Sterigenics.

December 2, 2008

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Division of Materials Safety & State Agreements
Office of Federal & State Materials & Environmental Management Programs
USNRC
Washington, DC 20555-0001

Reference: Docket # 030-37764

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 October 27, 2008.

In response to your question regarding the location from which distribution occurs, please keep in mind that Sterigenics does not trade in gem stones. Our company does not purchase, sell, exchange, or have legal ownership of gemstones. We provide the electron irradiation services to customers, who are typically but not necessarily wholesale gemstone distributors. The action that Sterigenics would perform under the exempt distribution license is to receive unirradiated gemstones from a customer, treat them with electron irradiation, and return the gemstones to the customer from whom they were initially received. It is our understanding that this falls under the definition of "distribution" in the context of gemstone irradiation.

With that understanding, the two locations as stated in the original license application will be the locations at which gemstones are received and from which they are returned to our customers. Distribution would occur from the Thailand and San Diego facilities at the addresses as previously provided.

B.1.a. and B.4. At this point, the only electron-irradiated gemstone for which the survey meter measurements would be considered adequate as a release method is topaz. Based on our own measurements and published literature, radionuclides may be present in other gemstones that would exceed the exempt concentration yet still be below the determination level for the survey meter. In some cases, particularly for gemstones such as tourmaline that are infrequently processed, we do not have an adequate in-house data base to state that the expected induced radioactivity would be amenable to release with the survey meter.

As we develop more data, it may be possible to change the release method for other gemstones to use the survey meter technique. However, at this time, there is insufficient evidence that this technique would comply with the requirement for ensuring induced radioactivity levels are below the exempt concentrations. Therefore, the direct answer to your question is that, in the absence of better data, Sterigenics procedures will be written to assume that one of the identified

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problematic radionuclides may potentially be present in any electron-irradiated gemstones other than topaz. Gamma spectroscopy will be used as the release method for other gemstones until such time as adequate technical justification can be made for use of the survey meter as a release method.

B.1.b. As we have not yet established a large enough database to make any definitive determination as to variations in induced activity relative to geographic origins, there is no current method in place to establish *a priori* the potential for differences in gemstone trace elemental composition. There is likely to be little information that we have in advance of processing that would indicate geographic origin, although each of our customers tend to have one or a few specific locations from which they acquire gemstones. Based on the limited amount of data that we have so far been able to correlate on gemstones, there appears to be as strong a correlation between the induced radioactive species and the electron energy used as there is for geographic origin.

At this time, except for electron-irradiated topaz, gamma spectroscopy will be used as a release mechanism for each batch of gemstones to ensure that radionuclide variability due to geographic origin, treatment conditions, or other factors is taken into account. As we are able to develop a larger database and draw more specific correlations, it may be possible to narrow this practice by knowing or controlling the influence factors.

B.2.d. Obviously, there was a misunderstanding as to what this question concerned. Our response was to give a history of the survey meter action level, but what was apparently intended was further technical justification for its use. As was stated in the original license application, the exempt concentration level for induced radionuclides that are expected to be present in electron-irradiated topaz, based on both literature and internal assay results, exceeds twice the background level that is normally observed on the survey meter as identified.

There is multiple precedent for using a twice background action level on a ratemeter as an acceptable approximation of the critical level, as defined in the seminal paper by Currie[1]. For example, the MARSSIM guide[2] in chapter 6 defines the critical level at the 95% confidence interval as, which would be close to the twice background approximation, depending on the magnitude of the background level.

$$L_C = 2.33\sqrt{background}$$

In addition, licensing for disposition of short-lived radioactive waste in nuclear medicine typically requires storing the material for a number of half-lives to ensure decay then performing a radiation survey to ensure that excess radioactivity is not present. The action level typically required in such surveys is twice the background count rate.

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[1] Lloyd A. Currie, "Limits for Qualitative Detection and Quantitative Determination; Application to Radiochemistry," *Analytical Chemistry*, volume 40, number 3, March 1968

[2] Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), NUREG-1575, rev. 1, EPA 402-R-016, rev. 1, DOE/EH-0624, rev. 1, August 2000

As proposed for the release method, the twice background dose rate action level is considered to be a close approximation of the critical level, which is the level at which there is a 95% probability of correctly identifying a measurement as being different from background. Note that this is the justification for using this action level for distinguishing measured levels from background radiation levels, not necessarily directly related to the determination of radioactivity in excess of exempt quantity.

In the technical justification provided in the original license application, the critical level approximation was used as an action level to determine whether certain defined radionuclides are present at levels exceeding the given concentration. By using spatial modeling and particle transport calculations, it was calculated that the presence of these specifically identified radionuclides at concentrations equal to or greater than the exempt concentration would result in a dose rate that would exceed the critical level approximation.

Note again that this method is only being proposed for electron-irradiated topaz. In addition, the minimum size of the sample for which this measurement may be made is adequate to ensure that, if the expected radionuclides were created at the exempt concentration level, the total quantity of radioactivity in the sample would be adequate to exceed the critical level approximation of twice background. As proposed, this would only apply to electron-irradiated topaz in quantities exceeding 500 g. All other gemstones would be subject to gamma spectroscopy to determine whether the exempt concentration has been exceeded.

B.2.f. The report can be filed as required in 10 CFR 32.12 based on the customer processing orders and billing records from the facility. While this information would have to be handled as business confidential, there is nothing that would preclude Sterigenics from providing a list of customers and the types of gemstones that have been processed during the preceding year. The basis for determining the amount of activity "introduced" into each type of gemstone would be based on gamma spectroscopic analyses of batches for release or on the known quantities of induced radioactivity that occur in topaz. The report would be filed by mail as required with the NRC Office of Federal and State Materials and Environmental Management Programs, although we would need to be told which, if any, NRC Regional Offices should receive copies.

C.2. As there is no definition that we have been able to find in regard to "major" and minor" radionuclides, and since the policy is that any induced radioactivity must be shown to be below the exempt concentration, it would appear that all anticipated radionuclides would be "major." However, assuming that the context defines "minor" as being present at lower concentrations, the radionuclides as identified in the following table are shown as to which one has, in our measurements, exhibited the highest concentration, as designated by the number "1" on the tabulation. All other radionuclides are shown as "2," which means they were observed at a lower concentration.

Note again that there is limited data from our measurements for any gemstones except topaz and beryl. As you are aware, there is almost no published data that addresses gemstones irradiated only with electrons, regardless of the species. All gemstones other than topaz and

beryl will have gamma spectroscopy performed prior to their release, which will allow construction of a larger database of radionuclides induced by electron irradiation.

Major Radionuclides Expected to be Present in Electron-Irradiated Gemstones									
			Topaz			Beryl			Others
			Electron Energy (MeV)			Electron Energy (MeV)			
Z	Element	Isotope	10	12	20	10	12	20	
9	F	18	2	2	2				Unknown or Limited Data to Make Determination
11	Na	22						2	
11	Na	24			2				
21	Sc	46					2	2	
21	Sc	47			2				
24	Cr	51							
25	Mn	54				2	2	2	
26	Fe	59							
27	Co	58							
27	Co	60							
29	Cu	64	2	2	2				
30	Zn	65	2	2	2			2	
31	Ga	68							
31	Ga	72							
32	Ge	69	1	1	1				
33	As	77							
37	Rb	84				2	2	2	
38	Sr	85							
40	Zr	95							
41	Nb	95							
50	Sn	113							
51	Sb	124							
51	Sb	125							
55	Cs	132				1	1	1	
55	Cs	134				2	2	2	
56	Ba	133							
58	Ce	141							
63	Eu	152							
73	Ta	182							
77	Ir	192							

C.3. There should have been no implication that the list of possible radionuclides (above) was "representative" of induced radioactivity in electron-irradiated gemstones. From a review of published literature, these radionuclides have been identified in one or more studies as potentially being present in irradiated gemstones. Most were based on neutron irradiation and would be expected to not be applicable to electron treatment. However, the dearth of published information on induced activity from electron treatment of gemstones and the limited number of gamma spectroscopic analyses in our internal database require that a conservative approach to

evaluating the potential for induced radioactivity be taken. Therefore, in the absence of information to the contrary and until such time as the assumption can be disproved, our procedures are being written to assume that any of the radionuclides identified in the open literature may potentially be present in those processed at our facilities. Only with topaz and beryl do we feel that there is enough information to make a definitive assessment.

C.5. Gemstones received at the facility are transferred from the containers in which they are received into trays specifically designed for the irradiator. All irradiations are done in a purified and filtered circulating water bath, which is necessary for cooling purposes. As such, any loose particulate materials that could become activated would be washed away during the processing under flowing water. Because the water is continuously circulating, there is no activation of the water or any trace contaminants in the water, due to the limited time any one portion would spend in the beam path.

In processing the gemstones within the Sterigenics facilities, various operations may be performed as a part of the coloration process. This may include acid wash, high temperature heating, and miscellaneous handling process such as sorting and weighing. No polishing or cutting operations are performed at Sterigenics facilities. None of the operations involve any process whereby abrasion or grinding might occur.

Based on Sterigenics internal risk assessment of the gemstone handling operations, no sources for radioactive contamination have ever been identified. Note that the activation process is different in electron irradiation than it is with neutron irradiation. While it may be possible to activate small quantities of material with neutron bombardment in a short time period, activation under electron beam irradiation would require that the material stay within the beam for an extended period, which only occurs for certain components of the water bath and tray assembly and for the gemstones themselves. Any loose material that could become activated would be removed in the circulating water.

In the San Diego facility, contamination surveys have been performed on a routine basis for several decades. There have been no instances of radioactive contamination being identified that resulted from gemstone irradiation and shipping. In first years of operation in the Thailand facility, extensive radioactive contamination surveys were done on both the irradiation room and the areas used for gemstone storage and handling without identifying any measurable contamination.

C.9. The measurement quality assurance program has not yet been completely proceduralized, as many aspects of what will be required are dependent on the licensing process. However, in general, the two types of measurements that have been proposed for release of gemstones are ratemeter measurements for topaz and gamma spectroscopy measurements for all other gemstones.

All measurements will be conducted under defined procedures that specify the conditions for the measurement, including geometry. As a general rule, measurements for the release of gemstones will be made at the time it is expected that any induced radioactivity would have

decayed to less than the exempt concentrations, which will be based on previous history with a supplier and for the particular gemstone type.

Measurements will be conducted using instruments from authorized vendors, as defined in the Sterigenics Quality Manual, with the specific arrangement of detector and sample being defined for each location and each specific instrument. Individuals conducting the measurements will have formal training in radiation detection and measurement and will receive training on the specific procedures to be used for these measurements.

The quality assurance program will include:

1. Ratemeter Measurements
   a. Annual dose rate calibration by a contractor specifically authorized to perform the calibrations. This calibration will be with a photon source to be determined by the contractor and will ensure that the meter responds accurately to within 10%.
   b. Constancy check of the instrument response each day the meter is used. This will consist of a measurement, in defined geometry, of a long-lived radionuclide check source to ensure that the meter reading does not vary during use.
   c. Each batch of topaz to be released will be measured under the applicable procedure. Any result exceeding the action level will prohibit the batch from being released at that time. Further investigation will be conducted to determine the cause that the action level is exceeded and the appropriate actions to be taken (e.g., longer storage for decay).
   d. The dose rate will be documented for each batch, noting that the dose rate from electron-irradiated topaz is below the action level.

2. Gamma Spectroscopy Measurements
   a. Energy and efficiency calibrations will be performed on the schedule and following procedures as recommended by the instrument manufacturer. In the absence of specific recommendations from the manufacturer, the calibration frequency will be determined on the basis of the stability of the instrument over time, which would require more frequent intervals at the beginning until the appropriate frequency has been established.
   b. Consistency checks will be performed each day the instrument is used, consisting of a measurement of a long-lived radionuclide to ensure that there is no signal drift or deterioration.
   c. Calculations of activity in the sample will be done by vendor-supplied software, with the applicable corrections made for geometry or other influence quantities as applicable to the calibration. Vendor-supplied software will also calculate detection limits and applicable counting statistics, which will be recorded for each measurement used for release of gemstone batches.
   d. Conditions of use will be determined for each location at which the measurements are made, and may vary according to local background levels or other influence quantities, requiring that sample counting times be adjusted appropriately to ensure that the critical level is below the exempt concentration for each identified radionuclide.
   e. Each batch of gemstones will be measured with the gamma spectroscopy system to ensure that the induced radioactivity levels are below exempt concentrations. The sample size may be as small as one stone, depending on the size and type of gemstone,

and will be limited to a maximum of 500 g for measurement purposes. The maximum size is that which it is reasonably expected (95% confidence interval) to be able to detect radionuclides at the exempt concentration level without undue self-shielding interference. The count time and geometry corrections will of necessity be adjusted to account for differences in sample size.

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