UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

March 11, 2009

Sterigenics International, Inc. Mail Control No. 022688
Attn: Mark A. Smith
Vice President, Radiation Services
10811 Withers Cove Park Drive
Charlotte, NC 28278

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Smith:

This refers to your application, dated May 27, 2008, for a Nuclear Regulatory Commission exempt distribution license to distribute irradiated gemstones under the provisions of 10 CFR 32.11, your responses, dated September 18, 2008, December 2, 2008, and February 6, 2009, to our Requests for Additional Information.

We do not have sufficient information to complete the review of your application. Upon consideration of the responses provided in your letter of February 6, 2009, further review of the technical justification in your original application was undertaken. As a result of this review, you are requested to provide additional clarification regarding the following:

(1) Identification of major radionuclides

(a) Apparent discrepancy

It appears that there may be a discrepancy between the information concerning the major radionuclides in electron-irradiated topaz that you provided in your original application of May 27, 2008, and that provided in NUREG/CR-5883, which you cited.

Your application stated, on page 8 of 9: “In electron-irradiated topaz, the most radionuclides expected are ^{18}F, ^{64}Cu, ^{65}Zn, and ^{68}Ga, according to NUREG/CR-5883.”

However, the NUREG/CR states: “The radionuclides produced by high-energy electron treatment include ^{64}Cu, ^{68}Ga, ^{49}Cr, and ^{18}F . . . ” [Executive Summary], and: “The daughter products of the parent nuclides, ^{69}Ga, ^{65}Cu, ^{64}Zn, ^{50}Cr, and ^{19}F, were the most likely to be produced by electron Irradiation.” These daughter products included ^{68}Ga, ^{64}Cu, ^{63}Zn, ^{49}Cr and ^{18}F [page 64]. Please explain why your analysis includes ^{65}Zn, but excludes ^{63}Zn and ^{49}Cr.

(b) Relative importance of radionuclides

You provided estimated dose rates at exempt concentrations in Table 1 of your application. It appears that additional information is needed to clarify whether these data actually support the assertion that the listed radionuclides are all detectable at their exempt-concentration levels using the proposed methodology.

For example, if it is assumed that Ba-133 is present in a sample of topaz in excess of the exempt concentration, while all other radionuclides in the table are present at, or below, their respective exempt concentration levels, would the survey instrument be able to identify this? (The same question could be asked of Na-22, or As-77, or Ce-141.)

(2) Capability of survey instrument

In order to better assess the capability of the survey instrument, please provide the following information:

(a) Efficiency

The specifications for the survey instrument indicate that it has a sensitivity of 3500 cpm/mR/hr referenced to Cs-137. However, this does not provide adequate information about its ability to detect each of the radionuclides that may be of concern for topaz. In order to assist in our evaluation, please provide the detector efficiency response curve for this instrument (i.e., how the detector response varies for the different energies of the radionuclides you listed in Table 1 of your application).

(b) Measurement uncertainty

At the stated sensitivity, and at a dose rate of about 0.01 mR/hr, the count rate for the instrument would be about 35 cpm, or about 0.6 cps. At that low level, would the counts from the topaz be distinguishable from background? Please provide information to support such a capability, which appears to be the basis for your proposed procedure.

(3) Quality Assurance Program

You indicated in your letter of February 6, 2009, that "the specific quality control and quality assurance procedures for gemstone radiation measurements are still in development because new gamma spectroscopy equipment was acquired in January." In addition, you stated, "the procedures will be finalized within the next month . . . ." Please describe the current status of the effort to develop these quality control and quality assurance procedures for the <u>gamma spectroscopy equipment</u>, and provide a copy if their status is final or near-final.

While we understand your position with regard to developing quality control and quality assurance procedures pertaining to the use of a <u>survey instrument</u> as the method for determining whether radionuclides in irradiated topaz are below exempt-concentration limits, please note that a license authorizing transfer to persons exempt under 10 CFR Section 30.14 can not be issued until such procedures have been developed. Please indicate whether quality control and quality assurance procedures for gemstone radiation measurements have been developed or are under development for this method, and provide a copy if their status is final or near-final.

If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Any correspondence regarding your amendment application should reference the control number specified above.

If you have any questions, please feel free to contact me at (301) 415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer, Health Physicist
State Agreements & Industrial Safety Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-37764

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If you have any questions, please feel free to contact me at (301) 415-5477 or electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,

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Richard K. Struckmeyer, Health Physicist
State Agreements & Industrial Safety Branch
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Docket No. 030-37764

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