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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-0004

Comment on FR Doc # 2016-05260

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RULES AND DIRECTIVES
 SEARCH

General Comment

See attached file(s)

Attachments

comment to 10 CFR part 37

SUNSI Review Complete

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Add= *lf. Smith (ges)*



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:

Becton Dickinson Co. 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.

BD uses multiple sterilization modalities to provide billions of safe effective medical devices world-wide. These technologies include ethylene oxide, cobalt gamma radiation, electron-beam radiation, and moist heat. Forty percent of these medical device and pharmaceutical products are sterilized with Co60, gamma radiation, many of which can only be sterilized with gamma radiation processing. Switching to an alternate sterilization technology could compromise the sterility of the product or compromise the functionality or integrity of the product. Gamma radiation sterilization plays a critical role in protecting public health with the safe and efficient delivery of sterile medical devices and pharmaceutical products.

The efforts that the NRC has put into the Part 37 regulatory process, has gone a long way to properly secure the transportation and use of radioactive materials. 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.

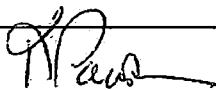
- The Personnel Background Investigation process, including the repeat of said investigation on a 10 year rotation, is extremely comprehensive and will result in additional burden to licensees as related to documentation, training, and implementation.
- Without an industry standard, the implementation of a detection system capable of detecting unauthorized removal of material can be very expensive, and very complex to coordinate and implement. BD would prefer to implement alternative security methods to increase the level of

access control. This could include biometrics or other modern security controls. Furthermore removal of significant quantities of source material would likely be detected during normal operations as the process is very tightly controlled to ensure correct dosage to each product family.

- BD agrees with requirement for each licensee to coordinate an annual meeting with the LLEA. Improving routine communications between the licensee and the LLEA will further enhance existing security programs.
- The "Official Use Only" security for documentation is a welcome improvement for licensees, allowing for appropriate level of security for information that must be conveyed to personnel.

Thank you again for 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 us according to the contact information below.

Regards,



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