



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

August 03, 2010

Sterigenics International, Inc.
Attn: Mark A. Smith
Vice President, Radiation Services
10811 Withers Cove Park Drive
Charlotte, NC 28278

Mail Control No. 022825

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Smith:

This refers to your correspondence, dated January 19, 2010, offering clarification of the relationship between Sterigencis domestic entities and the company's facility in Thailand and your responses dated June 7, 2010 and July 13, 2010 to our Requests For Additional Information.

We do not have sufficient information to complete the review of your amendment request. Upon consideration of the response provided in your letter of July 3, 2010, clarification on your Quality Assurance (QA) program is necessary. The previously submitted QA procedures do not fully describe the QA program required of importers. If your response makes reference to previously submitted information, please be certain the information requested below can be discerned.

Please respond to the following QA program elements:

1. Describe the radiation detection equipment used to analyze (identify and quantify) gemstones.
2. Describe the calibration frequency, testing, and standards applied to the radiation detection equipment used in gemstone analysis.
3. Provide a description of your counting procedures that includes:
 - a. Sample selection
 - b. Maximum and minimum sample size (# stones and mass)
 - c. Counting efficiency
 - d. Counting geometry
 - e. Time delay from completion of irradiation to transfer to unlicensed persons
 - f. Statistical methods for analyzing data
 - g. Procedure for minimizing false negatives
 - h. Sample calculation
 - i. Assurance your procedures are adequate to identify all induced radionuclides
 - j. Assurance gems are analyzed to ensure that concentrations in 10 CFR 30.70 are not exceeded.
 - k. Assurance that if the activity is not quantitatively measured in each gem individually, there is only 1 chance in a 1,000 that an outlier gem will contain more than twice the appropriate 10 CFR 30.70 maximum value (for single or multiple radionuclides).

Please respond to our letter at your earliest convenience. Upon receipt of the requested information on your QA program, we will resume our review. As stated in our May 12, 2010 correspondence, the NRC did not evaluate and subsequently authorize your intention of using the Thailand facility for the irradiation and exempt distribution of gemstones. Therefore, this additional authorization needs to be added to your license in order to distribute irradiated gemstones from Thailand.

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

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

If you have any questions, please feel free to contact Lisa Dimmick at (301) 415-0694 or electronic mail: lisa.dimmick@nrc.gov.

Sincerely,
/RA/
Shirley Xu,
State Agreements & Industrial Safety Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Please respond to our letter at your earliest convenience. Upon receipt of the requested information on your QA program, we will resume our review. As stated in our May 12, 2010 correspondence, the NRC did not evaluate and subsequently authorize your intention of using the Thailand facility for the irradiation and exempt distribution of gemstones. Therefore, this additional authorization needs to be added to your license in order to distribute irradiated gemstones from Thailand.

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

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

If you have any questions, please feel free to contact Lisa Dimmick at (301) 415-0694 or electronic mail: lisa.dimmick@nrc.gov.

Sincerely,
/RA/
Shirley Xu,
State Agreements & Industrial Safety Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-37764

DISTRIBUTION: CSeelig MMoriarty LEusebio Region I/DNMS/LAS Region IV/DNMS/LAS
ML

OFC	FSME/MSSA/LB		FSME/MSSA/LB				
NAME	LDimmick		SXu				
DATE	8/3/2010		8/3/2010				

OFFICIAL RECORD COPY