Sterigenics

June 7, 2010

Shirley Xu, Health Physicist
License Branch
Division of Materials Safety and State Agreements
US Nuclear Regulatory Commission
Washington, DC 20555-0001

Reference: Sterigenics Exempt Distribution License 32-31005-01E
Docket No. 030-37764, Mail Control 022825

Dear Ms. Xu:

In response to your letter of May 12, 2010, the following addresses the questions raised.

1. The Sterigenics facilities in Thailand and San Diego are both owned and operated by the same company. The facilities are under separate legal entities, which is done for simplicity in local employment laws, purchasing and billing, and other administrative functions. Accounting functions are split between the two facilities, with the revenue and cost accounting for Thailand falling in the Europe, Middle East, Africa, and Asia (EMEAA) division, while San Diego is included in the North and South America division. For financial and operation reporting, both divisions are combined into a single report for the corporation as a whole.

   The only operational difference between the two facilities is in the reporting structure, where the Thailand facility reports to the Vice-President for Asia Operations and the San Diego facility reports through the Senior Vice-President for Operations in the Americas. Both of those individuals report to and are accountable to the same Chief Executive Officer, located in Oakbrook, Illinois. All corporate policies and procedures, including the Quality Assurance system are implemented identically at the two facilities.

   Some slight differences in the radiation safety procedures exist between the two facilities as a result of differences in the accelerator equipment being used at each. In addition, there is a gamma irradiator at the Thailand facility, which creates a different set of procedures that are not in existence in San Diego, where there is an accelerator-based irradiator only.

   For operations such as transferring gemstones to customers in the United States, accounting and distribution functions can be managed in the centralized Management Information System implemented at all Sterigenics facilities. For example, it is a relatively trivial matter to change accounting information so that operations conducted at one facility may be charged to customers through a second facility that serves essentially as a subcontractor to the first. This sort of action is routinely done in facilities around the company and would be the means envisioned for San Diego to act as an agent for Thailand in reporting and tracking gemstones sent into the US.

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2. There are two principal individuals in Thailand who will be managing gemstone distribution: Mr. William Trevithick and Ms. Ampai Atirotpunya.

   Mr. Trevithick in the facility General Manager and has ultimate responsibility for all operations at the facility. He has been in the gemstone irradiation business for decades, having previous handling and distribution experience at the San Diego facility when it was still under the former owner, IRT Corporation, which also held a distribution license for irradiated gemstones. His previous experience includes gemstone irradiation at the General Dynamics reactor in San Diego, as well as various techniques for measuring the radioactivity content of gemstones following irradiation. Within Sterigenics, he has completed training at the Radiation Safety Officer level, the highest that is available in the company's structured radiation safety training program.

   Ms. Atirotpunya holds a Master's Degree in Nuclear Technology Engineering from Chulalongkorn University in Thailand. She is the manager of the gemstone laboratory, which includes several processing steps in the gemstone treatment process (e.g., cleaning, sorting, weighing, etc.) as well as measurement of radioactivity prior to releasing the gemstones. Having been in this position for approximately four years, she has been instrumental in developing gamma spectroscopy procedures for gemstone measurement.

3. All of the information previously submitted for issuance of the distribution license applies to the Thailand facility as well as the San Diego facility. The protocols as described in the license application will be employed at both facilities.

4. The analytical protocols as described in the license application will be carried out at the Thailand facility. As such, the gemstones will be certified to be below exempt concentration levels prior to leaving the facility and prior being shipped to the United States. To fulfil the company's commitment to ensuring that gemstones with unacceptably high concentrations of gemstones are not released to the market, it is necessary for this analytical evaluation to be performed at the point of irradiation and before the gemstones leave the facility.

   All applicable documentation for the process, including the quantity and type of gemstones and the gamma spectroscopic analysis, will be available for review in San Diego through the company management information system that is the same at all company facilities. As such, the company will certifying gemstone activity concentrations based on the analysis conducted in Thailand for each gemstone lot being released. There will not be any subsequent confirmatory measurements conducted by the San Diego facility.

5. All of the information previously submitted for issuance of the distribution license applies to the Thailand facility as well as the San Diego facility. The protocols as described in the license application will be employed at both facilities.

6. As discussed above, there are no plans for a confirmatory measurement program in San Diego, as the procedures for releasing gemstones and certifying that their concentration

is below exempt quantities that have been approved in the existing license will be conducted in the Thailand facility. Periodic audits of the gemstone distribution process, which may include confirmatory measurements, will be conducted at both locations by the corporate Radiation Services organization.

7. The material transfer reports will be submitted to include gemstones irradiated in both San Diego and Thailand. At this time, the Thailand facility is not importing irradiated gemstones into the United States.

8. There are no business plans for the Denmark facility to distribute gemstones into the United States. As such, it should not be included in the license.

Should you require further information, please let me know.

Sincerely,

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

cc: W. Trevithick
P. Baker