Sterigenics.

February 6, 2009

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 # 030-37764

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.

B.2.d. Apparently, the questions that I have been trying to answer and the direction you expected those answers to be taking are radically divergent. If I may start the explanation again from the beginning, our proposed method for release of electron-irradiated topaz is that a sensitive survey meter be used for a count rate or exposure rate measurement. This is based on the technical evaluation as presented in the original application, which assumed that the topaz has received uniform electron irradiation and would therefore be expected to have uniform concentrations of induced radioactivity. In that evaluation, calculations showed that, if the any of the radionuclides that may occur in electron-irradiated topaz were present at the exempt concentration level, the dose rate from a collection of 500 g of topaz would be greater than 0.2 mrad per hour. In addition, combination of radioisotopes in the relative ratios that would occur at two days post-irradiation and that would result in a sum-of-ratios greater than 1, would show a dose rate of greater than 0.2 mrad per hour.

Based on that evaluation, and on the relative wide-spread application of a twice background count rate as an action level for radiation surveys, we proposed an evaluation criterion of twice background as measured on a survey meter that has a response of no more than 0.1 mrad per hour for background levels. This level, which is an approximation of the critical level, is essentially saying that for topaz, any combination of the induced radioisotopes, present in the expected ratios that would be induced by electron irradiation, greater than the exempt concentration would give a dose rate under the defined geometry conditions that is distinguishable from background. If the dose rate is not distinguishable from background, then the induced radioactivity is present at levels below the exempt concentration.

This conclusion is based on published evaluations, including NUREG/CR-5883, and experience with radiation level measurements as compared to gamma spectroscopic analysis of electron irradiated topaz. Subsequent discussion of the twice background criterion appears to have only confused the issue, for which I apologize.

Sterigenics International, Inc.
10811 Withers Cove Park Drive
Charlotte, NC 28 282
Tel 704.588.6877• Fax 704.588.3667 • www.sterigenics.com

The definition of terms related to detection limits that were given in your letter are correct and are consistent with the way these terms are used within our company. The confusion arose because I was apparently not answering your previous question in the manner you expected. Again, I apologize for the confusion.

Note, however, that the discussion as presented in your letter deals with the statistics of a total count, whereas the discussion as I presented it dealt with a count rate. There are some subtle but significant differences in evaluating counting statistics with count rates, which would also have to account for such considerations as the time constant of electronic circuits used in the specific survey meter.

C.9. A large portion of our correspondence on this application has dealt with the use of a survey meter for release of electron-irradiated topaz. At this point, we have no assurance that this method will eventually be accepted by the NRC, which would require that release of topaz be done with gamma spectroscopy as would be for other gemstones. Therefore, the measurement quality assurance program is somewhat dependent on the outcome of the licensing process as it is related to the release methodology for topaz.

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. As we are still testing the equipment prior to implementation, we are also evaluating the appropriate levels for quality control on the instrumentation. The procedures will be finalized within the next month and will be in place prior to any activities as authorized under the distribution license.

Sterigenics has an extensive quality assurance program in place that has received ISO 9001 certification. This program covers all operations of the corporation, including many areas that are not directly relevant to gemstone irradiation or measurement systems.

Enclosed is a copy of the Table of Contents for the Sterigenics Quality System Procedures, which addresses the general requirements for establishment of a quality assurance program. Any work instructions that are in place or would be developed for radiation measurements of gemstones would fall under the provisions of this Quality Manual.

In addition, the Sterigenics quality program contains sections on Process Procedures and Corporate Work Instructions. The Table of Contents of those sections pertinent to electron beam operations is also attached.

Company procedures are periodically reviewed and updated as necessary to ensure continued safe and effective operations. Changes may be made in the procedures if items are identified that may improve safety or efficiency, provided that the changes do not compromise safety, are in compliance with the applicable NRC, Agreement State, or other controlling regulatory authority regulations, and are consistent with copies as submitted.

Specific procedures that deal specifically with measurement of radiation from electron-irradiated gemstones would be categorized as Facility Work Instructions. All revisions to procedures pertinent to these measurements must be reviewed and approved by the Corporate RSO and facility Quality Assurance Manager. Prior to implementation, all affected personnel will receive training on procedure revisions.

Any procedures or indices included with this application are examples of current practice and are subject to revision under the preceding guidelines. The specific contents of the gemstone measurement quality assurance work instructions will follow the outline as previously submitted.

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

Quality System Level Procedures Index

Rev. 34, 01/30/09

PROCEDURE	TITLE	REV#	DATE
QSP001	Quality System Record and Components	3	09/30/08
	This procedure identifies the Quality System Record and defines the components of the quality system at both the Corporate and Facility levels.		
	Corporate QSR	5	10/30/08
QSP002	Quality Planning	5	09/30/08
	This procedure defines the requirements for planning and determining quality objectives for the organization.		
	Attachment A	2	04/30/05
QSP003	Internal Communication	3	09/30/08
	This procedure defines the system of communication within and between the various levels and functions of the organization regarding the quality management system and its effectiveness.		
QSP004	Document Control	14	10/30/08
	This procedure defines the requirements for document control regarding the documented quality system and external reference documents.		
QSP005	Quality Records and Documentation Practices	6	09/30/08
	This procedure defines the requirements for managing quality records and good documentation practices.		
QSP006	Management Review	8	09/30/08
	This procedure defines the requirements for performing Management Review.		
QSP007	Training	7	09/30/08
	This procedure defines the training requirements for all personnel.		
QSP008	Contract Review	10	09/30/08
	This procedure defines the types of contracts, general requirements for performing contract review, changes to contracts, records required for performing contract review, and entering customer contract requirements into the applicable management information system.		
QSP009	Purchasing and Supplier Approval	11	09/30/08
	This procedure defines the requirements and controls for purchasing, assessment of suppliers, purchasing records, and verification of purchased supplies and services.		
QSP010	Product ID and Traceability	6	08/30/08
	This procedure defines how product is identified throughout all stages of production and delivery.		
QSP011	Software Validation	3	04/30/05
	This procedure defines the requirements for software system configuration and/or development, whether developed in-house or by a sub-contractor. Further detail can be found in the Software Design Manual.		
QSP012	Internal Audit	8	04/22/08
	This procedure defines the requirements form performing, scheduling, staffing, and reporting an internal audit.		

Quality System Level Procedures Index
Rev. 34, 01/30/09

PROCEDURE	TITLE	REV#	DATE
QSP013	Deficiency Handling *This procedure defines the requirements for ensuring nonconforming and deviated product is identified and controlled to prevent unintended use or shipment. Topics covered are: Definitions, ID of product, Remedial Action, Corrective Action and Preventive Action Follow-up, Disposition, and Documentation.*	10	01/30/09
	Attachment A	3	08/30/08
QSP014	Customer Complaints *This procedure defines the method for recording, investigating, and determining corrective action to customer complaints as they relate to Service and Good Manufacturing Practices.*	3	01/30/09
	Attachment A	2	01/30/09
QSP015	Medical Device Reporting Regulation *This procedure defines the organization's responsibility regarding Medical Device Reporting Regulation, 21 CFR part 803.*	1	07/30/04
QSP016	Corrective and Preventive Action *This procedure defines the program of continual improvement via the criteria and requirements of the Corrective and Preventive Action System. Topics covered are: Planning and Improvement methods, completing a Corrective Action Request, Determining Root Cause, Determining action to prevent recurrence, Follow-up and close out of corrective actions, and Preventive Action measures.*	7	01/30/09
QSP017	Data Analysis for Improvement *This procedure defines the requirements for data analysis (monthly quality reports) for improvement to determine the effectiveness of the quality system.*	4	08/30/08
QSP018	Facility and Customer Master Records *This procedure defines the documents required for the Facility Master Record and each Customer Master Record.*	2	09/30/08
QSP019	Personnel Hygiene *This procedure defines the personnel hygiene requirements for all personnel.*	1	07/30/04
QSP020	Building Security and Equipment *This procedure defines the Facility Security Requirements during and after business hours, and in addition, provides general building and equipment requirements.*	4	04/30/06
QSP021	Process Equipment/System Maintenance & Change Control *This procedure defines the requirements for performing repairs, preventive maintenance, and changes to process equipment.*	5	08/30/08
QSP022	Preservation of Product *This procedure defines the general controls required to handle, store, package, and deliver customer product.*	2	07/30/04
QSP023	Measurement and Monitoring of Product and/or Services *This procedure defines the requirements for monitoring purchased products, and delivery of services to our customers throughout all stages of processing including receipt, in-process, and final inspection activities.*	5	08/30/08
QSP024	Risk Management *This procedure defines risk management and provides risk management tools that can be applied to all aspects of the Sterigenics process model.*	1	01/30/07

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EBeam Medical Work Instructions Index
Rev. 36, 01/30/09

INSTRUCTION #	TITLE	REV #	DATE
ADMINISTRATION			
MDEB-ADM-001	REQUESTING A DOCUMENT CHANGE/ISSUE	3	01/30/07
MDEB-ADM-002	CUSTOMER SPECIFICATION CHANGE	4	01/30/07
MDEB-ADM-003	PURCHASING CONTROLLED SUPPLIES	3	04/30/07
MDEB-ADM-004	RECEIPT OF CONTROLLED SUPPLIES	5	05/30/08
MDEB-ADM-005	CUSTOMER MASTER RECORD	4	04/30/07
MDEB-ADM-006	STORAGE OF QUALITY RECORDS	2	01/30/07
MDEB-ADM-007	CORRECTION OF MISTAKES	1	07/30/04
MDEB-ADM-008	STATEMENT OF DOSAGE	3	07/30/04
MDEB-ADM-009	MANAGEMENT REVIEW	6	01/30/09
MDEB-ADM-010	CONTRACT REVIEW	2	01/30/07
MDEB-ADM-011	MANUAL CUSTOMER SET UP	3	01/30/07
MDEB-ADM-012	MANUAL PROCESSING OF CERTS, INVOICE, PACKING SLIPS & BOLS	2	07/30/04
MDEB-ADM-013	MANUAL WORK ORDER	3	01/30/07
MDEB-ADM-014	OMITTED		
MDEB-ADM-015	OMITTED		
STARS			
MDEB-STR-001	OMITTED		
MDEB-STR-002	OMITTED		
MDEB-STR-003	OMITTED		
MDEB-STR-004	OMITTED		
MDEB-STR-005	OMITTED		
MDEB-STR-006	OMITTED		
MDEB-STR-007	OMITTED		
MDEB-STR-008	OMITTED		
MDEB-STR-009	OMITTED		
MDEB-STR-010	OMITTED		
MDEB-STR-011	OMITTED		
MDEB-STR-012	OMITTED		
MDEB-STR-013	OMITTED		
MDEB-STR-014	OMITTED		

INSTRUCTION #	TITLE	REV #	DATE
QUALITY ASSURANCE			
MDEB-QAI-001	HYGROMETER CALIBRATION	2	10/30/05
MDEB-QAI-002	PROCESS HISTORY RECORD	4	04/30/07
MDEB-QAI-003	OMITTED		
MDEB-QAI-004	ISSUE OF EXPERIMENTAL PROTOCOLS	1	07/30/04
MDEB-QAI-005	WEIGH SCALE CALIBRATION	2	07/30/04
MDEB-QAI-006	NIST CALIBRATION OF CARY VARIAN	4	01/30/06
MDEB-QAI-007	RECEIPT OF POUCHED DOSIMETERS	5	01/30/06
MDEB-QAI-008	*t*-TEST & OUTLIER TEST Table 1	1 1	07/30/04 01/30/01
MDEB-QAI-009	OUTLYING DOSIMETRY OBSERVATIONS IN RUN DATA Table 1	1 0	07/30/04 01/30/01
MDEB-QAI-010	REPAIR & PM OF CARY VARIAN	2	07/30/04
MDEB-QAI-011	CALIBRATION OF MITUTOYO THICKNESS GAUGE	2	07/30/04
MDEB-QAI-012	CHART RECORDER CALIBRATION	1	07/30/04
MDEB-QAI-013	CALORIMETER THERMOCOUPLE CALIBRATION	2	01/30/07
MDEB-QAI-014	IN-SITU DOSIMETER CALIBRATION Figure 1 - OMITTED Figure 2 - OMITTED Figure 3 - OMITTED	5	05/30/08
MDEB-QAI-015	REPORTING CERTIFIED DOSE	2	04/30/07
MDEB-QAI-016	MANUAL DISTRIBUTION	1	07/30/04
MDEB-QAI-017	CALIBRATION MEASURING TAPE/RULER	1	07/30/04
MDEB-QAI-018	OSCILLOSCOPE CALIBRATION	1	07/30/04
MDEB-QAI-019	STOPWATCH VERIFICATION	2	04/30/05
MDEB-QAI-020	5W/2H ROOT CAUSE ANALYSIS & 8 D PROBLEM SOLVING	0	07/30/04
MDEB-QAI-021	MAINTENANCE EQUIPMENT CALIBRATION	0	07/30/04
MDEB-QAI-022	CALIBRATION OF FEDERAL THICKNESS GAUGE	0	01/30/05
MDEB-QAI-023	HAZARD ANALYSIS	0	01/30/05
MDEB-QAI-024	ENTERING SETTINGS IN SADA	0	04/30/07
MDEB-QAI-025	1930 GLASS REFERENCE FILTER RE-CERTIFICATION	0	04/30/08
VALIDATION			
MDEB-VAL-001	OMITTED		
MDEB-VAL-002	IRRADIATOR SYSTEM CHANGE	5	04/30/05
MDEB-VAL-003	DOSE MAPPING; INITIAL PRODUCT QUALIFICATION	3	01/30/08
MDEB-VAL-004	TEMPERATURE AND UV VALIDATION TEST	5	07/30/06

INSTRUCTION #	TITLE	REV #	DATE
WAREHOUSE			
MDEB-WHI-001	RECEIPT OF PRODUCT	11	09/30/07
MDEB-WHI-002	STORAGE/SEGREGATION OF PRODUCT	2	01/30/07
MDEB-WHI-003	HOLD PRODUCT	5	01/30/09
MDEB-WHI-004	SHIPMENT OF PRODUCT	7	04/30/07
MDEB-WHI-005	PALLET CONFIGURATION SHEET	3	01/30/07
OPERATIONS			
MDEB-OPS-001	SYSTEM START UP	1	07/30/04
MDEB-OPS-002	FACILITY SHUT DOWN	2	04/30/07
MDEB-OPS-003	PROCESS INTERRUPTIONS	2	07/30/05
MDEB-OPS-004	SHIFT CHANGE CHECKLIST	3	12/30/07
MDEB-OPS-005	SYSTEM CONFIGURATION LOG	2	01/30/07
MDEB-OPS-006	LOADING/UNLOADING	3	01/30/07
MDEB-OPS-007	IRRADIATOR SET UP	2	07/30/08
MDEB-OPS-008	DOSE AUGMENTING	1	07/30/04
MDEB-OPS-009	FILM DOSIMETER PREPARATION	2	01/30/07
MDEB-OPS-010	OMITTED		
MDEB-OPS-011	MISSING DOSIMETER	1	07/30/04
MDEB-OPS-012	DOSIMETER PLACEMENT/RETRIEVAL/RETENTION	1	07/30/04
MDEB-OPS-013	DAMAGED PRODUCT	3	07/30/05
MDEB-OPS-014	OMITTED		
MDEB-OPS-015	OMITTED		
MDEB-OPS-016	OPERATING CARY VARIAN AND CALCULATING DOSE USING SADA	3	07/30/07
MDEB-OPS-017	CARY VARIAN WEEKLY SELF TEST & START UP	3	01/30/06
MDEB-OPS-018	CREATING TUNE RECORDS	1	07/30/04
MDEB-OPS-019	CALORIMETER DOSE MEASUREMENT PROCESS	4	12/30/07
MDEB-OPS-020	CONVEYOR START/STOP TEST	1	07/30/04
MDEB-OPS-021	SCAN WIDTH TEST	1	07/30/04
MDEB-OPS-022	ELECTRON BEAM ENERGY AND DEPTH DOSE TEST	2	07/30/04
	Figure 1	0	01/30/03
MDEB-OPS-023	CONVEYOR PROCESSING	5	08/30/08
MDEB-OPS-024	CONVEYOR TRACKING TEST	2	07/30/07
MDEB-OPS-025	CALORIMETER TO FWT DOSIMETER RATIO TEST	2	07/30/04
MDEB-OPS-026	SURFACE DOSE MAP	1	07/30/04

INSTRUCTION #	TITLE	REV #	DATE
	Figure 1	1	01/30/04
MDEB-OPS-027	REMOVAL AND INSTALLATION OF CALORIMETER	3	01/30/05
MDEB-OPS-028	PRODUCTION PLANNING	1	07/30/04
MDEB-OPS-029	ENGINEERING CHANGE RECORD	5	12/30/08
MDEB-OPS-030	CORRECTIONS TO APPROVED WORK ORDERS	2	01/30/07
MDEB-OPS-031	OMITTED		
MDEB-OPS-032	GEMSTONE CHECK IN AND VERIFICATION	1	07/30/04
MDEB-OPS-033	GEMSTONE IRRADIATION PROCESS – San Diego	2	01/30/07
MDEB-OPS-034	GEMSTONE POST IRRADIATION PROCESS	1	07/30/04
MDEB-OPS-035	RADIATION HARDNESS PROCESSING	1	07/30/04
MDEB-OPS-036	THICKNESS CORRECTION RADIOCHROMIC	1	07/30/04
MDEB-OPS-037	CREATE ITEMPACK LOADING DIAGRAM	1	07/30/04
MDEB-OPS-038	THICKNESS GAUGE OPERATION	0	01/30/05
MDEB-OPS-039	VISIBLE BULB ALIGNMENT FOR THE VARIAN SPECTROPHOTOMETERS	0	04/30/07

RADIATION SAFETY

MDEB-RS-001	CELL ACCESS	2	04/30/07
MDEB-RS-002	CALIBRATION SURVEY METERS AND DIG. EXP. METERS	2	07/30/04
MDEB-RS-003	PERSONNEL DOSIMETRY	1	07/30/04
MDEB-RS-004	RESTRICTED AREA VISITORS	3	07/30/04
MDEB-RS-005	CELL SURVEY	2	07/30/04
MDEB-RS-006	OZONE MEASUREMENT	1	07/30/04
MDEB-RS-007	ACTIVATION CHECK	3	07/30/04
MDEB-RS-008	SYSTEM SAFETY CHECK	1	07/30/04

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Process Level Procedures Index
MEDICAL EBEAM
Rev. 25, 01/30/09

PROCEDURE	TITLE	REV#	DATE
PP-MDEB-001	Process History Record *Defines the components and documents included in the Process History Record.*	2	01/30/07
PP-MDEB-002	Quality Record Retention *Defines the quality record retention periods for Ebeam facilities processing healthcare products.*	11	01/30/09
PP-MDEB-003	Required Facility Work Instructions *Defines the Facility Work Instructions that are required for each facility to develop and maintain.*	1	07/30/04
PP-MDEB-004	Supplier Approval *This procedure summarizes the suppliers by type, level, approval frequency and criteria for Ebeam facilities processing healthcare and non-healthcare products.*	3	04/30/06
PP-MDEB-005	Dosimeter Environmental Controls *This procedure identifies the controls necessary to produce the most effective environment for the use and storage of dosimeters.*	2	07/30/07
PP-MDEB-006	Product Tracking & ID *Defines the assignment of an exclusive run number for product identification and traceability in the Ebeam process.*	5	09/30/07
PP-MDEB-007	Cleaning & Pest Control *Defines the requirements for acceptable cleaning, refuse disposal, cleaning schedules and pest control practices.*	2	01/30/05
PP-MDEB-008	Process Controls *This procedure outlines the overall controls required during Ebeam irradiation of healthcare products. Includes reference to: receiving/storage/shipment; work order/scheduling; loading pattern; loading/unloading; system configuration log; dosimeter placement.*	3	01/30/07
PP-MDEB-009	Deficiency Handling *Defines events, which result in either nonconforming products, deviations, reprocess, or documentation errors and the controls required for resolution and disposition.*	2	09/30/08
PP-MDEB-010	Environmental Health & Safety *This procedure defines the general requirements for complying with environmental, health and safety requirements, EHS manual, emergency drill, safety system checks, personnel dosimetry, general radiation safety requirements and testing.*	2	07/30/04
PP-MDEB-011	Preventive Maintenance *This procedure provides criteria for performing periodic checks and preventive maintenance on the irradiator system to ensure the proper and safe function of the system and the requirements for recording maintenance and engineering changes.*	6	03/30/08

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Process Level Procedures Index
MEDICAL EBEAM
Rev. 25, 01/30/09

PP-MDEB-012	Measurement Equipment	5	09/30/08
	This procedure defines the requirements for accuracy, calibration, identification, maintenance, and management of measurement equipment.		
PP-MDEB-013	OMITTED		
PP-MDEB-014	Radiation Safety Training	3	07/30/04
	This procedure defines the additional training requirements for irradiator personnel. These requirements are in addition to those defined in QSP007, Training.		
PP-MDEB-015	Irradiator Qualification and Requalification	4	04/30/05
	Defines the requirements for installation qualification of a new irradiator design and requalification of existing irradiator.		
PP-MDEB-016	Statistical Analysis	1	07/30/04
	Defines the use of statistical techniques for the analysis of data, e.g., statistical analysis of dose map data and dosimetry outliers.		