

Application for Import, Possession and  
exempt distribution of neutron irradiated Topaz

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## Appendix G

### Information Needed from Importer for §32.11 Application

Information Needed From an Importer to Support Application For License Pursuant to 10 CFR 32.11 to Distribute Neutron-irradiated Gems to Persons Exempt from Licensing (February 25, 1988)

#### **Notice**

This revised contains clarification with regard to the questions posed by the NRC, dated Oct 30, 2007. All clarification is highlighted similar to this notice.

#### **Introduction**

Gems such as topaz assume an attractive color when irradiated by neutrons in a reactor. These gems, which are used in jewelry (e.g., rings, pendants), remain radioactive as a result of the neutron irradiation.

We are planning to commercially import neutron-irradiated topaz into the United States need and herewith provide the information required for: (1) a "possession" license and (2) a "distribution" license issued for exempt distribution according to 10 CFR 30.70.

In analogy to other foreign manufactured devices that include radioactive sources and are then imported into the USA (such as smoke detectors) we desire to complete the manufacturing and certification process of neutron and electron irradiated gemstones outside of the USA. HBM Virginia LLC will audit the foreign manufacturing processes and maintain records of all relevant findings. HBM Virginia will also maintain all records pertaining to shipments reaching the US as required by the NRC. We commit to maintain all record the NRC determines to be necessary and will oblige our exporter to supply all NRC required records.

HBM Virginia LLC is part of a family business in irradiating and trading irradiated gemstones for 30 years. Helmut Zimmermann, Dr.h.c., has founded the business in Germany and has expanded it to Hong Kong and the USA. Long term relations with neutron reactors and the construction of our own electron accelerator systems (Herotron Technologies) provide BCS Stones GmbH with complete control over the manufacturing process and gemstone tracking. HBM Virginia LLC will exclusively import from BCS Stones GmbH. HBM Virginia LLC will be managed by Martin Zimmermann, the son of Helmut Zimmermann.

Until recently BCS Stones GmbH has only been requested to provide irradiated gemstones with 10 or 74 Bq/g batch average activity. Our spectrometry laboratories have performed isotope specific analysis for this purpose for several years. We are now implementing new processes to fulfill the more stringent 10 CFR 30.70 requirements.  
In the future we plan to amend our license to electron irradiated gemstones once the respective NRC regulations are in place.

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HBM Virginia LLC

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### **Content of Application**

#### A. Basic Information

1. Specify name of applicant  
HBM Virginia LLC
2. Specify applicant's mailing address  
c/o HBM Nevada LLC  
854 Beartooth Falls Ct  
Henderson, NV 89052
3. Identify the person with detailed knowledge of the application that the NRC staff can contact about the application, giving the person's:
  - a. Name  
Joern Meissner, PhD
  - b. Title  
Consultant to HBM Virginia LLC
  - c. Telephone number  
+49 179 5414652  
Meissner@herotron.de
4. Specify the location(s):
  - a. At which gems will be received and possessed  
98 Alexandria Pike Suite 42  
Warrenton, VA 20186
  - b. From which irradiated gems will be distributed to persons exempt from licensing  
98 Alexandria Pike Suite 42  
Warrenton, VA 20186
  - c. At which records pertaining to possession and distribution of irradiated gems will be maintained.  
98 Alexandria Pike Suite 42  
Warrenton, VA 20186

#### B. Background Information

1. Describe the material to be imported, including:
  - a. The type of gems  
Topaz
  - b. Extent to which gems have been processed before irradiation (e.g., cut and polished)

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Finished Topaz ready for mounting (Cut and polished or polished)

- c. The type(s) and sequence (e.g., neutron-irradiation only; neutron followed by accelerator or gamma irradiation) of irradiation or other treatment (e.g., heat) to which gems have been exposed before they are to be imported

See attachment "Product Flow" filed as confidential information under 10 CFR 2.390 for an overview on production processes.

- B 1. d. Where and by whom each irradiation or other treatment is performed. Identify U.S. reactors by name and location; identify foreign reactors by name and country.

Currently four reactors are utilized for neutron treatment of Topaz;

Please refer to attachment "Names of reactors utilized for neutron treatment of topaz" submitted as a confidential document under 10 CFR 2.390.

Electron accelerator treatment succeeding neutron treatment will be performed by Herotron Technologies GmbH, Germany, a radioactive material license holder according to German regulations.

Heat treatment succeeding all irradiation treatment will be performed by BCS Stone GmbH, Germany, a radioactive material license holder according to German regulations.

See attachment "Contractual Commitments" for information on relations between all involved companies.

BCS Stones GmbH offers its customers a service certification of cut and polished gemstones (see attachment "product flow"). Service certification allows HBM Virginia LLC to apply the same measurement process to gemstones that have not been irradiated by the BCS Zimmermann group of companies. It provides the possibility to our customers that we measure their existing stock of gemstones, verify compliance to NRC-exempt distribution regulations and release them for US-exempt distribution according to HBM Virginia's license. We provide this service only for gemstones that are not set into jewelry.

Gemstones reaching BCS Stones GmbH for this process are considered:

- Irradiated by third parties with unknown irradiation methods and parameters
- of unknown origin
- of unknown activity at the time of receipt

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Hence we will divide the customer's shipment in suitable lots of 500g – 1000g and determine the isotope specific lot average activity. The process described in item C.2.f will be applied.

- B 1. e. If gems are exposed to additional irradiation or treatment after importation, for neutron irradiation only, the type(s) and sequence and where and by whom each is performed

No additional irradiation treatment will occur after importation.

- B 1. f. 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 will result from differences in gems' origin and type(s) of irradiation or treatment received)

All stones sent to reactors are given lot numbers which correlate to:

- Customer owning the stones
  - Country of origin of stones
  - Reactor treating the stones
  - Date of reception from customer
  - End color desired: London, Super Swiss, Swiss, super sky, sky
- Note – see attachment "product flow" for color/process correlation

Geologic origin refers to the specific geologic formation that the gemstones were mined from. The information on geologic origin is not available from our customers. The isotopic impurities are generally similar from country to country but may very well vary from mine to mine or even inside one mine. The country of origin is declared by our customers but it cannot be verified.

BCS Stones GmbH is responsible for gemstone acquisition and the complete product tracking. Lots are formed as described in item D.2.f. All shipping gemstones will be traceable to lot numbers and therefore all certifying measurements performed through the BCS product tracking system.

Hence no stone will be imported that is not identified by shipping lot and therefore all stones traceable to certified radioactivity measurements.

The respective product tracking records will be available at HBM Virginia LLC.

- B 1. g. Identification of *all* radionuclides with physical half-lives greater than 2 hours (regardless of method of production) induced in gems and classification of each as either a "major" or "minor" radionuclide depending on its contribution to total activity in gems to be distributed to persons who are exempt from licensing

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Normal Reactor practice is to allow six to twelve months decay before processing the stones for analysis. The shorter half-life isotopes have only been detected in short experimental irradiations with increased counting time in order to lower MDAs. The results are listed in table 1 below.

The reactors have different neutron spectrums which result in slightly differing isotope yields. The same major isotopes are found at either reactor however the distribution of the isotope's specific activity is different.

In order to classify radionuclides as major or minor approximately 5000 sub-lots received from reactors in 2004 until 2006 have been statistically analyzed. In the analysis for each lot's certificate of radioactivity the respective specific activities were compared to the limits stated in 10 CFR 30.70. Normal distribution has been assumed and average values,  $\mu$ , as well as standard deviations,  $\sigma$ , have been computed.

We deem it sufficient proof that radionuclides whose  $\mu+\sigma < 0.2 \times$  its NRC limit do not contribute significantly to the total activity and we hence classify them as minor.

Hence we identify these isotopes as major:

46-Sc, 54-Mn, 59-Fe and 182-Ta.

It must be noted that the isotopes 134-Cs and 233-Pa are only seldom detected in lots. If present, they may however play a dominant role in the certification process:

Typically 134-Cs is only present finished gemstones which have a hole drilled into it and are neutron irradiated. We presume that the residue from the diamond drill and the cooling agents used during the drilling are responsible for activation of this isotope. In these gemstones the 134-Cs may well exceed the NRC limit.

The cause of 233-Pa presence is not known. When present, its activity often exceeds the NRC limit at the time of lot-measurement. With a 27d half-life decay to NRC limits is easily achievable.

Presence of 134-Cs and 233-Pa or any other radionuclide not mentioned in our list of isotopes in a lot will result in treatment of that lot with increased vigilance:

The isotope specific activity distribution inside a lot is determined by taking several random 30g samples. The result will be analyzed by the QA responsible and at his discretion the actions include:

- classification as minor isotope
- decay of isotope until a certification method (item D.2.f) can be applied successfully
- hot stone selection with special focus on the isotope in question

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Table 1.

List of radionuclides detected in irradiated topaz stones

Nuclide	Half-life $T_{1/2}$ Days	$E_{\text{gamma}}$ keV
Cr-51	27.7	320.0
Sc-46	83.81	889.3
Sc-47	3.34	159.4
Mn-54	312.1	834.8
Co-58	70.88	810.8
Fe-59	44.51	1099.0
	44.51	1291.6
Co-60	1924.9	1173.2
	1924.9	1332.5
Zn-65	243.8	1115.5
As-76	1.097	559.1
Br-82	1.47	554.3
Rb-86	18.65	1076.7
Nb-95	34.97	765.8
Zr-95	64.02	724.2
	64.02	756.7
Sb-124	60.2	602.8
	60.2	1691.0
Ba-131	11.53	123.8
	11.53	496.3
Ag-110m	249.76	657.8
	249.76	884.7
Cs-134	754.1	604.7
	754.1	795.9
Ce-141	32.5	145.4
Eu-152	4944.8	121.8
	4944.8	1408.0
Tb-160	72.3	86.8
	72.3	879.4
Hf-181	43.39	132.9
	43.39	482.0
Ta-182	114.43	152.4
	114.43	1221.4
	114.43	1231.0
W-187	1	479.5
Au-198	2.69	411.8
Pa-233	27	312.0
Np-239	2.355	106.1
	2.355	277.6

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- B 1. h. How the information provided in response to Item B.1.g above was obtained and how NRC can be assured that this information is representative of gems imported in the future

The isotopes listed in table 1, section B.1.g, above were obtained from the Neutron Activation Analysis Group at one of our partner reactors. The NAA Group is responsible for the analysis of all Topaz irradiated in their reactor. They follow the attached protocol for processing the Topaz following irradiation and for determining the isotopic distribution.

Please see attachment "Protocol for Topaz analysis" filed as confidential under 10 CFR 2.390 for details.

All other reactors performed similar tests with specific focus on the isotopes mentioned above. The resulting measurements confirm the isotopic contents at each of the reactors. The major isotopes in item B.1.g have been confirmed.

Several test irradiations and measurements on topaz samples were made utilizing the complete thermal and epithermal neutron flux of the reactor. As part of the ongoing developments we have reduced the thermal neutron flux as this is not contributing to the coloration change significantly. As a result we will in the future expect to see less of the short lived isotopes Sc-47, As-76, Ag-110m, Pa-233, Np-239, etc.

- i. 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.

No gemstone will be imported unless prior to shipping it is determined that exempt distribution requirements according to 10 CFR 30.70 are met on or before the day of shipment to the US.

We do not anticipate storage of product at this facility in excess of the time required to verify the shipping papers, re-package for customer shipping and occasionally quarantining product (e.g. for sample verification at a Spectroscopy lab in the USA). Our normal turnaround time for product entering and leaving the facility is expected to be 1 to 3 days. We estimate that the occasional quarantined sample may have to be stored for one week prior to release or return shipment to the exporter.

Long term we may process up to 400 kg per week.

Our statistical data shows that topaz fulfilling the sum-of-ratios rule of §30.70 have specific activities of 6-19 Bq/g. Hence we expect the maximum average

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activity to be < 20 Bq/g.

With reserve, we desire a maximum possession limit of 8 MBq ( $8 \times 10^6$  Bq), corresponding to 400kg at sum of ratios equal to 1.

B 2. Describe the handling of gems, including:

- a. 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.

All topaz received will be conform to the exemption requirements by 10 CFR 30.70. Gemstones are cleaned at multiple steps during cutting and polishing, irradiation and other processing prior to import. The imported gemstones are finished stones, cut and polished and ready for setting into jewelry.

All shipping lots are packed with great care at the exporters site (BCS) who has 30 years of experience in packing gemstones. Before shipping all topaz are cleaned and packaged in sealed plastic bags. Larger gemstones are packaged individually. In this way damage of the gemstones during transport is reduced to a minimum. Nevertheless, rough handling during transport may under some circumstances damage the gemstones and create small amounts of dust.

Radioactivity in dust conforming to 10 CFR 30.70 is normally below the detection limits for contamination control devices. Hence dust would normally not be detected as contamination.

Visual inspections of the shipping lots will identify shipping bags with dust inside and quarantine them. Damaged stones are a serious reason for customer complaint and we therefore have a commercial interest in not distributing gemstones with dust.

In the unlikely event that gemstones are damaged and dust is present in the shipping bags, HBM Virginia LLC will coordinate procedures with the exporter and our customers as adequate. Normally, shipping bags will then be opened and the damaged stones extracted. The remaining shipping lot is cleaned as follows:

1. Thirty minute ultrasonic cleaning in a 20% solution of Radiac-Wash (>50 degrees C), followed by a 30 minute ultrasonic cleaning in a heated DHW (>50 degrees C) counter-flow rinse.
2. The stones will be dried.
3. The stones will be re-packaged and distributed

Damaged stones will be returned to the exporter

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- B 2. b. The processing of irradiated gems at the importer's facility and the sequence of these activities (e.g., counting of gems and storage for physical decay; mounting in rings, pendants, or other settings)

The following protocols will be followed at the importer's facility in the US:

1. Receiving
  - a. Verification of correct packages
  - b. Verification content and weigh-in of internal packages
  - c. Verification of adequate shipping papers including certificates of radioactivity proving exempt concentrations according to 10 CFR 30.70
2. Sample verification – This step is intended to provide an independent verification of the certificate data provided by the exporter. The sample frequency and sample size shall be agreed with the NRC. HBM Virginia LLC will send samples to an accredited lab in the US for verification of the conformity to 10 CFR 30.70.  
Ideally the sample size are randomly selected stones from one shipping bag. Initially we propose to provide gemstone samples from 1% of the received shipping bags or at least one sample in every week that a shipment was received. Once sufficient data has been generated to demonstrate process effectiveness we propose to reduce the frequency in steps to 1 sample of a few gemstones per quarter.
3. Shipping - Samples conforming to the exempt requirements in 10 CFR 30.70 will be shipped on to the Customer. Samples with ratios greater than one will be returned to the exporter, or a facility licensed to receive them at the exporters discretion.
4. record keeping – all receiving and shipping paper work, as well as audit records, sample verification analysis and non-conformities will be kept on site on paper. Should the quantity of records exceed our storage capacity we will archive records externally and notify the NRC of this address.

HBM Virginia will require all contracted high resolution gamma ray spectroscopy labs to fulfill and follow minimum QA requirements concerning traceability of gemstones and related measurements, calibration procedures, and spectroscopy equipment.

HBM Virginia will audit BCS Stones GmbH, Herotron Technologies GmbH and the reactor sites for process effectiveness. This will include

1. verification if applicable calibration and maintenance has been performed on all relevant measurement equipment
2. verification of equipment self test data
3. sample verification with calibrated sources
4. verification of records leading to the issuance of the certificate for exempt distribution
5. verification and audit of QA program

| HBM Virginia will perform this task with own personnel and consultants.

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Herotron Technologies commits to being audited by an external company or body every three years. "External" in this context means by a company that is not belonging to the BCS Zimmermann group and that does not use key personnel from the operation of the certification processes. Such external company or body shall have demonstrated knowledge in radiation detection methods similar to the ones employed at Herotron.

Reactors act as suppliers to the BCS Zimmermann group. In a customer-supplier relationship it is customary and generally accepted to be independent if the supplier audits the customer. Measurement processes at the reactors will be audited by Herotron's responsible person for the QA program (see item D.4).

- B 2. c. The categories of unlicensed organizations to which irradiated gems will be transferred (e.g., wholesaler; manufacturing jeweler; retail jeweler; individual consumer)

Wholesaler and Manufacturing Jewelers

- B 2. d. What will be done with gems whose concentrations exceed the criteria specified in response to Item C.2.e. below (Alternatives include hold in storage for physical decay, transfer to a person specifically licensed to receive them, or disposal as radioactive waste in accordance with the requirements of 10 CFR Part 20 or equivalent regulations of an Agreement State.)

Stones with a sum-of-ratios greater than 1.0 will be returned to the exporter or sent to a facility authorized to receive them at the discretion of the exporter. Until then they will be quarantined on site.

C. Information Required by 10 CFR 32.11

1. Paragraph 32.11(a) requires that the general requirements of 10 CFR 30.33 be satisfied. To comply with this requirement (or equivalent requirements of Agreement States), the applicant will:
  - a. Explain how the facilities and equipment proposed in the application are adequate to protect health and minimize danger to life or property; specifically explain how irradiated gems will be stored and secured against unauthorized removal or, when not stored and secured, will be tended under the constant surveillance and immediate control of a knowledgeable, responsible person on the importer's staff.

Security

Short turnover times avoid the storage of large amounts of products on site. The potential black market value in the USA is very low as all wholesalers

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and end-customer sales points require a track record for the legal import and exempt distribution.

HBM Virginia will install a surveillance and burglar detection system for the site. One room will be reserved for incidental product storage and quarantine. This room will present an independent burglar detection zone. The intruder detection system will be monitored 24/7 by a local security company.

Fire requirements will be discussed with the fire marshall and implemented as required.

**Potential hazard**

Following our explanation in item E.2. of this application there is no hazard to anybody from the gemstones. All gemstones are expected to conform to 10 CFR 30.70. Quarantined material will typically not exceed the NRC limits by much more than the measurement **error** (hence 10%-20%) und is therefore also not considered a hazard.

- b. Identify by name the individuals who will be responsible for handling, irradiation, storing, counting, evaluating, and controlling the release of irradiated gems; correlate individuals' names with their responsibilities; and describe the training and experience of each of these individuals that assures protection of the public health and safety.

We are in the process of hiring a part time radiation safety officer who can be available on site with reasonable notice. As soon as we have identified a suitable RSO we will provide personal data under 10 CFR 2.390.

Everyday tasks will be performed by personnel trained by the radiation safety officer, BCS and Herotron.

Mr Martin Zimmermann will be the general manager of HBM Virginia LLC. He will be responsible for daily operation and for providing adequate training to persons handling gemstones. Martin Zimmermann has 15 years of experience in gemstone handling. He is part of the Zimmerman family business which consists of the companies BCS Stones GmbH, Herotron Technologies GmbH, BCS Stones Hong Kong Ltd, HBM Nevada LLC and HBM Virginia LLC. Five years ago he assumed the responsibilities for customer relations and business contacts in North Amerika and Asia. He is currently based in Nevada and will move to Virginia.

BCS Stones GmbH has a track record of 30 years in the neutron and electron irradiation of gemstones. Established procedures for handling stones and verifying compliant processes will be transferred from BCS to HBM Virginia by training.

Herotron has a track record of 3 years of electron irradiation and gamma ray

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spectroscopy.

One of the consultants to perform audits of the high efficiency sorting machine will be Mr Stephen Lewis Gunn.

One of the consultants to perform audits of reactor gamma ray measurements and QA program will be Dr. Joern Meissner. Dr Meissner will also perform internal audits of Herotron.

For further information on external audits of the measurement process please refer to item B.2.b.

- C 2. Paragraph 32.11(b) requires that certain information be provided. If information on one or more points has already been provided, reference the previous response by section and item number or provide a complete response. To comply with 10 CFR 32.11(b), the applicant will describe:
- The product or material into which byproduct material will be introduced (see response to B.1.a above)

Topaz

- The intended use of the byproduct material and the product or material into which it is introduced

The byproduct material is incidental to the fast neutron (>1 MeV) displacement that produces the color change in Topaz. The intended use is jewelry.

- C 2. c. The method of introduction (see response to B.1.c. and e. above)

See attachment "Product Flow" and overview on production processes filed under 10 CFR 2.390 as confidential.

- Initial concentration of byproduct material in the product or material

The Topaz does not leave the Reactors until the average concentration is less than 74 Bq/g. The actual concentration at the end of irradiation varies with impurity content. Actual decay time at the reactor will vary from six months to three years.

Only 10 CFR 30.70 compliant topaz will be imported to the USA.

- Estimated maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing

The maximum concentration will depend on the ratios of the isotopes present, but the average will range from ~6 Bq/g to ~19 Bq/g.

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- f. Control methods to assure that no more than the specified maximum concentration is in the product at time of transfer

The following describes processes in place at Herotron, BCS and the reactors, in order to guarantee the 10 CFR 30.70 requirements.

At an anticipated turnover of 400kg of gemstones per months it becomes evident that isotope specific activity determination for individual stones is not feasible. Our technique is based on high resolution gamma ray spectroscopy and activity data from several years of operation at BCS and Herotron.

**Definitions:**

Batch: gemstones that have been irradiated together

Lot: subdivision of a batch; hot stones have been removed and for each lot a gamma spectroscopy analysis is performed at the reactor. Lots are stored at the reactor until they reach UN2910 limits for transport back to BCS

Sub-lots: Herotron will subdivide lots on the basis of NRC-release criteria.

100% of all neutron irradiated topaz will be measured using high resolution gamma ray spectroscopy in order to determine batch average specific activity levels.

100% of all stones will be checked for activity using a high efficiency NaI sorting machine.

Irradiated gemstones are analyzed in a serial function consisting of several steps prior to import:

1. Hot stone removal

This step is designed to remove stones from the group that have dose rates discernibly different from the group. This step is geared to reduce the required decay time for a batch and is not intended to remove outliers as defined in 10 CFR 30.70. The method is slightly different at each reactor. All methods share the common trait that they remove stones based on total activity per stone, not specific activity. The respective batch of irradiated stones is spread out over a larger area or divided into several samples. The batch is then surveyed for dose rates above the average dose rate of the batch. Above average dose rate samples are subdivided until the hot stones are identified. Outliers found this was will be quarantined and typically require long decay times.

2. High resolution gamma ray spectrometry (creation of lots)

The remaining lot is analyzed in a high resolution gamma ray spectrometer for isotope specific activities (Bq/g). The spectrometers consist of high purity Germanium counters of at least 10% relative efficiency in a well shielded environment. Sample sizes for gamma spectrometry are typically up to 1kg.

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The analyzed samples will be identified and packaged in a bag (= lot). A data record for the lot will be created. The data record contains reference to all measurement results for the specific lot. The data record will be available at HBM Virginia LLC. HBM Virginia LLC will receive full documentation of all records relating to the certification process. Hence, for each of these lots it will be possible to track the respective gamma spectrometry analysis throughout the complete remainder of the production, import and exempt distribution process.

For each sub-lot a data record also exists. It refers to the data record of the respective lot and contains additional information on measurements of the sub-lot.

All lots are retained at the reactor site until the specified release date for transportation as exempt material under UN2910.

| 3. Sorting stones by activity (creation of sub-lots)

The University of Missouri was operating a high efficiency topaz sorting machine using automated measurements of weight and gamma activity while they held their NRC license. This machine was auctioned off and Herotron Technologies has purchased all available parts and re-assembled a working sorting machine in Germany in 2004. It has not been used extensively in the past years and is now being re-calibrated and tested. This sorting machine consists of scales to measure the weight of each individual stone and NaI detectors to measure its activity. Detectors are well shielded in lead castles. Depending on the pre-selected activity classes gemstones are sorted into bins.

Each stone of a lot will be measured for its specific activity using a high efficiency counting machine employing NaI detectors and balances. Only very small gemstones of less than 500mg will be grouped into samples of similar sized gemstones as long as the mass of the grouped sample is approximately 1g. This becomes necessary to increase the detector response for very small stones as the NaI is only registering total activity per gemstone. All larger gemstones will be measured individually. The counting machine sorts all gemstones of a lot into different specific activity classes, called bins. The content of the bins is later used to create sub-lots. The isotopic distribution received from the gamma spectrometry data is used to correlate isotope specific activity with the NaI detector's response. According to this response function the limits of each bin are set. The counting machine is computer controlled and equipped with 12 measurement channels, grouped in 2 apparatus with 6 channels each.

Each apparatus is equipped with 8 bins. Each measurement channel of the apparatus can sort gemstones into all 8 bins.

After measuring the specific activity each gemstone is sorted into 8 bins according to their specific activity.

The collection tubes (named Bins 1 -8) are organized as follows:

1. Bin 1 – the collection that should meet the sum of ratios requirement. The bin limit will be set with a safety margin.
2. Bin 2 (Cap Bin) – The upper limit of Bin 2 is set so that the average stone collected will also meet the sum of ratios requirement. The bin limit will be set with a safety margin to ensure that gamma spectroscopy audits of this bin will be consistently successful. When the average of the Bin 2 “Cap” meets the sum of ratios requirement we can infer that with proper machine operation that 100% of the stones in Bin 1 will meet that requirement.
3. Bin 3 – the collection Bin where the average sum of ratios should be less than 2. The bin limit will be set with the same safety margin as for bin 1.
4. Bin 4 (Cap Bin) - The upper limit of Bin 4 is set so that the average stone collected will also have a sum of ratios of less than 2. The bin limit will be set with a safety margin to ensure that gamma spectroscopy audits of this bin will be consistently successful. When the average of the Bin 4 “Cap” sum of ratios is less than 2 then we can infer that with proper machine operation that 100% of the stones in Bin 3 will have a sum of ratios of less than 2.
5. Bin 5 and Bin 6 are used for future use.
6. Bin 7 – catches all stones with a specific activity above the previous bins.
7. Bin 8 – Default Bin. Each time the machine is started, it is assumed that unidentified stones may still be in the machine and all channels are emptied to Bin 8. If during operation, a fault is detected during the counting of a stone, then the stone is placed in Bin8. All stones found in Bin 8 will need to be re-evaluated.

Knowing the average isotope specific activity of the lot allows us to set the bin limits to reflect the resulting total specific activity of stones.

Examples of bin limits are:

- Bin 1: NRC limit minus 20% safety margin
- Bin 2: NRC limit minus 5% safety margin
- Bin 3: 2xNRC limit minus 20% safety margin
- Bin 4: 2xNRC limit minus 5% safety margin

Bin 2 and bin 4 will be audited using high resolution gamma ray spectroscopy for every lot. The audit passes if

- the average activity of bin 2 fulfills the requirement of 10 CFR 30.70
- the average activity of bin 4 does not exceed twice the limits of 10 CFR 30.70

By definition of our bin limits we have captured gemstones with the highest activities that are still §30.70 compliant in bin 2. Hence bin 1 captured all the gemstones with less activity and gemstones in bin 1 are therefore compliant

if the average of bin 2 is compliant.

By definition of our bin limits we have captured gemstones with the highest activities that are still below twice the \$30.70 limit in bin 4. Hence bin 3 captured all the gemstones with less activity than in bin 4 and gemstones in 3 will therefore be compliant once their NRC ratio decays below 1, namely one half-life of the dominant isotope. The dominant isotope is determined high resolution gamma ray spectroscopy.

Providing the audit passed, sub lots are created as follows:

- the content of bin 1 is a sub-lot for immediate release for US exempt distribution
- the content of bin 2 is added to the content of bin 3. Together this forms a sub-lot that will be released for US-exempt distribution in one half-life of the dominant isotope.
- the remaining gemstones (bin 4-8) require further decay and will be re-analyzed by a release method before US-import is considered.

C 2. g. Estimated time interval between introduction and transfer of the product or material (i.e., between completion of all types of irradiation and transfer to unlicensed person).

Neutron treatment is performed at various dose levels. The trace impurities in Topaz range from almost none (Sri Lankan) to high Fe in Nigerian (long decay for Mn-54), high Ta in Brazilian and high Sc in others. The combination of varied impurities and varied neutron dose yield a large range of decay times.

Release times after reactor irradiation have been on the order of six months in the most optimistic case and two to three years in the most sever cases.

Release times after sorting the lots into sub-lots ranges from immediate up to 6 months. Gemstones not sorted in bin 1-3 will be re-analyzed before considered for release. These stones will be stored at Herotron or BCS.

C 3. Paragraph 32.11(c) requires applicants to provide reasonable assurance of the following:

a. Concentrations of byproduct material at time of transfer will not exceed the concentrations in 10 CFR 30.70, Schedule A.

See item 2.f. for details.

b. Reconcentration of the byproduct material in concentrations exceeding those specified in 10 CFR 30.70 is not likely (e.g., in the case of gemstones, one could consider that neutron-irradiation followed by accelerator-irradiation

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could increase the induced activity and thus be considered "reconcentration")

The stones are not sent to the US unless all treatments are finished and the shipment conforms to 10 CFR 30.70.

- c. 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)

Continuously ongoing research is being performed to reduce specific activity of the gemstones without affecting the desired color change. Among these efforts we have identified that surface contamination from rough stones plays a key part of the overall activation. Removing surface contaminants has resulted in reducing radioisotopes that are not typically present in topaz.

The reduction of irradiation dose has been studied but first results indicate that the irradiation dose is not a key parameter for the reduction of specific activity but the reduction of dose has a significant impact on the coloration change.

At present we have not found methods to further reduce specific activity levels and maintain the desired color change. Our current specific activity levels are safe as we are showing in item E.2 of this application. Maintaining the ALARA principle we are constantly trying to improve our process and we have an active research collaboration ongoing with all our reactor partners.

At the moment only a small fraction of neutron irradiated topaz will conform to §30.70. By far the larger fraction has activities up to 74 Bq/g and sum of ratios significantly greater than unity. The economic effect to select an even smaller fraction of irradiated stones than permitted by 10 CFR 30.70 is unreasonable since it is demonstrated in item E.2 that already the current limits expose unlicensed person to insignificant dose levels.

- d. The product or material is not likely to be incorporated into any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by a human being.

All material received will be finished Topaz ready for mounting in jewelry. Topaz is insoluble, and in the unlikely event that Topaz is ingested, its biological half-life would be measured in hours.

#### D. Information on Quality Assurance (QA) Program

1. Describe the radiation detection equipment and shielding associated with it that are to be used to identify and quantify the radioactivity induced in gems

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**High resolution gamma ray spectroscopy**

We are using gamma ray spectroscopy systems at each of the reactor sites and at Herotron Technologies. Typical detectors are high purity germanium and Ge(Li) detectors with a minimum of 10% relative efficiency and a typical energy resolution < 2 keV. The Germanium detectors are equipped with pre-amplifiers, amplifiers and PC-based multichannel analyzers. The equipment and software is manufactured by Ortec and Canberra. One reactor employs Hypermet Software for peak search and analysis; the other labs use Genie 2000 or Maestro.

All high resolution detectors are shielded with iron, lead and/or copper for background reduction.

The attachment "Protocol for Topaz analysis" filed as confidential under 10 CFR 2.390 provides more details on one reactor with its specific gamma spectroscopy laboratory. Similar protocols are in place at other reactors and laboratories.

The attachment "sample QA manual" filed as confidential under 10 CFR 2.390 provides more details on one reactor with its specific gamma spectroscopy laboratory. Similar protocols are in place at other reactors and laboratories.

Both of these documents should be regarded as samples. These documents may be changed by the respective responsible party. HBM Virginia will include all changed documentation in our audits and determine if the changes are appropriate to meet our standards.

- D 2. Specify the frequency, standards (including radionuclide, activity, and accuracy), and procedures used to calibrate such radiation detection equipment

All calibration sources and standards are obtained with a certificate linking their activity to a national standard. As batch measurements of topaz present a special challenge to detector efficiency calibrations we use form factors to adjust for typically point-source standards to our extended geometries. The form factors are determined experimentally using the standard as well as other sources of similar density as topaz.

Detection geometries have been defined in most cases for individual gemstones, 10-30g samples, 200g samples and larger samples up to 1000g.

Standards for calibration include the following isotopes: 241-Am, 133-Ba, 152-Eu, 109-Cd, 57-Co, 139-Ce, 203-Hg, 113-Sn, 85-Sr, 137-Cs, 88-Y, 60-Co, and 88-Y. The activity of the standards were given with an error of 1-3% at the reference date.

The detector efficiency is verified at least annually using the standards for calibration. The energy calibration of the multi channel analyzer is verified on a daily basis by verifying the correct energy of 182-Ta peaks present in almost every analysis.

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The attachment "Protocol for Topaz analysis" filed as confidential under 10 CFR 2.390 provides more details on one reactor with its specific gamma spectroscopy laboratory. Similar protocols are in place at other reactors and laboratories.

3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcuries per gram. Your description should include, but is not limited to:

- a. selection of samples;

100% of the samples are analyzed for isotope specific activities in batches. The average activities of a batch are determined. All gemstones are measured for their activity.

- b. maximum and minimum sample size (in terms of number of stones and mass);

Sample mass will range from 10 grams to approximately 1000 grams independent of the number of stones. In rare cases individual gemstones are measured independently.

- D 3. c. counting efficiency;

see D.2. above

- d. counting times;

Typical counting times range from 10min to 3 hours with 30min being the normal for 1000g samples.

- e. counting geometry;

see D.2. above

- f. time of counting (in relation to completion of irradiation and transfer to unlicensed persons);

Time of counting will range from six months to three plus years after irradiation. Stones are not released from the reactors until the average activity is less than 74 Bq/g.

Transfer to the unlicensed person will typically occur within one week of meeting the US release criteria. The determination of the release criteria takes place outside the USA and will be validated by HBM Virginia LLC.

- g. lower limit of detection;

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The calculation of Minimum Detectable Activity (MDA) for a given nuclide, at the 95% confidence level, is usually based on Currie's derivation (Currie, L. A., 1968, Anal. Chem. 40:586.), with one simplified formulation being:

$$\underline{LLD} \text{ (Bq/g)} = N_p(LD) / \epsilon_p t_m \gamma w,$$

where, the limits of net peak counts used for the calculations were defined by the  $N_p(LD) = \underline{4.65} (\sum N_{p(bkgd)})^{1/2}$  convention, where  $\sum N_{p(bkgd)}$  is the integrated background counts over the range of the peak width considered, corrected for pulse losses (dead time, true coincidence);  $\epsilon_p$  is detection efficiency at the energy of interest,  $t_m$  is the counting time (sec),  $\gamma$  is the absolute gamma-intensity (gamma-emission probability) and  $w$  is the mass (in g) of the measured sample. Lower limits of detection are calculated for typical irradiation and gamma spectroscopic measurement conditions ( $t_{irradiation}=12$  h,  $t_{decay}=30$  d  $t_{measurement}=0.5$  h)

Note: In this revision we corrected the equation for  $N_p$  as it displayed an incorrect factor. The correct factor in the original Currie publication is 4.65 and not 3. Similarly the "Safety Standards of the Nuclear Safety Standards Commission", KTA 1503.1 quote  $k_N=4.645$  for accumulating continuous measurement.

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Element	Nuclide	LLD [Bq/g]
Cr	Cr-51	0.11
Sc	Sc-46	0.03
Mn	Mn-54	0.03
Co	Co-58	0.03
Fe	Fe-59	0.05
Co	Co-60	0.03
Zn	Zn-65	0.06
As	As-76	0.05
Br	Br-82	0.03
Rb	Rb-86	0.34
Nb	Nb-95	0.03
Zr	Zr-95	0.05
Sb	Sb-124	0.02
Ba	Ba-131	0.03
Cs	Cs-134	0.02
Ce	Ce-141	0.02
Eu	Eu-152	0.03
Tb	Tb-160	0.12
Hf	Hf-181	0.02
Ta	Ta-182	0.17
W	W-187	0.02
Th	Pa-233	0.03
U	Np-239	0.05

Table 2 (revised): Limits of Detection (LD) for nuclides detected in Topaz.

Limits of Detection (LD) values are related to the experimental conditions: irradiation time=12 h, decay time= 30 d, counting time=0.5 h, w=500 g

- D 3. h. statistical methods for analyzing data, calculating background and lower level of detection, and determining confidence levels;

The software packages Genie 2000, Maestro and Hypermet are employed to perform gamma spectroscopy analysis. These programs have built in procedures for peak net area evaluation and background determination. Peak areas are given by these programs at the  $1\sigma$  level, hence at the 68% confidence level. Uncertainties of the measurement are propagated into the activity certificate by normal statistical propagation methods. A systematic error of all gamma spectroscopy measurements of 10-15% must be assumed due to non-homogeneous distribution of isotopes in each batch. resulting

| geometry effects and efficiency calibration.

In addition background spectra have been measured for each spectroscopy system. The respective background contributions will be taken into account for the gamma spectroscopy analysis of gemstones.

- D 3. i. procedures for minimizing "false negatives" (i.e., failure to identify individual gems with radionuclide concentrations greater than those specified in response to Item C.2.e.); and

The counting machine is computer controlled and will sort gemstones into the bin according to its specific activity classification. The overflow bins 2 and 4 will be audited for every lot for average specific activity using gamma spectroscopy. Pass criteria of item C.2.f. apply.

- D 3 j. sample calculations.

The attachment "sample calculation" filed as confidential under 10 CFR 2.390 provides more details.

- D 3. Note: indexing re-starts with (a) in conformance with appendix G of the NUREG 1556 vol 8 guidance document. We mark the respective indices with \*\*

At a minimum, your procedures must be sufficient to ensure that:

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

Please refer to D.3.g above

- b\*. Before release to unlicensed persons, gems are analyzed to ensure that the concentrations listed in 10 CFR 30.70 are not exceeded;

Please refer to C.2.f above.

- c\*. If the activity is not quantitatively measured in each gem individually

All stones are individually weighted and counted by our Sorted Machines. The Sorting Machines undergo a daily "Challenge" test with Eu-152 test sources of appropriate activities. The machine fails this challenge if any source is sorted into the wrong bin. In this case, remedial action is taken to determine the failure and all material counted on that machine since the last successful test is recounted.

- D 4. Specify who will be responsible for the QA program, and describe this individual's training and experience in detection and analysis of low-levels of

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radioactivity.

Jörn Meissner (see attachment background and training) will have complete responsibility for the QA Program for the measurement and certification process at Herotron.

In addition the Herotron QA-program will be audited by external companies every three years as mentioned in item B.2.b.

D 5. Describe the QA program used to assure reliable data, including:

- a. The standards, frequency and procedures used to perform constancy tests on the counting systems

Please refer to item D.2 above.

In addition the sorting machine undergoes daily checks with sources of known activities. See also D.3.c\* and D.5.b.

- b. The methods and frequency of introducing "spiked" samples into the routine counting process to assure identification of gems with concentrations in excess of your criteria (i.e., response to Item C.2.e. above).

Instead of spiked samples we will perform daily quality control checks on the sorting machine using sources of know activity above and below the respective bin limits of the sorting machine. The quality control procedures are repeated more frequently if components fail during normal operation.

D 6. Provide a commitment that, during the term of the license, the applicant will comply promptly with requests from NRC designed to monitor counting techniques. The general nature of these requests is outlined below:

- a. Upon request, the applicant will provide samples of irradiated gems to NRC for independent verification of radionuclide identity and concentration. NRC's request will be in writing, signed by the appropriate Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards. The request will specify who (i.e., NRC representative, NRC contractor, or applicant) will select the samples for independent verification. After analysis, samples will be returned promptly to the applicant.

HBM Virginia LLC will supply the requested samples.

- b. Upon request, the applicant will analyze qualitatively, quantitatively, or both gems or groups of gems provided by NRC or its contractor. The request will be in writing; signed by the appropriate Regional Administrator or Director, Office of Nuclear Material Safety and Safeguards; will specify the type of analysis requested and techniques to be followed; and will provide instructions for reporting results and for returning gems.

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HBM Virginia LLC will provide the requested analysis service provided the requested analysis meets the requirements for gemstones processed in our laboratories at Herotron and the reactors. This especially concerns minimum and maximum size, as well as shape, requirements set by the sorting machine. Only gemstones that are not yet included in Jewelry can be analyzed.

**E. Information Needed to Support Request for Exemption from Portion of 10 CFR 32.11(c)**

Note that 10 CFR 32.11(c), among other things, prohibits the incorporation of exempt concentrations into products or materials designed for application to human beings. Neutron-irradiated gems with induced activity could be expected to be set in jewelry and worn by consumers, i.e., "applied to human beings." In order to grant licenses authorizing distribution of these gems to unlicensed persons, it will be necessary to grant a limited exemption from the requirements of 10 CFR 32.11(c) as was directed by the Commission. Section 30.11 provides for the granting of exemptions.

1. To fulfill the requirements of 10 CFR 30.11(a), make a specific request for an exemption from that portion of 10 CFR 32.11(c) that prohibits incorporation of exempt concentrations in products or materials designed for application to a human being. Your request may be worded as follows: "If NRC considers gems to be products intended for application to human beings, then an exemption from this portion requirements in 10 CFR 32.11(c) is requested."

Assuming the NRC considers gems to be products intended for application to human beings, then HBM Virginia LLC request an exemption from this portion of the requirements of 10 CFR 32.11 (c).

- E 2. Using a worst case scenario, calculate the annual radiation dose and assess the health risk to unlicensed persons. Calculate the dose at contact and at 4 cm from jewelry (e.g., pendant) containing neutron-irradiated gems that is worn continuously (24 hours per day, 365 days per year). Assume that these gems contain those radionuclides (identified in your response to Item B.1.g) with the longest physical half-lives and highest energy emissions at the maximum concentrations (identified in your response to Item C.2.e.) you propose to release to unlicensed persons. Dose calculations must consider *all* types of emissions (e.g., beta, gamma) from the identified radionuclides.**

The release of gemstones will result in no significant risk to the public. All gemstones fulfill 10 CFR 30.70 with a maximum of 1 stone in 1000 having twice the limits.

We base our analysis on documentation available in the Public Reading Room of the NRC, relating to the NRC license application by the University of Missouri.

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In a letter dated April 15, 1988 the University of Missouri responds to specific requests for additional information among them on page 20 following specific information regarding the annual radiation dose to unlicensed persons.

Relating to these two documents that resulted in the granting of an NRC license to the applicant we present the same method and results:

Isotope	max concentration Bq/g	at surface with movement	First year dose		
			gamma dose at 3mm from surface	at 4cm tissue depth	beta dose
Sc-46	14.8	26	68	4	3
Mn-54	37	61	160	9	0
Fe-59	2.2	1	4	0.2	0.4
Cs-134	3.3	13	33	2	9
Ta-182	14.8	21	55	3	9

The NCRP Report 91 recommends a 5 rem/year as the skin dose limit for non-occupational exposure. Even the highest contact dose estimate for a 5g stone is only 3% of this limit. Further NCRP report 93 estimates the total annual whole body dose from all natural sources in the United States to be on average 360mrem/year. The actual annual dose can vary by 70mrem/year based on different locations within the US. Whole body dose is best compared to our estimates for 4cm tissue depth. Clearly our dose estimates lie well within the variation reported by NCRP report 93.

Because no health effects have been observed by the variation in natural radiation levels, the health risk from wearing jewelry containing these gemstones is negligible.

In reality the annual dose will be lower than quoted above. It is unlikely that a 5g (25 carat) stone is worn 24hrs/day and 365days a year for reasons of comfort. As the limits apply to specific activity, smaller stones would proportionally to their mass have less total activity and hence proportionally less dose rate.

- E 3. Provide similar calculations and assessments for gems that are outliers (i.e., gems with concentrations as much as twice the criteria you plan to use).

An outlier calculation would result in multiplication of all dose rates mentioned in section E.2. by a factor of two. The same reasoning as in section E.2. holds true also for the outliers with double the specific activity.