe why you believe the minimum and maximum sample sizes you choose in item b will ensure compliance – with particular attention directed toward addressing item D.5.c. Note that all gemstones should be evaluated for radioactivity. Please clarify your intent regarding choosing sample size.
3. In item c, how the counting efficiencies for your equipment will be determined by a licensed calibration facility, identify this facility, and discuss how this will be implemented within your QA program.
4. Specifically discuss your instrument set up's counting geometry for item e.
5. In item f, clarify why you discuss and what you mean to imply by the reference to the exporter in the second sentence.
6. Why we should have confidence in your QA program given your response to items g, h, and j, which indicate you are unable to accurately address these items as you do not actually possess the radiation detection instruments you've identified.
7. Specifically discuss how information contained in NUREG-1156 and Report No. 58 of the National Council on Radiation Protection and Measurements would be utilized in developing your QA program
8. Why quarterly program reviews as identified in h should be adequate to ensure compliance.
9. What procedures and/or agreements you have in place with exporters to ensure i will be met. Please provide information identifying your exporters so that we can confirm their procedures.

16. Item D.4 requests that for the individual who will be responsible for the QA program, you describe their training and experience in detection and analysis of low-levels of radioactivity.

    In your response you indicate that Heather Johnson, the RSO, will be responsible for the QA program and that HNJ has retained a licensed medical physicist who will provide training and conduct quarterly reviews of HNJ's radioactive materials program.

    Please provide a complete description of the training and experience in detection and analysis of low-levels of radioactivity for both Ms Johnson and the medical physicist. Please confirm the identity of the medical physicist. Please describe in detail the training that will be provided to the HNJ staff as indicated in your response. Describe in detail how the staff's understanding and qualifications to independently conduct the QA program and analyze gemstone concentration to ensure compliance will be determined.

17. In your response to Items D.5 a and b, you indicate that constancy tests on the scaler will conducted using a NIST-traceable Cs-137 rod source and that rather than using spiked samples, HNJ will use reference sources at the beginning of each day.

    We note that HNJ's State possession license does not include any licensed reference sources. Please clarify. The intent in Item 5.b to introduce "spiked" samples into the routine counting process is to randomly and unknowingly "test" the system – please describe how the use of reference sources at the beginning of each day will accomplish this goal.

18. For your response to Item E, you indicate that you used information and calculations from license applications submitted by the University of Missouri and HBM Virginia. We note that at least HBM Virginia's license only authorizes distribution of topaz. In view of your request to distribute tourmaline and spinal gemstones in addition to topaz, please provide the information requested in Item E.2 and 3 for the radioisotopes that may be expected to be found in these gemstones.

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/reading-rm/adams.html.

Please provide your response within 30 days of the date of this letter and refer to the mail control number listed below. If you have any questions, please contact me at (301) 415-7826.

Sincerely,

/RA/

J. Bruce Carrico
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs
Washington, DC 20555

Mail Control No. 022794
ML_____
DOCUMENT NAME: H:\EXEMPT\32.11\Defltrs\HNJ, Inc

OFC	LB											
NAME	JBCarrico											
DATE	2/ 17 /2010											