Sterigenics.

September 18, 2008

Richard K. Struckmeyer, Health Physicist
State Agreements & Industrial Safety Branch
Division of Materials Safety & State Agreements
Office of Federal & State Materials & Environmental Management Programs
USNRC
Washington, DC 20555-0001

Reference: Docket # 030-32720

Dear Mr. Struckmeyer,

This letter is in response to your request for additional information regarding Sterigenics International, Inc.'s application for an exempt distribution license to distribute irradiated gemstones. The responses are given in the order they were requested in your letter dated August 5, 2008.

A.1. – Item 3 of Sterigenics original application lists the addresses of the Sterigenics facilities where the accelerator irradiations are performed. The list currently includes the San Diego California facility and the Rayong Thailand facility. (Please note that records for Thailand will be made available in the U.S. at the address listed in Sterigenics original application, page 3of 9, Supplemental Information A.) To that list we now request to add our Espergaerde Denmark facility. The address of this facility is as follows:

Sterigenics International, Inc.
Aa. Louis-Hansens All, 11,
3060, Espergaerde
Denmark

There are no reactors associated with these facilities. They are accelerators and are only capable of performing electron irradiations.

A.2. – Energies may be 10, 12, 14, 16 or 20 MeV, depending on the particular gemstone (type and size) and desired effect. No threshold for activation is assumed.

A.3. - The 2 mR/h nominal dose rate applies to gem stones moved from one storage location into another. This value was agreed upon with the pertinent regulatory authorities that issued the possession license for the facilities. Note that this application current under review does not incorporate possession, only distribution. Possession licenses have already been issued to the facilities by the controlling regulatory authorities for each location.

Dose rates are measured with a portable survey meter, but are not construed to be absolute inviolable criteria requiring precise measurement geometries. The purpose is only to delay direct handling until the initial dose rate has decayed. Note again that this does not apply to any

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gemstones released from the facility, which is the purpose of this license application. Internal safety and handling procedures are governed by licenses issued by the individual controlling regulatory authorities for each facility. This application is for distribution only.

B.1.a. - From previous gamma spectroscopy analysis of irradiated gemstones, radionuclides have been identified that are likely to be present based on the type of gemstone, geographic origin, and electron energy. For electron irradiations, there appears to be only slight dependence on geographic origin for the radioactive species induced during irradiation, with slightly more dependence on electron energy. In addition, published literature was used to identify potential activation products even though internal analyses may not have ever detected their presence.

B.1.b. – In general, gemstones are received from a consistent customer base, that in turn have consistent suppliers as far as geographic origin of the gemstones is concerned, although there may be some variation. Based on previous experience with a given customer, including analytical results, and the type of gemstone involved, there is a reasonable expectation of the activation products. For any new customers or suppliers, or any significant variation in the gemstone composition (e.g., geographic origin) a simple qualitative scan will be performed on each irradiation batch to determine whether the radionuclides in question are present.

Note that electron-irradiated topaz is consistent with respect to material composition and activation products, as shown in the references cited in the initial license application. Some variation may be present in other gemstones, however.

B.2.a. - Several calculation models may be used for this purpose. In the context of testing multiple radionuclides independently under the same geometry and measurement conditions, point kernel provides an easier and more rapid evaluation of dose rates. Additionally, point kernel methods tend to lend themselves toward use of spreadsheets for ease of analysis and comparison, which is more difficult with Monte Carlo or discrete ordinate models.

In general, the issue with close distances in point kernel approximations is potential for variability in calculations as the inverse square term approaches infinity. Methods for minimizing this variability include dependence analysis on the number of kernels, particularly since results may differ with an odd number versus an even number as a function of the differential between the center of the kernel and its edge in relation to the distance at which the dose rate is calculated. Varying the distance by small increments and determining the degree of difference in the results can determine whether the distance is too close for reliable results. Variability and reproducibility may also be tested by using a second program for confirmation (e.g., QAD versus Microshield).

As an example, the initial calculation results as given in the license application for ^{65}Zn have been reproduced in MicroShield under the same assumptions. The results, which are attached, are within 1.3% of the value shown in the application, indicating that the distance factor for

these calculations is not of particular concern. MicroShield uses a distance of one centimeter or less as "too close."

B.2.b. - The geometry considered in the calculation was as a uniform distribution of material within the source volume. Density variations within the mass were not considered, but the difference between the density of the gemstones and the surrounding void space was normalized over the volume of the material, all of which was considered to be the radioactive source. The gemstone plus void space density variations were taken into account by using a total density of 1.54 g/cm^3, which is the gemstone density of 2.2 g/cm^3 times 0.70 to account for approximately 30% void space within the package.

The standard proof of closest packing geometry for spheres, as shown by Gauss, is a maximum of 74%. Our assumption of 70% represents a near-perfect packing of gemstones within the volume. Note that, if a lower packing efficiency is assumed, the bulk density of the gemstone package is reduced, which will lead to lower self-absorption and a higher than predicted dose rate from the given exempt concentration. This would actually improve the ability of the survey meter technique to detect radionuclides at the exempt concentration.

B.2.c. - Standard packages of gemstones received for irradiation are 500 g or more. In general, an irradiation batch in any of the accelerators will be on the order of several kilograms. For packages that are less than 500 g, gamma spectroscopic analysis will be used for release.

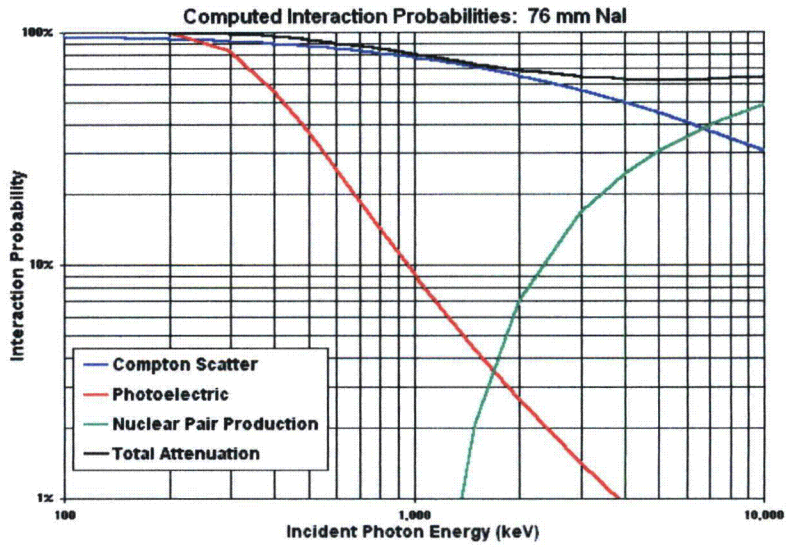
B.2.d. - The release criterion of twice background was established in the now-terminated California radioactive materials license issued to IRT Corporation at the address in San Diego shown in this application for release of electron irradiated gemstones.

Note also that the US NRC has indicated in public statements that an action level of twice background is acceptable. Refer to Public Affairs Officer David McIntyre, as quoted in the National Jeweler Network article, "NRC Blue Topaz Testing Shows No Health Threat" (August 9, 2007).

B.2.e. – For any gemstone for which gamma spectroscopy will be used as the release evaluation, the sum of ratios can and will be calculated directly from the analysis. In electron-irradiated topaz, the most radionuclides expected are ^{18}F, ^{64}Cu, ^{65}Zn, and ^{68}Ga, according to NUREG/CR-5883. After the length of time required for post-irradiation storage and processing of gemstones, which is typically at least several days, only ^{64}Cu and ^{65}Zn would still be present. Based on previous point kernel calculations, the relative ratio of dose rate per unit activity concentration is approximately 2.8 times higher for the longer-lived zinc isotope, which indicates that the dose rate would be dominated by emission from that radionuclide. In addition, the relative ratio of the copper to zinc isotopes will decrease with increasing time, such that the zinc isotope would also dominate the activity concentration. For equal concentrations, the dose rate resulting from the zinc isotope is approximately four times larger after five hours, but more than 32 times larger after 45 hours. Therefore, measurement based on release criteria for the zinc isotope would provide a conservative estimate of the total activity in the gemstone.

B.2.f. – The requirements of 10 CFR 31.12 do not apply, as they relate to general licenses in distribution of self-luminous devices.

B.3. – In addition to the proposed method of clearance for topaz using a pancake GM survey meter, gamma spectroscopy analysis will be performed using a 3" x 3" sodium iodide detector coupled to a multichannel analyzer. Detection efficiency for this type of system can be estimated by the energy versus interaction probability graph shown at right.



B.4. – The manufacturer's specifications for the PalmRAD 907 are for a range of 0.001 to 100 mR/hr, although typical background measurements at operating irradiators within Sterigenics range up to approximately 0.01 mR/h. Evidence that this is capable of detection of radionuclides at the exempt concentration level is shown under the technical justification of the license application.

C.1. – Sterigenics utilizes electron accelerators, capable of operating at the energies of 10, 12, 14, 16 or 20 MeV, dependent on the particular gemstone (type & size), and desired effect. As stated in Sterigenics original application, all stones accepted by Sterigenics International, Inc. have had no prior irradiation, electron, neutron or otherwise.

The maximum electron energy for any irradiations is 20 MeV, which is obtainable only in Thailand. The minimum electron energy is 10 MeV, which is obtainable at any of the facilities listed. The San Diego facility also has the capability of providing electron energy in the intermediate range from 10 to 16 MeV. Both the Thailand and San Diego facilities are linear accelerators, although from different manufacturers. The Denmark facility is a Rhodotron™ manufactured by Ion Beam Applications in Belgium.

C.2. – Whether a radionuclide is major or minor in any given irradiation is dependent on the type of gemstone and the nature of the electron irradiation. For example, ^{22}Na is a major radionuclide in irradiation of beryl with 20 MeV electrons, but a minor radionuclide in irradiation of beryl with 12 MeV electrons and not present at all in topaz with any electron energy. For the purposes of evaluating release of gemstones, the list of radionuclides provided in the license application are considered to be "major" for one or more or the type of gemstone that may be irradiated.

With one exception, the list is complete as far as is known to Sterigenics. All of the radionuclides that we have observed in gamma spectroscopic analysis of gemstones are included, except for ^{132}Cs, which has been detected in electron-irradiated beryl and was inadvertently omitted from the initial list. The list also includes several radionuclides that one or more of the references stated or implied could be present in electron-irradiated gemstones, although they have never been observed in any of the irradiations performed by Sterigenics. If the NRC believes this list is incomplete, please provide a reference to published data that includes additional pertinent radionuclides.

C.3. – Please see footnote 1, on page 7 of Sterigenics original application for a list of literature used to identify radionuclides.

C.4. - This information is already incorporated into the possession licenses issued to the facilities by the respective regulatory authorities. Note that the license application under review is only for distribution and not for possession.

C.5. – Gemstones irradiated at electron accelerators in Sterigenics are not subject to any grinding, polishing, or other actions that may create loose particles that contain radioactive material while they are at the company's facilities. Activation products created within the irradiation process are contained within the gemstone and do not appear in the form of small, loose particles.

C.6. – There is no expected radioactive material present upon receipt at the Sterigenics facility. Upon release, the radioactive material concentration is expected to be below the exempt concentration as specified in the NRC regulations and as determined by procedures discussed elsewhere in the license application and this letter.

C.7. – This item has been addressed previously.

C.8. – Gemstones are not incorporated into any material that is expected to be inhaled or ingested by humans.

C.9. – Note that Sterigenics is not an importer or exporter of gemstones and does not distribute gemstones to the retail or wholesale market. The company's function is only to provide irradiation and treatment services to achieve the desired color change. Any gemstones received from a customer, typically a wholesale distributor, are returned to that customer.

Sterigenics will adhere to the manufacturer's specifications and recommendations on instrument calibration and required quality control checks for all instrumentation used as part of this process. Validated software, as supplied by the instrument manufacturer for gamma spectroscopy equipment, will be used to calculate activity concentration of radioactive materials. For gemstones released on the basis of radiation surveys, specific concentrations will not be calculated. Instead, the given action level for dose rate has been shown to be at or below the exempt concentration level, which will be used as justification for activity concentrations.

Procedures will require measurement of all gemstones in an aggregate package post irradiation, as described elsewhere in this application.

During the period of this license, upon request and with the appropriate financial and security controls, samples of irradiated gemstones can be provided to the US NRC for independent measurement and verification. As Sterigenics is not the owner of any gemstones irradiated at any location, this can only be done with the consent of the customer and with the explicit understanding that all samples will be returned immediately to Sterigenics following analysis. In addition, should the US NRC institute a intercomparison program for gemstone measurements, Sterigenics will participate in making measurements to the extent defined by and in accordance with the guidelines of the program.

C.10. – 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. Health risk assessments and dose assessment for irradiated gemstones have been previously performed and are reported extensively in NUREG-1717 and NUREG/CR-5883.

I trust that this response provides adequate information to continue the review of the license application. Should you need further information, please contact either Joe Harless or me at the address shown on this letterhead.

Sincerely,

Mark A. Smith, CHP
Vice-President, Radiation Services

cc:
J. Harless
W. Trevithick
C. Zinn
P. Baker

MicroShield v5.05 (5.05-00092)
SteriGenics

Page : 1
DOS File : STONES.MS5
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Run Time : 10:06:08 AM
Duration : 00:00:00

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Date: _____
By: _____
Checked: _____

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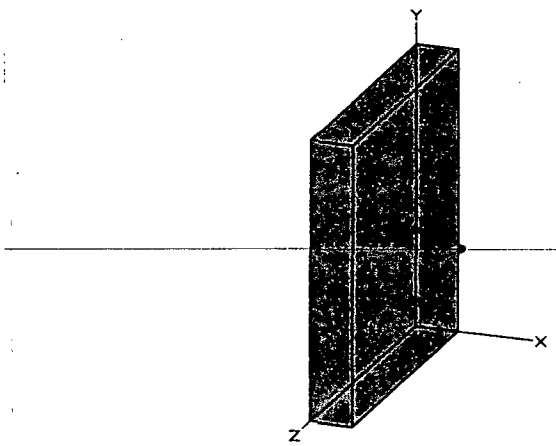

Source Dimensions

Length	2.0 cm	0.8 in
Width	13.6 cm	5.4 in
Height	13.6 cm	5.4 in

Dose Points

	X	Y	Z
# 1	4.5 cm 1.8 in	6.53 cm 2.6 in	6.53 cm 2.6 in

Shields

Shield Name	Dimension	Material	Density
Source	369.92 cm³	Gemstones	1.54
Air Gap		Air	0.00122

Source Input
Grouping Method : Actual Photon Energies

Nuclide	curies	becquerels	µCi/cm³	Bq/cm³
Zn-65	2.7559e-007	1.0197e+004	7.4500e-004	2.7565e+001

Buildup
The material reference is : Source

Integration Parameters

X Direction	10
Y Direction	20
Z Direction	20

Results

Energy MeV	Activity photons/sec	Fluence Rate MeV/cm²/sec No Buildup	Fluence Rate MeV/cm²/sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
0.511	2.886e+02	2.955e-01	3.475e-01	5.799e-04	6.820e-04
0.5577	6.118e-01	6.881e-04	8.011e-04	1.348e-06	1.569e-06
1.1155	5.175e+03	1.219e+01	1.337e+01	2.202e-02	2.414e-02
TOTALS:	5.464e+03	1.249e+01	1.371e+01	2.260e-02	2.482e-02