



030-37764

May 27, 2008

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards
US Nuclear Regulatory Commission
Washington, DC 2055-0001

Reference: New License Application, Distribution of Electron-Irradiated Gemstones

Dear Sir or Madam:

Enclosed is a new license application for distribution of electron-irradiated gemstones to persons exempt from licensing. As a guide to preparing the application, we used existing US Nuclear Regulatory Commission (NRC) documents, the vast majority of which dealt with neutron-irradiated gemstones. As you will see in the technical discussion of induced activity in this application, there are some significant differences between expectations of induced radioactivity with electrons versus neutrons.

I expect there to be differences between our respective understanding of the NRC requirements, and some clarification required for the information included in this application. Should you wish to discuss any such items with us prior to sending a letter, you may speak to either Joe Harless or me. Both of our telephone numbers are included in the application.

Thank you for your time and attention.

Sincerely,

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

cc:

P. Baker, San Diego
J. Harless, Charlotte
W. Trevithick, Thailand
Carl Zinn, San Diego

Sterigenics International, Inc.
10811 Withers Cove Park Drive
Charlotte, NC 28278
Tel 704.588.6877 • Fax 704.588.3667 • www.sterigenics.com

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NRC FORM 313 (10-2002) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005	Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.				
<h2 style="margin: 0;">APPLICATION FOR MATERIAL LICENSE</h2>							
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.							
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO: LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415 ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: SAM NUNN ATLANTA FEDERAL CENTER U. S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORSYTH STREET, S.W., SUITE 23T85 ATLANTA, GEORGIA 30303-8931		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-8064					
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.							
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input checked="" type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) Sterigenics International 10811 Withers Cove Park Drive Charlotte, NC 28278					
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED <div style="text-align: center; padding: 20px;">See attached</div>		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION <div style="text-align: center; padding: 10px;">Mark A. Smith</div>					
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.					
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.		8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.					
9. FACILITIES AND EQUIPMENT.		10. RADIATION SAFETY PROGRAM.					
11. WASTE MANAGEMENT.		12. LICENSE FEES (See 10 CFR 170 and Section 170.31) <table style="width:100%; border: none;"> <tr> <td style="border: none;">FEE CATEGORY</td> <td style="border: none; text-align: center;">3.I.</td> <td style="border: none; text-align: right;">AMOUNT ENCLOSED</td> <td style="border: none; text-align: right;">\$ \$8,700</td> </tr> </table>		FEE CATEGORY	3.I.	AMOUNT ENCLOSED	\$ \$8,700
FEE CATEGORY	3.I.	AMOUNT ENCLOSED	\$ \$8,700				
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO							
CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE Mark A. Smith, Vice-President, Radiation Services		SIGNATURE 	DATE May 27, 2008				
FOR NRC USE ONLY							
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS		
APPROVED BY				DATE			

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Item 3: Address Where Licensed Material Will Be Used And Possessed

Sterigenics International, Inc.
7695 Formula Place
San Diego, California 92121-2418

See attachment (A) for copy of Sterigenics International, Inc State of California
Department of Health and Human Services Agency Radioactive Materials License.

Sterigenics International, Inc.
Eastern Seaboard Industrial Estate, North
109/16 – Moo 4
Tambok Pluak Daemg Daemg
Rayong 211440
Thailand

Item 4: Name Of Person To Be Contacted About This License

Mark Smith, CHP
Vice President Radiation Services
Sterigenics International, Inc.
10811 Withers Cove Park Drive
Charlotte, NC 28278
(704) 587-8914
msmith@sterigenics.com

Joe Harless, BSHP
Director, Radiation Safety
Sterigenics International, Inc.
10811 Withers Cove Park Drive
Charlotte, NC 28278
(704) 587-8916
jharless@sterigenics.com

Item 5: Radioactive Material

5.A - Element And Mass Number

Isotopes with atomic numbers 1 – 94, inclusive

5.B - Chemical And/Or Physical Form

Solid components of activated materials

5.C – Maximum Amount That Will Be Possessed At Any One Time

Total not to exceed 1 Curie

Item 6: Purpose For Which Licensed Material Will Be Used

Electron-irradiated gemstones will be accepted from and delivered back to wholesale distributors, which are Sterigenics customers. Incidental to the irradiation, some radioactivity may be induced in the gemstones from electron irradiation.

Sterigenics International, Inc. does not accept, irradiate nor distribute neutron irradiated gemstones. The company accepts only unirradiated stones, which are then submitted to electron irradiation. This application is only for electron-irradiated materials.

Supplemental Information as Requested in NUREG-1556, Vol. 8, Appendix G (as applicable to electron-irradiated gemstones)

A. Basic Information

Records related to the possession and distribution of gems at Sterigenics International, Inc. San Diego operations will be located at the facility specified in the San Diego address as indicated in Item 3 above.

Records related to the possession and distribution for Sterigenics International, Inc. Thailand facility will be made available for NRC review, upon their prior request, at:

Sterigenics International, Inc.
10811 Withers Cove Park Drive
Charlotte, NC 28278

The licensee requests that all records request be made in advance to allow time to procure copies of the requested records from the Thailand facility.

B. Background Information

1. Describe the material

The type of gems included in this application are topaz, beryl, tourmaline, spodumene, quartz, and diamond.

All stones accepted for electron-irradiation have been previously cut and polished. They are ready for mounting, post electron-irradiation.

All stones accepted for electron-irradiation by Sterigenics International, Inc. have had no prior irradiation, electron, neutron or otherwise. Sterigenics will electron-irradiate the unprocessed stones and follow with the appropriate heat annealing

process. The stones are then weighed, color graded and bagged for shipment to the supplying wholesaler.

Sterigenics is involved only with the irradiation processing, storage and release of goods to the customer and not in the gemstone setting or mounting process. The sequence of our activities is as follows:

- a) Confirmation of weight of customer goods, description of treatment requested by customer, unit price for treatment requested, total projected value of invoice (this information is contained in "Confirmation Letter" - see attachment (B) for sample copy)
- b) Upon receipt of a signed Confirmation Letter from the customer, our operations process sequence is recorded on a "Process Control Report" document that accompanies each batch for electron beam treatment. The document contains customer identification, batch weight, desired dose, date and time for all stages of processing, signatures of employees handling goods at all stages of operations, radiation levels recorded for each batch during each stage of operations, and final release data (radiation levels, invoicing data, certification). See attachment (C) for "Process Control Report" example.

As previously stated, Sterigenics International, Inc. does not accept, irradiate nor distribute neutron irradiated gemstones, only unirradiated stones that are then submitted to electron irradiation. Likewise, stones accepted for electron-irradiation have had no prior gamma or accelerator treatment performed prior to receipt.

Gemstones are not segregated by geologic origin, but by customer. The customer typically supplies material from similar locations (i.e., Brazilian stones from a customer who normally uses Brazil product, Nigerian stones from a customer who normally uses Nigerian product). When a customer does not know the origin of his product, we assume it is Nigerian, as this is the most common on the market and also the least expensive.

In general, the differences in activation associated with varying locations of origin and resulting color differences are more significant for neutron-irradiated gemstones. However, for electron-irradiated gemstones, topaz in particular, the geologic origin of the gemstones is less significant in the type of induced radioactivity that may be encountered (refer to NUREG/CR-5883). The same principle also applies to other types of gemstones treated by electron irradiation only.

Identification of all radionuclides with physical half-lives greater than 2 hours (regardless of method of production) induced in gems is addressed under "Technical Justification" below.

2. Describe the handling of gems

Stones are irradiated in a water bath. The stones are then washed and dried.

Sterigenics returns the gemstones to the original supplying wholesaler. The wholesaler then distributes the gemstones to manufacturing jewelers, retail jewelers, etc. for mounting and further distribution.

Gems, whose concentrations are found to exceed the maximum concentration of the radioisotopes in the product or material at the time of transfer to persons exempt from licensing, will be held in storage for physical decay until such time as they no longer exceed the specified concentration.

C. Information Required by 10 CFR 32.11

1. Paragraph 32.11(a)

By their nature and intrinsic value, gemstones require high levels of security. All gemstones are handled in specified areas that are kept under locked with access restricted to persons authorized and responsible for their surveillance and control. Facilities have alarm systems and are protected against unauthorized access.

All activities are conducted under the oversight of the facility Radiation Safety Officer. The RSO will maintain a list of specific individuals authorized to handle electron-irradiated gemstones, which will be limited to those persons (a) for whom background investigations have shown to be trustworthy and reliable, and (b) who have completed, as a minimum Basic Radiation Safety training, which is a part of the overall training program for the irradiator facilities operated by Sterigenics.

Self-study, video, or computer-based training may be used for all or part of the Basic course, which is approximately 8 to 16 hours on radiation protection practices. The training would address the following topics:

1. Atomic structure
2. Types of radiation
3. Interaction of radiation with matter
4. Radiation units
5. Biological effects
6. Legal limits on radiation exposure
7. Radiation signs, labels, warning lights, and alarms
8. Detection instruments
9. Personnel monitoring badges
10. Protection methods
11. Emergency procedures
12. Overview of irradiator operation

2. Paragraph 32.11(b)

Procedure for evaluating induced radioactivity

1. Gemstones are treated with an electron accelerator. No neutron-irradiated gemstones are handled by the facility.
2. Immediately following irradiation, gemstones are moved into a shielded storage vault, where they remain until the dose rate is low enough to allow safe handling, typically less than 2 mR/h (20 μ Sv/h).
3. After irradiated gemstones have reached low enough radiation levels for safe handling, they are moved into the post-irradiation treatment laboratory, where heating, color grading, packaging, and invoicing are performed.
4. After packaging, the radiation level from the gemstones is measured with a ratemeter coupled to a pancake GM detector.

A. Electron-Irradiated Topaz

- (1) If the electron-irradiated topaz package is 500 g or larger, the ratemeter provides adequate detection levels to verify that radionuclides in excess of the exempt concentration limit are not present (see attached technical justification).
- (2) If the radiation levels on electron-irradiated topaz are less than or equal to twice the background level for the measurement procedure, the level of induced radioactivity in the gemstones is less than the exempt concentration levels. The gemstones are suitable for unrestricted release.
- (3) If the radiation levels on the gemstones are greater than twice the background level for the measurement procedure, the level of induced radioactivity in the gemstones is greater than the exempt concentration levels. The gemstones must continue to be stored at the facility until radiation levels have reduced to less than the action level defined above.

B. Other Electron-Irradiated Gemstones

- (1) If, based on previous analyses, none of the radionuclides listed in subpart (4) below are expected to be present in the electron-irradiated gemstones, and if the electron-irradiated topaz package is 500 g or larger, the ratemeter provides adequate detection levels to verify that radionuclides in excess of the exempt concentration limit are not present.
- (2) If the radiation levels on electron-irradiated gemstones are less than or

equal to twice the background level for the measurement procedure, the level of induced radioactivity in the gemstones is less than the exempt concentration levels. The gemstones are suitable for unrestricted release.

- (3) If the radiation levels on the gemstones are greater than twice the background level for the measurement procedure, the level of induced radioactivity in the gemstones is greater than the exempt concentration levels. The gemstones must continue to be stored at the facility until radiation levels have reduced to less than the action level defined above.
 - (4) If the radionuclides ^{22}Na , ^{77}As , ^{85}Sr , ^{134}Cs , ^{133}Ba , or ^{141}Ce are expected to be present, a gamma spectroscopy analysis will be used to determine whether these radionuclides are present in the sample. If none are identified, the pancake GM survey is adequate to detect all other expected species at the exempt concentration level and can be used as justification for release of the gemstones. If any are identified, gamma spectroscopic analysis will be used to determine whether these radionuclides are present at concentrations greater than exempt concentration. These gemstones may not be released until it has been shown that residual activity of any of these species is less than the exempt concentration.
5. The estimated time interval between completion of irradiation and transfer to unlicensed person is approximately 5 days under routine, optimum operating conditions. In the event that induced activity in excess of the defined exempt concentration levels is found, the gemstones will be retained until the radioactivity has decayed to levels that are below the exempt concentrations. For electron-irradiated gemstones, most activity has decayed in less than one week, although certain species may retain residual activity in excess of the exempt concentration for longer periods.

Technical Justification

From a review of available literature¹, several radioisotopes were identified that may be present in irradiated gemstones. From these, the gamma dose rate expected from an exempt concentration² of the radioisotope was calculated, assuming package dimensions 2 centimeters tall and 13.6 centimeters each of two sides, with the dose rate being determined at a distance of 2.5 centimeters.

¹ S. Schneider, et. al., *Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials*, NUREG-1717 (June 2001)

K. Nelson, J. W. Baum, *Health Risk Assessment of Irradiated Topaz*, NUREG/CR-5883, BNL-NUREG-52330 (January 1993)

Charles E. Ashbaugh III, "Gemstone Irradiation and Radioactivity," *Gems & Gemology*, Winter 1988

Charles E. Ashbaugh III, "Gamma-Ray Spectroscopy to measure Radioactivity in Gemstones," *Gems & Gemology*, Summer 1992

² 10 CFR §30.70 Schedule A--Exempt Concentrations

The estimated dose rates were calculated using point kernel methods for this geometry, assuming the density of gemstones to be 2.2 g/cm³ and a packing efficiency of 70% (i.e., 30% air space between stones, cumulative through the volume). These values are all presented on Table 1.

Table 1. Estimated Dose Rates at Exempt Concentrations

Z	Element	Isotope	T _{1/2}	Dose Rate (mrem/h)
9	F	18	h	3.68E-01
11	Na	22	2.6 y	9.48E-05
11	Na	24	14.96 h	2.89E-01
21	Sc	46	83.79 d	3.44E-02
24	Cr	51	27.7 d	2.90E-02
25	Mn	54	7,495 h	3.69E-02
26	Fe	59	44.5 d	2.96E-02
27	Co	58	2.95 h	4.35E-02
27	Co	60	1,925. d	5.14E-02
29	Cu	64	12.7 h	2.62E-02
30	Zn	65	244.26 d	2.45E-02
31	Ga	68	67.6 m	4.39E-02
31	Ga	72	14.1 h	4.16E-02
33	As	77	38.8 h	3.13E-04
38	Sr	85	64.8 d	2.37E-03
40	Zr	95	64 d	1.98E-02
41	Nb	95	34.98 d	3.42E-02
50	Sn	113	115.1 d	1.25E-02
51	Sb	124	60.2 d	1.49E-02
51	Sb	125	2.8 y	2.03E-02
55	Cs	134	2.06 y	6.31E-03
56	Ba	133	10.5 y	1.89E-05
58	Ce	141	32.5 d	3.03E-03
63	Eu	152	13.5 y	2.89E-02
73	Ta	182	114.4 d	1.95E-02
77	Ir	192	73.8 d	1.51E-02

The ability to detect the exempt concentration levels was evaluated against the manufacturer's specifications for the palmRAD 907³, incorporating the reported efficiency for gamma and beta detection. Based on operational experience with this particular meter at various locations (i.e., different background levels), the average background count rate in routine use is approximately 0.007 to 0.01 mR/h.

In electron-irradiated topaz, the most radionuclides expected are ¹⁸F, ⁶⁴Cu, ⁶⁵Zn, and ⁶⁸Ga, according to NUREG/CR-5883. Based on the calculations presented in

³ Datasheet for palmRAD 907, Berkeley Nucleonics, 2008, www.berkeleynucleonics.com

Table 1, each of these radionuclides, if present at the exempt concentration level, would result in a measured dose rate more than twice the background level as measured with this meter. For electron-irradiated topaz, where the induced radioactivity within a single batch would be expected to be essentially uniform based on the necessity of color development occurring in all stones within the batch, measurement of a 500 g sample with the pancake GM detector is adequate to determine if the expected radionuclides are present at levels in excess of the exempt concentration.

For other radionuclides, the species that would result in a dose rate less than background on the survey meter if present in the configuration as described above are ^{22}Na , ^{77}As , ^{85}Sr , ^{134}Cs , ^{133}Ba , and ^{141}Ce . Available literature is not clear on whether these radionuclides would be expected in electron-irradiated gemstones, but have been identified only with neutron irradiation of beryl. However, for conservatism, if there is an expectation that these radionuclides might be present, a gamma spectroscopic analysis will be performed to determine if the species are present. If they are not, the pancake GM survey meter would be adequate to detect all other radionuclides present at the exempt concentration level.

3. Paragraph 32.11(c)

Concentrations of byproduct material at time of transfer will not exceed the concentrations in 10 CFR 30.70, Schedule A.

Reconcentration of the byproduct material in concentrations exceeding those specified in 10 CFR 30.70 is not likely, as only electron-irradiated gemstones are handled by the company, with any induced radioactivity having decayed to less than the exempt concentration levels prior to release.

**Attachment A Radioactive Material Possession License for
Sterigenics, San Diego, California**

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	Sterigenics International, Inc.	3. License Number	6510-37	Amendment Number: 6
2. Address	7695 Formula Place San Diego, CA 92121-2418	4. Expiration date	January 13, 2009	(3)
Attention:	Carl Andrew Zinn Radiation Safety Officer	5. Inspection agency	San Diego County Department of Environmental Health	

License Number 6510-37 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Any radionuclide except alpha emitters	A. Solid components of activated materials	A. Total not to exceed 1 curie.
B. Phosphorus-32	B. Solid (in vascular brachytherapy devices)	B. Total not to exceed 12 curies.
C. Any radionuclide except alpha emitters	C. Solid components of activated materials	C. Total not to exceed 100 microcuries.

9. Authorized Use

- A. To be used incidental to the handling and processing of irradiated gem stones.
- B. To be used for possession incidental to irradiation of vascular brachytherapy devices containing Phosphorus-32.
- C. To be used incidental to machining of LINAC equipment.

LICENSE CONDITIONS

- 10. Radioactive material shall be used only at the following locations:
 - (a) 7695 Formula Place, San Diego, CA.
- 11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.
- 12. Radioactive material may be used only by individuals who have successfully completed the training program described in Condition 13. Records of such training shall be maintained for Department inspection.
- 13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

RADIOACTIVE MATERIAL LICENSE

License Number: 6510-37Amendment Number: 6

- (a) The application dated April 9, 1998, signed by Mark A. Smith; as modified by the letter dated July 8, 1998, signed by Mark A. Smith; the letters dated October 26, 1998, with attachments and December 2, 1998, both signed by Roswell Pund, Radiation Safety Officer.
- (b) The letter dated December 11, 2000, signed by Mark A. Smith, CHP, regarding the new ownership and consequent name change of this company.
- (c) The letter with attachments, dated November 19, 2001, modified by the letter dated November 19, 2002, both signed by Roswell Pund, regarding new floor plan, instrumentation update and replacing film badge with OSL badge.
- (d) The letter dated May 4, 2004, signed by Mark A. Smith, CHP, and the letter dated July 21, 2004, with attachments signed by Mark A. Smith, CHP, regarding change in ownership and name.
14. (a) The Radiation Safety Officer in this program shall be Carl Andrew Zinn.
- (b) The Alternate Radiation Safety Officer in this program shall be Bert Whitt.

Prepared By: <i>Bonnie Bessemer</i>	Reviewed By: <i>Rene Obear</i>	Issued For the Department of Health Services By: <i>Stephen Hsu</i>
Printed Name: Bonnie Bessemer	Printed Name: Rene Obear	Printed Name: Gary W. Butner
Date: <i>8/17/04</i>		Radiologic Health Branch MS 7610, PO Box 997414 Sacramento, CA 95899-7414

Attachment B Sample Confirmation Letter



Confirmation Letter

Date: _____

Ref. P.O. :

To: _____

Company: _____

Fax: _____

Thank you for order to process gemstones. Please verify the following information. If acceptable, please denote your approval by signing below and FAX to Sterigenics (Thailand) Ltd. at (66 38) 954-281. We will process your order after we receive this approval.

Customer Total weight: _____ carats, Sterigenics received: _____ carats, Discrepancy: 0carats

Work Order Number#	Weight (cts)	Overage (cts) ¹	KiloGrays (kGy)	Process Type (s)	Need date ²	Process Charge (Baht/CT)	Shipping Charge	Other ³	Total Charge (Baht)

Note: Total processing charge is _____ Baht. This price excludes VAT7%.

- 1 Overage will be returned unprocessed.
- 2 *Sterigenics (Thailand) Ltd. does not guarantee return ship time.*
- 3 Other charges.

Acceptable payment methods:

- ✓ Cashier's check
- ✓ Wire transfer (*subject to bank clearance*)
- ✓ Company check (*subject to bank clearance*)
- ✓ Cash on delivery (COD)
- ✓ Other: _____

If you have any questions, please call Ampai Atirotpunya, Wilaiporn Khaojam at (66 38) 954-279, ext. 26 or Bangkok Office at 02-637-8132.

Non-returned Confirmation letter within 7 days will assume that you accept our conditions

Prepared by: _____

Date: _____

I understand that Sterigenics (Thailand) Ltd. must receive full payment for the run in the method noted above before it may be return shipped to me. Furthermore, I accept all other Sterigenics conditions for gemstone processing (Refer to gemstone processing agreement).

Approved: _____

Date: _____

Attachment C Example Process Control Report

E-Beam Gemstone Process Control Report

E-BEAM SHIPMENT INFORMATION

WO Number _____

Date and Time Received at Control Room: ____/____/____ : ____

Received By: _____

Sent By: _____

Weight (Carats)	Tray # _____	Tray # _____
Net		
Gross		

Total Dose Required: _____ kGy @ _____ kGy/min.

SPECIAL INSTRUCTIONS

Activated Stone: ☐ Yes ☐ NoFlip: ☐ Yes @ _____ % ☐ No

Are there special instructions included with shipment?

Yes / No

If yes describe: _____

SIDE 1: Required Dose: _____ kGy

Run Start: Date: ____/____/____ Time: ____:____ By: _____

Run End: Date: ____/____/____ Time: ____:____ By: _____

Elapsed Cycle Time: _____ minutes Dose Received: _____ kGy

SIDE 2: Required Dose: _____ kGy

Run Start: Date: ____/____/____ Time: ____:____ By: _____

Run End: Date: ____/____/____ Time: ____:____ By: _____

Elapsed Cycle Time: _____ minutes Dose Received: _____ kGy

Total Dose Received: _____ kGy**Transferred to Hot Storage**

Radiation Level: _____ Date: ____/____/____ Time: ____:____ By: _____

Operator Comments: _____

Transferred from Hot Storage to Gem Lab

Radiation Level: _____ Date: ____/____/____ Time: ____:____

Sent By: _____ Received By: _____

Gem Lab Shipment Released☐ Heat ☐ No Heat☐ Less than double background

Date: ____/____/____ By: _____

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