



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

May 12, 2010

Docket No. 030-37764
Mail Control: 022825

License No. 32-31005-01E

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

SUBJECT: STERIGENICS INTERNATIONAL, INC.. LICENSE AMENDMENT, REQUEST
FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 022825

Dear Mr. Smith:

This refers to your correspondence, dated January 19, 2010, offering clarification of the relationship between Sterigenics domestic entities and the company's facility in Thailand. The correspondence further describes that the Sterigenics San Diego facility will act as the domestic agent for Sterigenics Thailand. The correspondence did not specifically request an amendment to your license. However, given the nature of the correspondence, the NRC will treat the letter as an amendment request for licensing action.

During the review of your initial license application for the exempt distribution of irradiated gemstones, 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. To proceed with the licensing action, additional information is requested.

To complete the review of the stated relationship and delineation of responsibilities between San Diego and Thailand and assurance that requirements under 10.CFR 30.70, 32.11, 32.12 and 110.53 are being met, we ask that you submit the following:

1. Provide a complete description of the business between Sterigenics in San Diego and Sterigenics in Thailand. Please comment on the ownership, management, business scope, organizational structure for San Diego and Thailand and the relationship between the two organizations.
2. Information under 10 CFR 32.11(a) requires that general requirements of 10 CFR 30.33 be satisfied. Identify by name the individuals in Thailand who will be responsible for handling, irradiation, storing, counting, evaluating and controlling the release of irradiated gems.

M. Smith

Correlate the individual names with their responsibilities and describe their training and experience.

3. Information under 10 CFR 32.11(b) requires information about the product be submitted. Please describe the methods to assure that no more than the specified maximum concentration is in the product at the time of transfer to persons exempt from licensing. Include the estimated time interval between irradiation and transfer.
4. Paragraph 10 CFR 32.11 (c) requires the applicant to provide reasonable assurance that concentrations of byproduct material at the time of transfer do not exceed concentrations in 10 CFR 30.70, Schedule A. As the importer agent for Sterigenics Thailand, how will you assure irradiated gemstones do not exceed exempt concentrations at the time of import? Please provide us with your methods of control and sampling frequency for imported gemstones.
5. Please describe the QA program for gemstone analysis in Thailand. Describe the equipment used to determine concentrations of byproduct material in irradiated gemstones. Describe the frequency, standards and procedures used to calibrate radiation detection equipment. Describe counting procedures and how counting measurements are converted to concentration values. Please describe how you assure the reliability of data. Specify who is responsible for the QA program.
6. Please describe the QA program (ie auditing, sampling) that Sterigenics in San Diego will implement to assure gemstones from Thailand are acceptable for exempt distribution in the United States.
7. Pursuant to 10 CFR 32.12 licensees must submit material transfer reports. Please confirm irradiated gemstone data distributed from the Thailand facility is included with the material transfer reports for gemstones distributed from the San Diego facility. Please clarify whether your Thailand facility has imported any irradiated gems to this country.
8. Based on your letter dated September 18, 2008, requesting to add your Denmark facility, please explain whether your Denmark facility will be used the same way as your Thailand facility. If so, questions No. 1 through 7 of this letter also apply to your Denmark facility.

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

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

M. Smith

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/

Shirely Xu, Health Physicist
License Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

M. Smith

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