# Gunter Meelis USA, Inc.

# Application for an Exempt Distribution License

**June 5, 2008**
**Revision 1**

PUBLICLY-AVAILABLE VERSION

## A. Basic Information

*1. Specify name and mail address of applicant.*

Gunter Meelis USA, Inc.
1554 Creek St.
San Marcos, CA 92069
(760) 505-6546

*2. Identify the person with detailed knowledge of the application that the NRC staff can contact about the application, giving the person's title and phone number.*

Dr. Horst Krupp
Scientific Director
Gunter Meelis USA
(760) 753-6771

*3. Specify the location(s).*

The gemstones will be received and possessed at Gunter Meelis USA's facility at 1554 Creek St. in San Marcos, CA. Gemstones will be distributed to persons exempt from licensing from the same address. Records pertaining to import, possession, and distribution of irradiated gems will be maintained at the same address.

All gemstones received at the Gunter Meelis USA facility will be imported directly from a Gunter Meelis facility in Germany pursuant to two licenses issued by Germany regulatory authorities. Specifically, Dr. Horst Krupp, Scientific Director, Gunter Meelis USA, is the executing officer for an Umgangsgenehmigung ("UG") license issued by German regulatory authorities, which permits the possession and use of radioactive material as well as the import, export, and transport of topaz and other irradiated gemstones.

## B. Background Information

*1. Describe the material to be imported, including:*

a. *The type of gems (e.g., topaz)*

Gunter Meelis USA will primarily import and distribute topaz gemstones. Gunter Meelis USA may also import other irradiated gemstones (*e.g.*, tourmaline).

b. *Extent to which gems have been processed before irradiation (e.g., cut and polished).*

All gemstones imported and distributed by Gunter Meelis USA will have been cut and polished prior to importation and exempt distribution. Both cut and rough stones will be subject to irradiation. Only cut stones will be imported into the United States.

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.*

The gemstones will have been subject to one of the following processes:

(1) reactor irradiation (mainly neutron) only; or

(2) reactor irradiation, followed by accelerator-irradiation.

(3) accelerator-irradiation (mainly electron) only.

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.*

Reactor treatment takes place at the following facility:

- National Atomic Energy Agency
  Centro for Multipurpose Reactor Puspiptek
  Complex OB No.31
  15310 Serpong - Tangerang
  Indonesia

Accelerator-irradiation takes place at the following facility:

- Linear Accelerator in Harwell, England.

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.*

The gemstones will not be exposed to additional irradiation or treatment after import into the United States or prior to distribution to unlicensed persons.

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.*

[redacted] Each group of gemstones obtained at a particular point in time will be maintained in a separate lot (*i.e.*, gemstones purchased at different points in time or from different locations will not be mixed or commingled).

Gemstones from a specific lot will typically receive the same treatment. In certain circumstances, however, a single lot may be separated into sub-lots for further treatment, in which case each sub-lot will be maintained separately and will not be commingled with gemstones from a different lot or sub-lot. A continual and permanent booking of total grams and Bq per lot will be maintained and each stone in each lot will be accounted for.

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.*

| Radionuclide | Half Life | Release Criteria | Description |
|---|---|---|---|
| Tantalum-182 | 115 days | 15 Bq/g | Major |
| Scandium-46 | 89 days | 15 Bq/g | Major |
| Manganese-54 | 312 days | 37 Bq/g | Major |
| Cesium-134 | 2.06 years | 3.33 Bq/g | Major |
| Sodium-22 | 2.6 years | 0.037 Bq/g | Minor |
| Silicon-31 | 2.62 hours | 333 Bq/g | Minor |
| Chromium-51 | 27.7 days | 444 Bq/g | Minor |
| Manganese-56 | 2.58 hours | 37 Bq/g | Minor |
| Iron-55 | 2.7 years (no gamma) | 296 Bq/g | Minor |
| Iron-59 | 44.6 days | 22.2 Bq/g | Minor |
| Cobalt-60[1] | 5.27 years | 18.5 Bq/g | Minor |
| Copper-64 | 12.74 hours | 111 Bq/g | Minor |
| Europium-152 | 12.4 years | 3.33 Bq/g | Minor |
| Europium-154 | 8.6 years | 3.33 Bq/g | Minor |

As discussed further below, Gunter Meelis USA will only release stones where the total activity in any one stone is below 15 Bq/g (the maximum activity for most major and minor radionuclides) and where additional measurements confirm

1 [redacted]

that each stone meets the release criteria for those radionuclides with maximum concentrations of less than 15 Bq/g (*e.g.*, Cs-134, Europium-152 and -154, and Na-22). The contribution from the minor radionuclides is typically far less than 1 Bq/g.

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.*

Gunter Meelis has more than 25 years of experience in irradiated gemstones. Dr. Krupp, in particular, has been working with irradiated gemstones since 1982 and has been licensed to possess radioactive irradiated material since 1986 (*e.g.*, the UG license issued by Germany). Through this experience, Gunter Meelis and Dr. Krupp have confirmed that the radionuclides identified above are the major and minor radionuclides created through their reactor and accelerator irradiation.

These values will be representative of future gemstones because of the source of topaz, pre-treatment of the stones, and careful calibration of the irradiation treatment.

[redacted]

[redacted] This proven treatment is highly effective.

[redacted]

[redacted]

[redacted]

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.*

Gunter Meelis USA requests a possession limit of 50 kg or 250,000 carats of topaz (5 carats = 1 gram). This corresponds to $3.7 \times 10^6$ Bq (at maximum of 74 Bq/g).

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.*

Each stone that will be released under the exempt distribution license has been subject to the following processes and procedures.

(1) [redacted] This proven treatment is highly effective.

(2) Treatment in reactor (primarily neutron) only, treatment in a linear accelerator (primarily electron), or treatment in a reactor followed by treatment in a linear accelerator. [redacted]

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2 [redacted]

[redacted]

(3) Storage at the irradiator following treatment to allow for physical decay of short-lived and other radionuclides. Following removal from the pool, the gemstones are stored at the reactor site for physical decay. [redacted] This initial on-site decay period is intended to minimize possible occupational exposures or exposures in the event of an accident during transportation. All stones are pre-measured prior to shipment to Germany to identify any stones with abnormally high levels of radiation (*e.g.*, from unusual inclusions).

(4) Transfer of gemstones from irradiator to the sorting facility in Germany.

(5) The testing of individual irradiated gemstones is performed at the Gunter Meelis facility in Germany prior to exportation to the United States. These activities are performed under the UG radioactive materials license issued to Dr. Krupp by German regulatory authorities. The UG license imposes recordkeeping requirements and requires Dr. Krupp to submit an annual certification to regulators. All sensitive operations (calibrations, maintenance, etc.) are performed by individuals with a radiation health certificate.

Each stone is cycled a minimum of two times through a sorting machine that analyzes stones individually (*i.e.*, not in bulk). The sorting process begins by sorting stones into various weight categories (*e.g.*, 1 to 2 carats, 2 to 3 carats, etc.). When calculating the appropriate activity "bin" for each stone, the lower end of the weight range is used as the denominator, ensuring that the calculation for each stone is conservative. Sorting criteria are set such that the individual measurement result plus the margin of error is below the exempt distribution concentration limits. These procedures introduce significant conservatism into the sorting process.

The sorting machine utilizes sodium iodide scintillation detectors, which have a high efficiency, to detect gamma radiation in each individual gemstone. Prior to the testing of each batch of gemstones, the detectors are calibrated using both volume and individual stone standards. Every run of stones includes a set of marked standards (Hot, Medium, Low and Free) to ensure that the sorting machine places each stone in the appropriate bin.

In order to increase the accuracy of the counting and reduce the effect of stone orientation (*e.g.*, where the inclusion is on one side of the stone), the equipment relies upon simultaneous measurements of two 1.5" Na-I detector heads, one on each side of the stone at an angle of 45 degrees. The total count is based on the sum of both measurement heads. Attachment A contains a photograph of the sorting machine that identifies various aspects of the sorting process (note: the third set of detectors is not shown).

In the first cycle, the stones are sorted for total radioactivity at three stations and binned as Hot, Medium, Low, or Free according to the following criteria:

| Category | Criteria | Description |
|---|---|---|
| Hot | Requires cool down for two years | ~6 half-lives for tantalum |
| Medium | Requires cool down for one year | ~3 half-lives for tantalum |
| Low | Requires cool down for 6 months | ~1.5 to 2 half-lives for tantalum |
| Free | Overall activity is less than 15 Bq/g[3] | Meets U.S. exempt distribution concentration limits |

In the second cycle, stones are individually tested to ensure that Cs-134 levels are below exempt concentration limits (as discussed above, the actual set point is 3 Bq/g). This confirmatory test is necessary because of the low exempt distribution concentration criteria and long half-life of Cs-134. The second cycle utilizes a different type of measurement head. A 3" Na-I detector is positioned vertically above each stone and the counting time is much longer (~30 seconds). Gunter Meelis uses an "electronic window" to isolate an energy peak associated with Cs-134 and reduce interference from other nuclides (*e.g.*, one Cs-134 peak is under the tantalum/scandium peak). This measurement uses only a few channels of the nearly 4000 channels in the Na-I detector; all other energies are filtered electronically.

Following these initial two runs, measurements will be made using a germanium gamma spectrometer to determine whether Europium-152 or

[3] During the first sorting cycle, the maximum activity in any individual stone in the Free category is 15 Bq/g (*i.e.*, the sum of the ratios is less than unity). During the second cycle, the Free criteria for Cs-134 is set at 3 Bq/g. These settings introduce significant conservatism into both cycles of the sorting process.

Europium-154 are present (a very rare occurrence). If so, an additional screening run will be made to ensure that each stone meets the Europium release criteria of 3.33 Bq/g. The germanium gamma spectrometer can also be used to assess the presence of Na-22 and calculate the activity in each stone.[4]

Only stones that meet the Free criteria following all cycles will be released for export to the United States.

Gemstones that do not meet the Free criteria will be stored for further decay. Each individual stone will be re-analyzed (*i.e.*, sorted) prior to export to confirm that the stone satisfies the Free criteria.

Using a germanium gamma spectrometer, Gunter Meelis will produce representative spectra that identify individual radionuclides for a set of stones that are to be shipped to the United States. These stones will be identified in a "release certificate." Once approved for export, the gemstones are exported pursuant to the UG license.

As discussed below, upon arriving in the United States, Gunter Meelis USA will produce a second representative set of spectra using a similar germanium gamma spectrometer and will compare these spectra to the spectra shipped with the stones in order to confirm that they "match."

By testing each stone individually, Gunter Meelis ensures that <u>every stone</u> imported into the United States is well below the U.S. exempt distribution concentration limits. Nevertheless, as described below, Gunter Meelis USA will perform additional tests to prove that no stones were mistakenly imported into the United States and certify that the stones satisfy U.S. exemption distribution concentration criteria.

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).*

Gemstones are exported directly from Germany and imported by Gunter Meelis USA. Once the stones arrive at the Gunter Meelis facility in the United States, each batch is tested using an ORTEC GAMMA-X Coaxial N-type HPGe Gamma-Ray Detector, Model GMX30P4, to demonstrate compliance with exempt distribution concentration limits and certify that the stones satisfy the U.S. exemption distribution concentration criteria. The testing relies upon a

4 [redacted]

computerized auto-evaluation that identifies the individual radionuclides present in the stones.

Gunter Meelis USA will not mount the gemstones in rings, pendants, or other settings.

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

The gemstones will be distributed primarily to wholesalers. On rare occasions, gemstones may be distributed to large jewelry manufacturers.

d. *What will be done with gems whose concentrations exceed the criteria specified in response to Item C.2.e. below.*

Because each individual stone will be tested at the Gunter Meelis facility in Germany prior to export, every stone imported by Gunter Meelis USA will meet the U.S. exempt distribution concentration limits. In the highly unlikely event that a gemstone exceeds the exempt distribution criteria, the gemstone will be placed into a special lead house (a lead tube with bottom and head with 6 cm of lead shielding) and either stored for physical decay at the Gunter Meelis USA facility until such time as the stone satisfies the exempt concentration criteria or returned to the Gunter Meelis facility in Germany to be stored for physical decay until such time as the stone satisfies the exempt distribution criteria.

**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.*

Following import and receipt, the gemstones will be stored at the Gunter Meelis USA facility in a lead-shielded safe. In order to provide enhanced radiation protection to workers and members of the public, Gunter Meelis will work with the stones in sub-lots that will not exceed 1 kg at any one time. In addition, the primary workspace will be outfitted with a surface contamination monitor and there will be a room radiation level monitor. Technical Associates (a California company) will provide the monitoring systems for Gunter Meelis USA. Gunter Meelis USA will set the alarm function to detect low levels of radiation.

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.*

Dr. Horst Krupp, Scientific Director, Gunter Meelis USA, will be primarily responsible for handling, storing, counting, evaluating and controlling the release of irradiated gems in the United States. Dr. Krupp is a physicist with a PhD from Heidelberg University in Germany. Dr. Krupp worked for 6 years at GSI, a heavy ion research center located in Darmstadt, Germany and funded by the Federal Government of Germany and the state of Hessen. The laboratory performs basic and applied research in physics and related natural science disciplines using a heavy ion accelerator facility (UNILAC). Dr. Krupp has also worked at numerous reactors throughout the world. His expertise in radiation shielding and his strong background in ALARA have been sought at facilities in the Netherlands, Indonesia, and South Africa, among others. Dr. Krupp regularly presented at linear accelerator conferences throughout the world, including most major National Laboratories in the United States.

Dr. Krupp has been irradiating gemstones since 1982 and has been licensed to conduct these activities since June 13, 1986. Dr. Krupp holds a Radiation Health certification in Germany and is the executing officer for a UG license issued by the department for radiation health within the Gewerbeaufsichtsamt Mannheim, the regulatory authority for all businesses in that respective German State. The license authorizes possession of radioactive material up to 10 mCi/nuclide (in general, irradiated topaz) and also authorizes storage of irradiated topaz for as long as is necessary for the gemstones to be released. The license also permits the import, export, and transport of topaz. Gunter Meelis Germany activities are performed under Dr. Krupp's license.

As executing officer, Dr. Krupp must actively maintain his radiation health certificate. This requires completion of a 3-day refresher/training course in radiation health and safety at a government-licensed facility every five years. This course is followed by an examination, which Dr. Krupp must pass in order for the license to remain in effect. Dr. Krupp successfully completed the last recertification course on November 30, 2004. In addition, the license requires submission of an annual certification report, which ensures that all incoming stones are certified and that all exported stones are deducted. This enables a comprehensive bookkeeping (via lots) of the number of grams of stones and total activity (in Bq).

*2. Paragraph 32.11(b) requires that certain information be provided.*

a. *The product or material into which byproduct material will be introduced (see response to B.1.a above).*

Gunter Meelis USA will mainly import and distribute topaz gemstones. The byproduct material will be introduced into the gemstones at the facilities identified in Item B.1.d above.

b. *The intended use of the byproduct material and the product or material into which it is introduced.*

Gemstones are irradiated in order to produce, enhance, and deepen their color. Most irradiated gemstones would be incorporated into jewelry to be worn by individuals. Some may be used for display purposes by collectors and others.

c. *The method of introduction.*

See response to Item B.1.c. and e. above.

d. *Initial concentration of byproduct material in the product or material.*

Immediately following reactor treatment, there are high levels of short-lived radionuclides in the gemstones. Consequently, the gemstones cannot be removed from the pool (*i.e.*, the bombarding site) right away. [redacted]

Following removal from the pool, the gemstones are stored at the reactor site for physical decay. [redacted] This initial on-site decay period is intended to minimize possible occupational exposures or exposures in the event of a transportation accident. All stones are pre-measured prior to shipment to Germany to identify any stones with abnormally high levels of radiation [redacted].[5]

For accelerator-irradiated gemstones, the activity falls below 1 Bq within a few minutes, and activity for most stones is in the order of milli-Bq. [redacted]

5 [redacted]

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

The maximum concentration of the radioisotopes will not exceed the exempt distribution concentration limits or the limits identified in the table in Item B.1.g above. Based on past experience and the conservatism in the sorting/measuring process, the actual concentrations are expected to be far below these limits.

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

See response to Item B.2.a and b. As discussed above, the sorting process is inherently conservative. The total activity of a stone in the Free category will not exceed 15 Bq/g, which is well below the standard of 74 Bq/g used in many countries.[6] Additional measurements are made to confirm that each stone meets the release criteria for those radionuclides with maximum concentrations of less than 15 Bq/g (*e.g.*, Cs-134, Europium-152 and -154, and Na-22).

The actual activity in any individual stone will be less than the calculated activity because the calculation uses the weight at the low end of the weight range.[7] In addition, the release limits are set such that the measurement plus the margin of error is below the exempt distribution concentration limits. This introduces additional conservatism at multiple points in the testing protocol.

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).*

[redacted] Once the gemstones arrive in Germany, they are sorted within approximately two weeks. Only those stones that meet the U.S. exempt distribution concentration limits will be exported; other stones are stored for further physical decay and then tested again prior to export. Shipping from Germany to the United States typically takes between two and four days. Once the gemstones arrive at the Gunter Meelis USA

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6 Gunter Meelis USA recognizes that 74 Bq/g is not a regulatory limit utilized by the NRC. Nevertheless, this standard is mentioned throughout this application in order to illustrate the relative reduction in risk associated with the U.S. limits as compared to that in use in other countries.

7 For example, for a stone weighing 5.75 carats (*i.e.*, in the weight range of "5 to 6 carats") and a measured activity of 30 Bq, the calculation is as follows:

| | | |
|---|---|---|
| <u>Calculated</u>: | 30 Bq total activity / 5 carat | = 6 Bq/carat |
| <u>Actual</u>: | 30 Bq total activity / 5.75 carat | = 5.21 Bq/carat |

facility, they will be certified and sent to customers, typically within a few weeks. Once the gemstones are sent to the customers, they are stored until ready to incorporate into jewelry (typically on the order of weeks to months).

*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.*

As described in Items B.1.h, B.2.a-c, and C.1, Gunter Meelis sampling, counting, sorting, and recordkeeping processes ensure that concentrations of byproduct material at the time of transfer will not exceed the concentrations in 10 CFR 30.70, Schedule A. The exempt distribution concentration limits identified in the table in Item B.1.g are based on the "sum of the ratios" method described in Note 2 of 10 CFR 30.70, Schedule A. However, the maximum activity for a stone in the Free category is set to 15 Bq/g, which is far below the standard of 74 Bq/g used in many countries. Additional measurements will be made to confirm that each stone meets the release criteria for those radionuclides with maximum concentrations of less than 15 Bq/g (*e.g.*, Cs-134, Europium-152 and -154, and Na-22).

Moreover, inventory-testing protocols are set such that conservative weights are used when calculating concentration and the measurement plus the margin of error is below the exempt distribution concentration limit.

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

Because all gemstones exported by Gunter Meelis Germany to the United States and imported into the United States by Gunter Meelis USA will not be subject to any further treatments (*e.g.*, reactor or accelerator irradiation), there is no potential for reconcentration of byproduct material. Gunter Meelis USA will confirm and certify that the imported gemstones satisfy exempt distribution concentration limits following receipt of the gemstones and prior to their distribution to unlicensed persons.

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).*

The procedures outlined above ensure that no stone will have a total activity in excess of the exempt distribution concentration limits. Nevertheless, the overall process introduces several elements of conservatism. First, the sorting machine will be set such that the maximum activity in any individual stone in the Free category is 15 Bq/g (the lowest maximum activity for most major and minor radionuclides). During the second cycle, the Free criteria for Cs-134 is set at 3 Bq/g (rather than the maximum of 3.33 Bq/g). Additional measurements will be made to confirm that each stone meets the release criteria for those radionuclides with maximum concentrations of less than 15 Bq/g (*e.g.*, Cs-134, Europium-152 and -154, and Na-22). This introduces significant conservatism into the sorting process.

In addition, as discussed above, the activity calculations for sorting individual stones relies on conservative/assumed stone weights (the denominator in the concentration calculation). Moreover, testing criteria are set such that the testing results plus the margin of error are below the exempt distribution concentration limits. Finally, there are periods of physical decay following the testing of individual stones in Germany (both during the testing/sorting process, which can take several days, and prior to and during shipment to the United States) and at the Gunter Meelis USA facility in the United States.

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.*

Topaz gemstones are valuable items used exclusively for ornamentation and jewelry purposes. Topaz is not water-soluble and is unlikely to be incorporated into a product designed for ingestion or inhalation. [redacted]

D. Information on Quality Assurance (QA) Program

Gunter Meelis USA will perform QA and will conduct appropriate audits and review to ensure that QA is conducted as described in this license application. Stones sent from Germany will be listed on a release certificate (*i.e.*, the free portion of each batch is assigned a unique number). These records are maintained in Germany on CD or DVD indefinitely. The gemstones are shipped from Germany with a duplicate of the release certificate and spectra, which will be maintained at the Gunter Meelis USA office. Once the gemstones arrive in the United States, Gunter Meelis USA will confirm the radionuclide content using the HPGe Gamma Spectrometer. The spectra readout from the machine with be matched to the batch of stones and maintained in Gunter Meelis USA's office in paper and electronic form (with appropriate backup), and stored for ~10 years. Gunter Meelis USA will also maintain a record of all transfers of stones (by batch and weight) to exempt persons.

*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*

The radiation detection equipment used in Germany are sodium-iodide detectors. As discussed in Item B.2.a, the first sorting cycle uses each set of two 1.5" Na-I detectors (at three different stages), one on each side of the stone, to minimize the effects of inclusion geometry. See Attachment A for visual presentation of sorting equipment. The second sorting cycle, which is only for assessing Cs-134, relies upon a single 3" Na-I detector arranged vertically.

The radiation detection equipment used at Gunter Meelis USA will be an ORTEC GAMMA-X Coaxial N-type HPGe Gamma-Ray Detector (PopTop), Model GMX30P4. The detector has a useful energy range from ~ 3 keV to 10 MeV. All GAMMA-X PopTop detector capsules include a sealed detector element, preamplifier, high-voltage filter, and a Be window 0.02 inches thick and with diameter ≥ that of the detector element. Some key attributes of the detector are listed below:

| **ORTEC GAMMA-X Coaxial N-type HPGe Gamma-Ray Detector (PopTop) Model GMX30P4** | |
|---|---|
| Useful Energy Range | ~3 keV to 10 MeV |
| Relative Photopeak Efficiency | >= 30% |
| Energy Res. FWHM @ 5.9 keV | <= 715 eV |
| Energy Res. FWHM @ 1.33 MeV | <= 1.90 KeV |
| Peak to Compton | >= 52:1 |
| Peak Shape, FW.1M/FWHM | <= 1.9 |
| Peak Shape, FW.02M/FWHM | <= 2.8 |

Digital signal processing for the spectrometer is performed by Ortec's DSPEC jr 2.0 with MAESTRO-32 Software and DIM-NEGGE, for use with non-SMART-1 detector, Model No. DSPEC-jr-2.0-NEGGE. Attachments B and C provide additional information on the germanium gamma spectrometer and the signal processor.

Gunter Meelis USA will utilize a lead chamber, Model No. HPLBS1, or similar shielding with equivalent performance. Model No. HPLBS1 is a vertical lead chamber with 4-inches of lead surrounding an interior cylinder of 11-inch interior diameter by 16-inch interior height with a Sn/Cu liner with table. Shielded cavity dimension are: 28-cm i.d. X 40-cm high (11-in. i.d. X 16-in. high). The shielding type is solid-cast virgin lead with steel casing and graded-Z liner. Shield specifications include: 9.5 mm (3/8 in.) low-carbon steel casing, 101 mm (4 in.) certified Doe Run lead, 0.5 mm (0.02 in.) tin sheet liner, and 1.6 mm (0.064 in.) soft-copper sheet liner. The shield has a total assembled weight of 1,134 kg (2,500 lb). Attachment D contains additional information on the HPLBS1 shield.

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

Gunter Meelis uses both volume and sample stone standards. Two different volumes standards are used depending on the measurement to be performed. One volume standard is used for volumes of between 30 and 50 g topaz; a different volume is used for individual stones weighing between 1 and 2 grams (5 to 10 carat stone). The smaller standard is used for calibration prior to measuring individual stones, the larger volume when making bulk measurement.

Gunter Meelis creates the topaz standards using specialized measurement equipment (*i.e.*, the Ortec Germanium Gamma Spectrometer). Based on a known activity at a given point in time, a computer program calculates the actual activity at the time of calibration.

In Germany, calibration is done according to a written standard procedure that takes into account various parameters (*e.g.*, room temperature, aging of equipment, equipment maintenance). Calibration of the digital set points in the sodium iodide detectors is performed before every sorting run using four different standards (*i.e.*, standard stones) – one each in the Hot, Medium, Low and Free range – to confirm that stones are properly sorted. The use of the HPGe detector, which requires at least 60 times greater count times than the Na-I detector, to set the standards significantly reduces the margin of error in the digital set points for the Na-I detector. This ensures that the sorting equipment properly bins each stone.

The same types of standards will be used in the United States. The known activity standards are used to calibrate the Ortec Germanium Gamma Spectrometer detector across a wide range (from few keV to 3 MeV). The detector is calibrated along the whole energy range of the spectrometer. Gunter Meelis USA will calibrate the spectrometer on a weekly basis or whenever the measurement geometry changes. All hardware parameters are saved with the spectral data to ensure traceability. The margin of error is very small once the machine has been calibrated.

*3. Describe counting procedures and how external measurements are converted to concentration values in terms of microcuries per gram.*

a. Selection of samples;
b. Maximum and minimum sample size (in terms of number of stones and mass);
c. Counting efficiency;
d. Counting times;
e. Counting geometry;
f. Time of counting (in relation to completion of irradiation and transfer to unlicensed persons);
g. Lower limit of detection;
h. Statistical methods for analyzing data, calculating background and lower level of detection, and determining confidence levels;
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
j. Sample calculations.

In Germany, the sample size is one stone. The weights of individual topaz range from below 1 carat to 30 carats and above (1 carat = 0.2 g). The actual activity in any individual stone will be less than the calculated activity because the sorting calculation uses the weight at the low end of the weight range (*e.g.*, for a stone in the 0.5 g to 1 g weight range, the calculation assumes a 0.5 g stone, introducing conservatism into every calculation). Concentration is simply the total activity divided by the assumed weight of the stone. Thus, Gunter Meelis can ensure that each stone meets the exemption concentration limits prior to export to the United States. Once the stones arrive at the Gunter Meelis USA facility, they will be tested in lots that will not exceed 30 g with a minimum weight of 1 g.

The sodium iodide detectors used in the sorting process are 60-200 times more efficient than a germanium detector. Each individual stone is counted for approximately 10 seconds during the first sorting cycle. As discussed above, the count is based on the use of simultaneous measurements with two 1.5" Na-I detectors (one on each side at the three different stages) to reduce the effects of counting geometry (*e.g.*, inclusions only on one side of stone). Each 1.5" crystal has a counting efficiency of about 2500 counts/minute at background (5000 for both crystals). In the second cycle, which is used to test for Cs-134, the counting time is much longer (~30 seconds). The 3" crystal has a counting efficiency of about 25,000 counts/minute at background.

Measurements using the Ortec HPGe Gamma Spectrometer in the United States take between 15 minutes and 30 minutes, depending on the size of the lot. This is because the counting efficiency of a germanium gamma spectrometer is much lower than a Na-I detector.

The geometry of the stones varies, even among calibrated stones. Thus, the testing is done using a volume count in a 30 g cylinder. When testing individual stones, the stones are typically set a certain distance from the measurement head (typically 5-10 cm). The spectrometer is calibrated each time the measurement geometry changes.

The Ortec Ge Gamma X N-type Detector, Model No. GMX30P4, has a lower limit of detection in 3 keV range and a maximum detection limit is 10 MeV.

Gunter Meelis will use Special Model A66-B32 GammaVision-32 Gamma Ray HPGe Spectral Analysis Software. This software meets the following performance standards: ANSI/ISO/ASQ 9001:2000, ASME/NQA-1-1989, and ASME/NQA-2a-1990. The software includes Quality Assurance features that comply with the demands of ANSI N13.30 and for each detector allows tracking of: (1) Total detector background; (2) Total (decay corrected) activity for all calibration nuclides; (3) Average FWHM ratio (spectrum to calibration standard); (4) Average FW1/10M ratio (spectrum to calibration standard); (5) Average peak shift from library values; and (5) Actual peak centroid energies. All hardware parameters are saved with the spectral data to ensure traceability. See Attachment E for additional information on the spectroscopy software.

The overall testing protocol [redacted] through the individual stone testing in Germany to the confirmatory testing in the United States — is designed to eliminate "false negatives." [redacted] The testing in Germany is done on a stone-by-stone basis to confirm that radionuclide concentrations in each stone do not exceed exempt distribution concentration limits. When the stones are exported from Germany and into the United States, each stone is below the exempt distribution concentration limits. This permits use of a volume measurement in the United States to identify the specific radionuclides that are present in a lot of stones. This additional testing in the United States proves that no stones with radionuclide concentrations greater than those specified in response to Item C.2.e. were exported from Germany.

Example: Initial Sorting Calculations

For a stone weighing 5.75 carats (*i.e.*, in the weight range of "5 to 6 carats") and a measured activity of 30 Bq, the calculation is as follows:

| | | | |
|---|---|---|---|
| *Calculated:* | 30 Bq total activity / 5 carat | = 6 Bq/carat * 5 carats/g | = 30 Bq/g |
| *Actual:* | 30 Bq total activity / 5.75 carat | = 5.2 Bq/carat * 5 carats/g | = 26 Bq/g |

Confirmatory Testing Calculations

The gamma spectrometer makes a spectrum for a batch of stones weighing 30 g (or 150 carats). The spectrometer output is in standard units: # of Bq per kilogram

*Output:* (2000 Bq/kg) * (1 kg /1000 g) * 30 g = 60 Bq total activity
*Calculation:* 60 Bq / 30 g = 2 Bq/g

*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.*

   The Ortec HPGe Gamma Spectrometer measures and identifies individual radionuclides in the gemstones. The spectrometer will be calibrated weekly and at every change in measurement geometry.

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.*

   As discussed above, the procedures ensure that no stones will be released for exempt distribution until Gunter Meelis has individually measured each stone and determined that its meets exempt distribution concentration limits. The total activity of a stone in the Free category will not exceed 15 Bq/g, which is well below the standard of 74 Bq/g used in many countries. Additional measurements will be made to confirm that each stone meets the release criteria for those radionuclides with maximum concentrations of less than 15 Bq/g (*e.g.*, Cs-134, Europium-152 and -154, and Na-22). The procedures also introduce conservatism at several independents stages of the overall testing protocol. In addition, Gunter Meelis USA performs supplemental testing, which measures and identifies individual radionuclides, in order to certify that each stone meets U.S. exempt distribution concentration criteria.

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).*

   Gunter Meelis quantitatively measures the activity in each individual gemstone in Germany. This ensures that no gemstone with activity in excess of U.S. exempt distribution concentrations is exported to the United States. In addition, Gunter Meelis USA performs quantitative measurements on groups of gems to identify concentrations of specific radionuclides and to certify that no gems exceed the U.S. exempt distribution concentration limits.

*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 radioactivity. If this individual was identified in response to Item C.1.b, it is not necessary to repeat the individual's qualifications, provided that the response to Item C.1.b. includes a clear description of the person's training and experience in low-level counting techniques.*

Dr. Krupp, the individual identified in the response to Item C.1.b above, will be responsible for the QA program. His qualifications and experience were described previously.

*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.*

Gunter Meelis uses both volume and sample stone standards. Two different volumes standards are used depending on the measurement to be performed. One volume standard is used for volumes of between 30 and 50 g topaz; a different volume is used for individual stones weighing between 1 and 2 grams (5 to 10 carat stone). The smaller standard is used for calibration prior to measuring individual stones, the larger volume when making bulk measurement.

In Germany, Gunter Meelis creates the topaz standards using specialized measurement equipment (*i.e.*, the Ortec Germanium Gamma Spectrometer). As discussed above, the standards and sample stones will be used prior to every run/batch of stones.

The same types of standards will be used in the United States. The standards are used to calibrate the Ortec Germanium Gamma Spectrometer detector across wide range (from few keV to 3 MeV). The detector is calibrated along whole energy range of the spectrometer. Gunter Meelis USA will calibrate the spectrometer on a weekly basis or whenever the measurement geometry changes. The margin of error is very small once the machine has been calibrated.

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).*

As discussed above, "spiked" samples or testing stones are used prior to every sorting run in Germany. In the United States, the Ortec Germanium Gamma Spectrometer is calibrated across the range of detectable energies on a weekly basis or prior to conducting a measurement using different measurement geometry. The spectra produced in the United States are "matched" to the spectra taken in Germany prior to export to the United States. This ensures that a batch of gemstones has not been tampered with or otherwise altered during shipment.

*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:*

Commitment GM-01: Gunter Meelis USA commits that, upon written request by the Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards, Gunter Meelis USA will provide samples of irradiated gems to the NRC for independent verification of radionuclide identity and concentration.

Commitment GM-02: Gunter Meelis USA commits that, upon written request by the Regional Administrator or the Director, Office of Nuclear Material Safety and Safeguards, Gunter Meelis USA will analyze qualitatively, quantitatively, or both, gems or groups of gems provided by NRC or its contractor.

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

*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.*

If NRC considers gems to be products intended for application to human beings, then an exemption from this portion of the requirements that prohibits the incorporation of exempt concentrations into products or materials designed for application to human beings in 10 CFR 32.11(c) is requested. The exemption is authorized by law and, as the information in this application demonstrates, will not endanger life, property or the common defense and security. Such an exemption is also in the public interest because it facilitates an efficient regulatory program without undue expense.

*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 complete calculations for partial body doses at contact (assumed to be 0.5 cm from the skin when mounted in jewelry) and at 4 cm from a 5 carat topaz gemstone, assuming the presence of the radionuclides in Item B.1.g and at maximum concentrations are located in Attachment F. The dose at 4 cm is 1/64 of the dose at 0.5 cm. The results of the calculations are summarized as follows (note: these "starting" values will decrease with decay time; the exposure is highest during the first half-life period of each nuclide):

| | **Max Dose Rate** | | **Annual Dose (1st year)** | |
|---|---|---|---|---|
| **Radionuclide** | **At Contact** | **At 4 cm** | **At Contact** | **At 4 cm** |
| Cs-134 | < 2.5 μR/h | < 0.04 μR/h | < 18 mrem | < 0.28 mrem |
| Ta-182 | < 10 μR/h | < 0.16 μR/h | < 37 mrem | < 0.58 mrem |
| Sc-46 | < 18 μR/h | < 0.30 μR/h | < 52 mrem | < 0.81 mrem |
| Mn-54 | < 19 μR/h | < 0.30 μR/h | < 117 mrem | < 1.83 mrem |
| **Total** | **< 49.5 μR/h** | **< 0.80 μR/h** | **< 224 mrem** | **< 3.50 mrem** |

Although this calculation is based on the sum of the maximum doses from individual radionuclides, the total worst-case dose represents a physically-impossible scenario because the disparate decay times and the limits on total radioactivity preclude the presence of maximum concentrations simultaneously.

The health risks associated with these dose rates are practically non-existent. This partial body dose is limited to a small restricted area of the hand or chest. There is no radiation absorption at other areas of the body. The annual exposure to a person from wearing topaz at maximum exempt concentrations (*i.e.*, worst case) is less than the dose resulting from a single round-trip flight from Los Angeles to Germany (for example, 1 round-trip between New York and Los Angeles is "worth" 5 mRem whole body dose.). In practice, exposures would be less than calculated as individuals are not likely to wear the jewelry continuously. In addition, the dose decreases substantially as the activity present at release decays naturally over time. Thus, this calculation represents the maximum dose from the first year of the worst-case gemstone; subsequent annual doses will be considerably less.

*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).*

A gemstone with twice the maximum activity as the gemstones referenced in Item E.2 will have twice the dose. The dose from such an outlier is summarized below:

| | **Max Dose Rate** | | **Annual Dose (first year)** | |
|---|---|---|---|---|
| **Radionuclide** | **At Contact** | **At 4 cm** | **At Contact** | **At 4 cm** |
| Cs-134 | < 5 μR/h | < 0.08 μR/h | < 36 mrem | < 0.56 mrem |
| Ta-182 | < 20 μR/h | < 0.32 μR/h | < 74 mrem | < 1.16 mrem |
| Sc-46 | < 36 μR/h | < 0.60 μR/h | < 104 mrem | < 1.63 mrem |
| Mn-54 | < 38 μR/h | < 0.60 μR/h | < 234 mrem | < 3.65 mrem |
| **Total** | **< 99.0 μR/h** | **< 1.60 μR/h** | **< 448 mrem** | **< 7.00 mrem** |

The health risks associated with this dose rate are practically non-existent. This partial body dose is limited to a small restricted area of the hand or chest. There is no radiation absorption to other areas of the body. The annual exposure to a person from wearing topaz at twice the maximum exempt concentrations (*i.e.*, twice as much activity as the worst case) is less than the dose resulting from two round-trip flights from Los Angeles to Germany. In practice, exposures would be less than calculated as individuals are not likely to wear the jewelry continuously. In addition, the dose decreases substantially as the activity present at release decays naturally over time. Thus, this calculation represents the maximum dose from the first year of the worst-case gemstone; subsequent annual doses will be considerably less.

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