

To: 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

From: Kristin Holcomb  
HNJ Jewelry  
5525 N. MacArthur Blvd., Suite 160  
Irving, TX 75038

Re: Response to NRC Request Dated 2/17/2010  
**MAIL CONTROL NO. 022794**

Dear Mr. Carrico,

Please accept this letter as HNJ's response to your letter dated February 17, 2010 regarding our application for a distribution license for irradiated gemstones.

Given that the response to our application of December 8, 2008 took 14 months to arrive, we request a prompt response to this letter. If it may help expedite the process, please contact our medical physicist, Todd Anderson, with any questions related to this application. This is a high priority for HNJ and we wish to work with the NRC so that the license may be granted as quickly as possible.

Sincerely,

Kristin Holcomb

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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.

**Irradiation is done at the following facilities;**

**University of Missouri Research Reactor Center  
Columbia, MO**

**ZIMMERMANN BCS STONES GMBH**

**IM SPIELBERG 6, D-55296 HARXHEIM, GERMANY**

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.

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.

**Since gamma-ray treatments are not covered by the NRC requirements, the answer to this item is restricted to neutron and electron irradiation. Sky blue topaz results from electron irradiation, London blue topaz from neutron treatment, and Swiss blue topaz is produced by neutron bombardment followed by electron irradiation. Therefore, grouping the gemstones by type effectively separates them by irradiation process.**

**Information regarding geologic origin is simply not tracked as the stones go from the mine to the irradiation facility and out to distributors. Also, the variations in activation products for stones of different geologic origin do not affect the release criteria. It is noted that, based on information available in the electronic reading room, other applicants, such as HBM Virginia, have been granted licenses by stating that information on geologic origin is also not available to them.**

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.

**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.**

**Information regarding the major and minor radionuclides that are produced from neutron and electron irradiation of topaz was obtained from the following sources;**

- a. Chapter 2 of NUREG/CR 1717
- b. NUREG/CR-5883
- c. Gemstone Irradiation and Radioactivity, Ashbaugh CE. Gems & Gemology, Winter 1988

**d. Radioactive and Radiation Treated Gemstones, Ashbaugh CE. Radioactivity and Radiochemistry 2(1): 42-57**

**The radionuclides are included in our application dated 12/4/08 along with their half-life and classification as major or minor.**

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.

**Upon arrival at HNJ, all shipments containing radioactive materials will be placed in a secure area. Within three hours of receipt, the Radiation Safety Officer or designee will conduct a radiation survey.**

**The gemstones will be moved to a secure container and the interior of the shipping package will be checked for contamination. Wipe tests for removable contamination will be taken on five items.**

**Any wipe test of more than 50 counts per minute with the pancake probe or more than 150 counts per minute with the scintillation probe, will be considered contaminated. A valid wipe test must include the entire surface of the gem.**

**If contamination is found, each item will be cleaned, after which 1% of the items in the shipment will be surveyed for removable contamination. This process will continue until the items are deemed to be free of contamination. Items will be determined to be free of removable contamination when a wipe test yields counts below the values given above.**

**Any items that cannot be decontaminated will either be returned to the vendor or held in a designated storage area at HNJ for physical decay until they are determined to be free of removable contamination.**

**The NRC's response to our previous application stated that sampling five gemstones is not sufficient. This same level of sampling was approved for the license application of Prime Art Jewelry. If the NRC believes that this sampling is not appropriate, we request an answer on why such sampling is not appropriate and why such sampling was acceptable for the Prime Art Jewelry application.**

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.

**Zimmerman BCS holds the irradiated stones for six months to three years after irradiation. Gemstones irradiated at the University of Missouri Research Reactor Center are held for a few months up to a few years.**

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.

**Any gemstones with concentrations exceeding the criteria in C.2.e will be held for physical decay in a secure storage area. The gemstones will not be released until it is confirmed by measurement that the concentrations are lower than the limits given in 10 CFR 30.70.**

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.

**Heather Johnson and Kristin Holcomb will receive training in the following;**

1. **Basic Radiation Concepts**
  - a. **What is radiation?**
  - b. **Definition of ionizing radiation**
  - c. **Source of background radiation**
  - d. **Interaction of Radiation with the human body**
2. **ALARA**
3. **Cardinal Principles of Radiation Protection**
  - a. **Time**
  - b. **Distance**
  - c. **Shielding**
4. **Personnel Monitoring**
5. **Regulatory Issues and Source of Regulatory Information**
  - a. **NRC**
  - b. **Texas Dept. of State Health Services**
  - c. **Required record-keeping ( inventory, area surveys, etc.)**
6. **Receiving and Opening Packages of Irradiated Gemstones**
7. **Proper Storage of Irradiated Gemstones**
8. **Radiation Surveys**
9. **Removable Contamination ( Wipe Tests )**
10. **Instrumentation**
  - a. **Scaler**
  - b. **Survey Meter**
    1. **Pancake Probe attachment**
    2. **Scintillation Probe attachment**

**All of the above topics will be addressed in detail as part of an initial training session which will be done before HNJ distributes gemstones under its license.**

**Training will be conducted by a medical physicist from Radcom Associates. Radcom's physicists are all licensed through the Texas Department of State Health Services and have several years of experience in training radiation workers. Todd Anderson from Radcom will conduct the training.**

**All HNJ employees will complete the full training program with the medical physicist before performing any of the tasks expected of a radiation worker.**

**Detailed training records will be maintained on site.**

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.

**Again, spinel and tourmaline are not produced by neutron or electron irradiation so it is appropriate to limit this discussion to irradiated topaz.**

**The value of 740 Bq/g which was stated in our last application is incorrect. The correct value is 74 Bq/g and is based on information from Zimmerman BCS. Zimmerman BCS does not release the irradiated gemstones until the average concentration is below 74 Bq/g.**

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.

**Zimmerman BCS gives the maximum concentration at the time of transfer as 6-19 Bq/g. They provided a range of values since the ratio of radionuclides will vary from lot to lot.**

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.

**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.**

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."

**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.**

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.

**Zimmerman BCS does not ship gemstones into the United States until all treatments are completed and the requirements of 10 CFR 30.70 are satisfied.**

**Since HNJ does not perform irradiation, heating, or any type of treatment that could alter the radionuclidic concentration, there is no possibility of reconcentration after HNJ receives the stones.**

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.

**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". I see nothing in the publicly available documents to suggest that the NRC disagreed with HBM's conclusion.**

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 HNJ's procedures, and identify who will conduct these activities and describe their applicable training and experience.

**Calibration will be done by one of the following licensed facilities;**

**MPM Products  
415 Lillard Road  
Arlington, TX 76012**

**Ludlum Measurements, Inc.  
501 Oak Street  
Sweetwater, TX 79556**

**HNJ will ensure that the survey meter and scaler are calibrated annually by one of the facilities listed above. MPM or Ludlum will use NIST-traceable calibration sources and provide a detailed summary of the results on the calibration certificate. The training described in item C.1.b will ensure that HNJ employees know how to use the information on the calibration certificate; particularly the detector efficiency.**

**The radiation detection equipment will be operated by HNJ employees who have completed the training described in item C.1.b above.**

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  $1 \times 10^{-6} \mu\text{Ci/gm}$ .)

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.

**Each type of irradiated gemstone referred to the different types of topaz that HNJ will receive; Swiss Blue, Sky Blue, and London Blue.**

**Each type of jewelry referred to rings, bracelets, or necklaces.**

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.

**We feel that our response to this question; a minimum sample size of 10 pieces with a mass of 2 grams or greater and a maximum sample size of 5% of the number of items in the shipment is appropriate.**

**We would like to point out that PAJ gave a maximum sample size of 5% of total number in any single shipment if contamination is found, minimum sample size of 10 items. We based our response to this question on PAJ's answer because it was accepted by the NRC.**

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.

The counting efficiency will be determined using the following procedure;

**A one-minute background count is first obtained. Then a Co-60 reference source is placed in the instrument and another one-minute count is taken. Since the calibration date and initial activity of the (NIST-traceable) reference source are known; the expected count number can be calculated. The measured count is divided by the expected count and multiplied by 100 to express the counting efficiency as a percentage.**

The calibration will be done by one of the following licensed facilities;

**MPM Products  
415 Lillard Road  
Arlington, TX 76012**

**Ludlum Measurements, Inc.  
501 Oak Street  
Sweetwater, TX 79556**

**The counting efficiency will be given on the calibration certificate from the calibration facility and will be included on the worksheets for reporting wipe test results to ensure that the results will be converted from cpm to dpm using the correct efficiency.**

4. Specifically discuss your instrument set up's counting geometry for item e.

**The calibration facilities perform the calibration with the radiation source 1 cm from the detector face. The same geometry will be used at HNJ and the importance of geometry in relation to counting efficiency will be stressed during the training sessions with the medical physicist.**

5. In item f, clarify why you discuss and what you mean to imply by the reference to the exporter in the second sentence.

**Our response to item f in the previous application was simply stated incorrectly HNJ will conduct a radiation survey of all packages containing irradiated gemstones within three hours of receipt. All packages containing**

**irradiated gemstones will be received during regular business hours.**

**In addition, weekly area surveys will be done on the storage area where the gemstones are held.**

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.

**HNJ will purchase the radiation detection equipment as soon as the NRC license is granted. Because of conflicting answers from the NRC regarding instrumentation, HNJ felt that this was the best approach. HNJ will obtain the radiation detection equipment as soon as it is certain that the equipment inventory is acceptable to the NRC.**

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

**These documents were referenced since they address the Lower Limit of Detection. Perhaps it is better to respond with a discussion using values appropriate for the scintillation probe.**

**Based on values obtained from Ludlum, 10% is a typical Co-60 efficiency for the 1" x 1" NaI probe. For a 1-minute background count of 1000 cpm, the LLD is determined to be 150 cpm above background with a confidence level of 95%. Applying the efficiency correction gives  $150 \text{ cpm} \times 10 = 1500 \text{ dpm}$ , which corresponds to 67.6 pCi.**

**The exemption limits for the five major radionuclides involved (Ta-182, Sc-46, Mn-54, Zn-65, and Cs-134) ranges from 90 pCi/gm to 1000 pCi/gm. The LLD is 67.6 pCi/gm for a 1-gram sample. Therefore, this method can detect concentrations that exceed the respective exemption limits.**

8. Why quarterly program reviews as identified in h should be adequate to ensure compliance.

**The quarterly audit will be a thorough review of all elements of the radioactive materials program. These audits will be conducted by a licensed medical physicist and will ensure that the proper procedures for radiation surveys, wipe testing, receiving and opening packages, and record-keeping are followed.**

**While the quarterly reviews are an important part of the program, they are just one component and compliance will also be ensured through the initial training of HNJ staff and ongoing communication between the staff and the medical physicist.**

**The medical physicist will also be responsible for tracking changes to the NRC and Texas DSHS requirements and incorporating these changes into the program.**

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.

**The exporters have procedures in place for this which are available upon request. Further, the method outlined in Item 7 of this response used the 95% confidence interval so the possibility of a false negative is statistically very low.**

**Irradiation Facilities;**

**University of Missouri Research Reactor Center  
Columbia, MO**

**ZIMMERMANN BCS STONES GMBH  
IM SPIELBERG 6, D-55296 HARXHEIM, GERMANY**

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.

**The training program is outlined in item C.1.b. above. Training for receiving, opening, and storage of packages containing irradiated gemstones, radiation surveys, wipe tests, and 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. The training will be thoroughly documented by the medical physicist and maintained by HNJ for review.**

**Todd Anderson of Radcom Associates is the consulting medical physicist for HNJ. Mr. Anderson is licensed through the Texas Department of State Health Services in both radiological physics and medical nuclear physics. He is based in the Dallas-Ft Worth area and will be available to HNJ as needed. After the initial training, the**

**physicist will conduct quarterly program reviews for at least the first year of operations. The medical physicist will verify that Ms. Johnson can perform all functions of the Radiation Safety Officer and will confirm that all procedures and record-keeping requirements are being met as part of the quarterly program audits.**

17. In your response to Items D.5 a and b, you indicate that constancy tests on the scaler will be 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.

**The Texas Administrative Code allows for the possession of reference and calibration sources to all licensees without explicitly stating these sources on each license.**

**The use of a known source is preferred because it tests the constancy of the scaler. The most common problem with these instruments comes from fluctuations in the line voltage from the building's power supply which alters the meter's detection efficiency. The use of a known, long-lived reference source is the best way to test the constancy of the instrument.**

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.

**The fact that our initial application mentioned spinel and tourmaline without explaining that these gemstones are not produced through electron or neutron irradiation understandably led to confusion on this issue. As stated above, tourmaline is produced via gamma-ray irradiation and spinel production does not employ irradiation of any kind.**