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Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials

Comment On: NRC-2015-0109-0001
Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material; Request for Comment

Document: NRC-2015-0109-DRAFT-0003
Comment on FR Doc # 2016-05260

Submitter Information

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Name: Kathleen Hoffman

General Comment

(1)

See attached file(s)

Attachments

Sterigenics Comments-Docket NRC-2015-0109

SUNSI Review Complete
Template = ADM – 013
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Add= K. Smith (GES)

Sterigenics.

April 25, 2016

Via Electronic Submittal to Docket ID NRC-2015-0109

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Comments on the Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material (Docket ID No. NRC-2015-0109)

Dear Ms. Bladey:

Sterigenics International LLC ("Sterigenics") appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission (NRC) security regulatory requirements contained in 10 CFR part 37 and its guidance documents.

Sterigenics is one of the world's largest contract sterilization companies. We have 47 global contract sterilization facilities and utilize four different types of sterilization technologies to treat medical and food products. These technologies include ethylene oxide processing, cobalt gamma radiation, electron-beam radiation, and x-ray radiation. With our cobalt gamma radiation technology, we sterilize medical device and pharmaceutical products as well as reduce the bioburden on spice and other food products. Some of the medical device and pharmaceutical products that we treat with gamma radiation can only be sterilized with gamma radiation processing. Switching to an alternate sterilization technology could compromise the product's integrity or sterility assurance. Gamma radiation sterilization plays a critical role in protecting public health with the safe and efficient delivery of sterile medical devices and pharmaceutical products to the medical community.

First, we would like to express our sincere appreciation for the efforts that the NRC has put into the Part 37 regulatory process. We think it has gone a long way to properly secure the transportation and use of radioactive materials.

Next, we would like to submit comments on the overall effectiveness and clarity of the NRC requirements for security measures to product category 1 and category 2 sources of radioactive materials as requested. Following are some comments on the regulatory requirements contained in 10 CFR part 37:

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- Having multiple Orders was somewhat confusing for licensees. Although the new Part 37 regulation is extremely comprehensive and challenging to wade through, the new regulations justifiably codify the previous Orders. The regulations cover a multitude of topics ranging from Background Investigations, Best Security Practices, Access Authorization, Physical Protection, Protection in Transit, Recordkeeping, etc. Some areas seem to be non-definitive and open to personal interpretation (i.e. the applicable requirement for "continuous physical barriers").
- The Personnel Background Investigation process required under the new regulation is extremely comprehensive and requires extensive training for the "Reviewing Officials" to ensure compliance is being met.
- The new requirement for personnel background investigations to be re-conducted every ten years is probably warranted, but adds another regulatory compliance burden to the licensees.
- Without an industry standard, the implementation of a detection system capable of detecting unauthorized removal of material from the security zones has been expensive, and very complex to coordinate and implement. Overall, however, this has been a good upgrade to overall security.
- The requirement for each licensee to coordinate an annual meeting with the LLEA is justified given the potential threats that exist in transporting, storing and using Category 1 radioactive materials. Improving routine communications between the licensee and the LLEA is a simple defense tactic that most licensees can easily implement into their security program.
- The conversion to "Official Use Only" security related documentation has been a welcomed improvement for licensees. The "Official Use Only" designation of security related documentation will improve communications between authorized staff members while retaining an appropriate level of security for information that must be conveyed to personnel.

Following are some comments on the usefulness of the guidance documents for 10 CFR Part 37:

- NUREG 2155 (Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material") was found to be most informative and useful for breaking down each regulation by specific subsection. Terminology definitions and a brief explanation of each Rule are provided, with specific Q&A's covering the Rule and the application to various types of licensees.
- NUREG 2166 (Physical Security Best Practices for the Protection of Risk Significant Radioactive Material) was found to be an extremely useful document for providing guidance in developing the facility specific Security Plan required under the regulation. The document is easy to understand, provides "best practices" for regulatory compliance and is categorized for

applicability to the various types of licenses. It was extremely helpful for licensees to better improve their facility security program.

Sterigenics appreciates the opportunity to comment on the regulatory requirements in 10 CFR Part 37. If you have any questions or require additional information, please do not hesitate to contact me at (630) 928-1758 or by e-mail at khoffman@sterigenics.com.

Sincerely,

KAHoffman

Kathleen A. Hoffman
Senior Vice President, Global Environmental, Health & Safety