NRC FORM 464 Part I
(12-2015)

U.S. NUCLEAR REGULATORY COMMISSION

# RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

| FOIA | RESPONSE NUMBER |
|---|---|
| 2017-0109 | 1 |

RESPONSE TYPE ☐ INTERIM ☑ FINAL

| REQUESTER: | DATE: |
|---|---|
| Joem Meissner | NOV 16 2016 |

**DESCRIPTION OF REQUESTED RECORDS:**

Application data May 27, 2008 (ML081610729) with all appendices; Letter dated September 18, 2008 (ML082820164)

## PART I. -- INFORMATION RELEASED

☐ Agency records subject to the request are already available in public ADAMS or on microfiche in the NRC Public Document Room.

☑ Agency records subject to the request are enclosed.

☐ Records subject to the request that contain information originated by or of interest to another Federal agency have been referred to that agency (see comments section) for a disclosure determination and direct response to you.

☐ We are continuing to process your request.

☑ See Comments.

## PART I.A -- FEES

AMOUNT*
$ ____
*See Comments for details

☐ You will be billed by NRC for the amount listed.

☑ None. Minimum fee threshold not met.

☐ You will receive a refund for the amount listed.

☐ Fees waived.

## PART I.B -- INFORMATION NOT LOCATED OR WITHHELD FROM DISCLOSURE

☐ We did not locate any agency records responsive to your request. *Note*: Agencies may treat three discrete categories of law enforcement and national security records as not subject to the FOIA ("exclusions"). 5 U.S.C. 552(c). This is a standard notification given to all requesters; it should not be taken to mean that any excluded records do, or do not, exist.

☐ We have withheld certain information pursuant to the FOIA exemptions described, and for the reasons stated, in Part II.

☐ Because this is an interim response to your request, you may not appeal at this time. We will notify you of your right to appeal any of the responses we have issued in response to your request when we issue our final determination.

☐ You may appeal this final determination within 30 calendar days of the date of this response by sending a letter or email to the FOIA Officer, at U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or FOIA.Resource@nrc.gov. Please be sure to include on your letter or email that it is a "FOIA Appeal."

## PART I.C COMMENTS ( Use attached Comments continuation page if required)

In conformance with the FOIA Improvement Act of 2016, the NRC is informing you that you have the right to seek assistance from the NRC's FOIA Public Liaison.

ADAMS Accession Number ML082820164 is identified as Sterigenics letter dated September 18, 2008.
ADAMS Accession Number ML081610729 is identified as Sterigenics letter dated May 27, 2008.

**SIGNATURE - FREEDOM OF INFORMATION ACT OFFICER**

*Nina Argent, Acting FOIA Officer* Nina Argent

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

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

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.

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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.

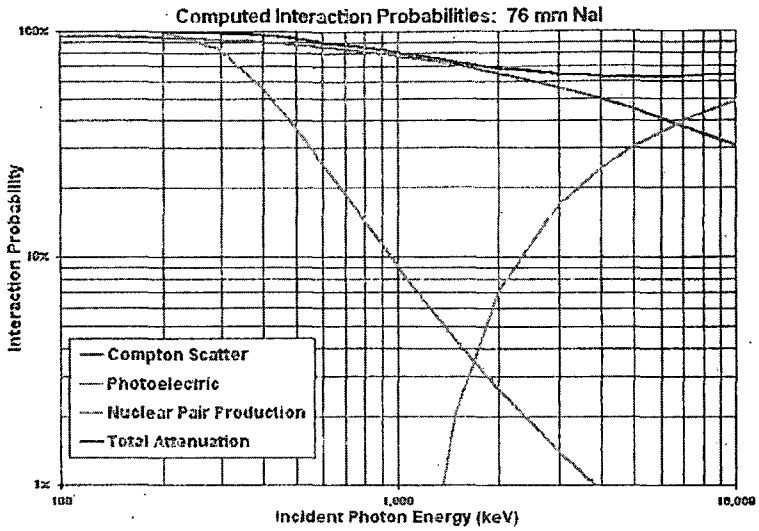
**B.2.d**. - The release criterion of twice background was established in the now-terminated California radioactive materials license issued to IRT Corporation at the address in San Diego shown in this application for release of electron irradiated gemstones.

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,

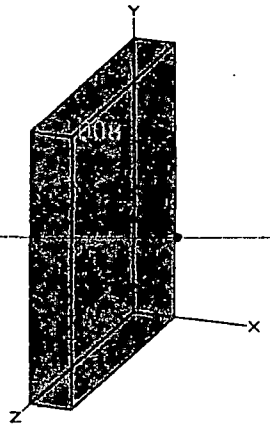
Mark A. Smith, CHP
Vice-President, Radiation Services

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

Page : 1
DOS File : STONES.MS5
Run Date: September 18, 2008
Run Time: 10:06:08 AM
Duration : 00:00:00

File Ref: _____
Date: _____
By: _____
Checked: _____

**Case Title: Case 1**
**Description: Case 1**
**Geometry: 13 - Rectangular Volume**




**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 | 6.53 cm | 6.53 cm |
| | 1.8 in | 2.6 in | 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 |

Sterigenics.

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 you 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

022688

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION
(10-2002)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

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.

# APPLICATION FOR MATERIAL LICENSE

**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

ICODE 31005

**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)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] 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

See attached

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mark A. Smith

TELEPHONE NUMBER
704-587-8914

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maiximum 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)*
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 CONTANED 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 | SIGNATURE | DATE |
|---|---|---|
| Mark A. Smith, Vice-President, Radiation Services | Mark A. Smith | May 27, 2008 |

**FOR NRC USE ONLY**

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|---|---|---|---|---|---|
| | | | $ | | |
| APPROVED BY | | | | DATE | |

NRC FORM 313 (10-2002) PRINTED ON RECYCLED PAPER

022688

## TABLE OF CONTENTS

## 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 μSv/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 literature[1], several radioisotopes were identified that may be present in irradiated gemstones. From these, the gamma dose rate expected from an exempt concentration[2] 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/cm$^3$ 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 907[3], 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 $^{18}$F, $^{64}$Cu, $^{65}$Zn, and $^{68}$Ga, 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<br>San Diego, CA 92121-2418 | 4. *Expiration date* January 13, 2009 | (3) |
| *Attention:* | Carl Andrew Zinn<br>Radiation Safety Officer | 5. *Inspection agency* | San Diego County<br>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: 6510-37

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

# Attachment B Sample Confirmation Letter

Sterigenics.

# 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: _____



Issue Date: July 27, 2000

# Attachment C Example Process Control Report

*Sterigenics*

# 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 ☐ No

Flip: ☐ 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: _____

022688

NWMI
NORTHWEST MEDICAL ISOTOPES

September
NWMI-LTR-2

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
11555 Rockville Pike
Washington. DC 20555

Mr. David Drucker. Senior Project Manager
Division of License Renewal
Office of Nuclear Reactor Regulation

**RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information (Letter June 16, 2016) – Additional Clarification on POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1**

**References:**

1. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2016-007 to U.S. Nuclear Regulatc Commission, dated July 18, 2016, Docket No. 50-609, Responses to Request for Addition Information dated June 16, 2016 (ADAMS Accession No. ML16210A305)
2. U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated Ju 2016, Docket No. 50-609, Request for Additional Information for the Environmental Revi the Northwest Medical Isotopes, LLC Construction Permit Application (ADAMS Accessi ML16176A114) (TAC Nos. MF6134 and MF 6135)
3. Northwest Medical Isotopes, LLC Letter NWMI-LTR-20 15-006 to U.S. Nuclear Regulat Commission, dated July 20, 2015 *NRC Project No. 0803 - Northwest Medical Isotopes, Li Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility* (ADAMS Accession No. ML16056A122)
4. Northwest Medical Isotopes, LLC Letter to U.S. Nuclear Regulatory Commission, dated February 5, 2015 (ADAMS Accession No. ML14349A501) *Environmental Report and Associated Part One Submittal* (ADAMS Accession Nos. ML14349A501, ML15210A12: ML15210A128, ML15210A129, and ML15210A131)

Dear Mr. Drucker:

Northwest Medical Isotopes, LLC (NWMI) is providing additional clarification on POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1 and to the response to the U.S. Nuclea Regulatory Commission request for additional information (RAI) dated June 16, 2016. These clarifications are provided in Attachment 1. NWMI submitted their original response the above referenced RAIs on July 25, 2016.

NWMI is submitting these clarifications to the NRC in accordance with 10 CFR 50.30(b), "Oath c Affirmation," and 10 CFR 50.4, "Written Communications."

Northwest Medical Isotopes, LLC | 815 NW 9th Ave, Suite 256 | Corvallis, OR 97330

I solemnly declare and affirm that the foregoing information is true and correct under the penalty o perjury.

Executed on September 1, 2016.

If you have questions, I can be reached at (509) 430-6921 or carolyn.haass@nwmedicalisotopes.c

Sincerely,

Carolyn C. Haass

Carolyn C. Haass
Chief Operating Officer

Enclosures: Attachment 1

cc: Mr. Michael Balazik
Research and Test Reactors Branch A
Office of Nuclear Reactor Regulation

Mr. Alexander Adams
Research and Test Reactors Branch A
Office of Nuclear Reactor Regulation

NWMI
NORTHWEST MEDICAL ISOTOPES

**ATTACHMENT 1**

**Northwest Medical Isotopes, LLC**
**Response to the U.S. Nuclear Regulatory Commission**
**Request for Additional Information**
**Regarding Chapters 4, 13, and 19 of the**
**Preliminary Safety Analysis Report and Environmental Review of the**
**Northwest Medical Isotopes, LLC**
**Construction Permit Application Docket No. 50-609**

**Clarification to July 25, 2016 Submission on Request for Additional Informatio**
**POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1**

NWMI
NORTHWEST MEDICAL ISOTOPES

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**Clarification Response to POSA3-1A**: Northwest Medical Isotopes, LLC (NWMI) is continuing tc chemical release accidents and will establish preventative or mitigative controls for chemical release with U.S. Nuclear Regulatory Commission (NRC)-licensed material or for chemical accidents that ir processing of licensed radioactive material with high consequences for workers, members of the pub the environment (as determined by the criteria in 10 CFR 70.61, "Performance Requirements"). The controls identified in NWMI's Construction Permit Application, Chapter 13.0, "Accident Analysis," other controls that NWMI may develop, will either reduce the accident likelihood to highly unlikely the accident consequences to be intermediate or low consequences.

**Clarification Response to POSA3-1B**: NWMI is continuing to evaluate chemical release accidents establish preventative or mitigative controls for chemical release accidents with NRC-licensed mater chemical accidents that involve processing of licensed radioactive material with intermediate conseq workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70 set of controls set of controls identified in NWMI's Construction Permit Application, Chapter 13.0, a other controls that NWMI may develop, will either reduce the accident likelihood to unlikely or redu accident consequences to be low consequences.

**Clarification Response to POSA3-2A:** NWMI is continuing to evaluate radiological accidents and establish preventative or mitigative controls for radiological accidents with high consequences for w members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). The controls identified in NWMI's Construction Permit Application, Chapter 13.0, will either reduce the likelihood to highly unlikely or reduce the accident consequences to be intermediate or low consequ

**Clarification Response to POSA3-3A:** Clarification to this response was discussed at the non-publ

of a meeting held between NWMI and the NRC on August 11, 2016. In summary, the Radioisotope Facility (RPF) bounding radiological source term is based on the number of low-enriched uranium (L targets irradiated at the nearby research reactor (MURR). Each irradiated MURR LEU target has no four times the radioactivity of an irradiated OSTR (or the hypothetical third reactor) LEU target. Ev LEU targets from both MURR and OSTR (or the hypothetical third reactor) were both processed in a week, the OSTR (or hypothetical third reactor) LEU target would dilute the radiological source term RPF.

**Clarification Response to NOI3-1B:** The nearest resident used in noise modeling is nearest to both Highway 63 and to the proposed RPF. The approximate distance to the residence from U.S. Highwa 85.3 meters (m) [280 feet (ft)], and the distance to the proposed RPF site is 792.5 m (2,600 ft). The receptor used in the noise model is 85.3 m (280 ft).

**Clarification Response to PA3-1:** Off-specification uranium can be generated during target fabrica target fabrication system. The off-specification uranium is anticipated to be generated intermittently. general approach to deal with off specification uranium is for it to be recycled and processed into fre target material. The exception is if the uranium is not suitable for LEU target material production (e. enrichment is too low). Any LEU material with low enrichment will be stabilized, packaged for secu storage, and then returned to DOE per the Uranium Lease and Take-Back contract.

For the RPF preliminary design, the off-specification uranium operations will be sized to accommod 25 percent of the total throughput. An allowance has been made in the mass balance for the generatic off-specification uranium. There are three potential areas in the target fabrication system that off-spe uranium may be recovered including:

- Uranium that has been irradiated, recovered during irradiated target processing, and recycled LEU target material may eventually be unacceptable for continued $^{99}$Mo production due to th of $^{235}$U and buildup of unwanted uranium isotopes. This material, which is recovered as ura will be converted into a stable form for disposition, packaged for secured storage, and return

- If uranium is identified as being off-specification due to the presence of chemical impurities, material will be recycled to the uranium recycle system within the hot cells. The purified ur will then be recycled to the target fabrication process.
- If LEU target material is identified as being off-specification after being produced (e.g., doe process requirements), the material will be recycled to the uranium dissolution step in the tar fabrication system.