

PUBLIC SUBMISSION

As of: 5/12/16 2:04 PM
Received: May 11, 2016
Status: Pending_Post
Tracking No. 1k0-8pkf-1asm
Comments Due: May 13, 2016
Submission Type: Web

Docket: NRC-2015-0109

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-0005

Comment on FR Doc # 2016-05260

Submitter Information

3/14/2016

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81FR 13263

General Comment

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Nordion (Canada) Inc. response to request for comment on 10 CFR part 37

Attachments

Comments to NRC on 10 CFR part 37

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Template = ADM - 013

E-RIDS= ADM-03

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May 11, 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,

We are pleased that the USNRC has provided licensees the opportunity to comment on the implementation of 10 CFR part 37 regulations. As a major exporter to the US and service provider of Category 1 and HRCQ sources, we are dedicated to implementing and maintaining a security program that provides for the safe and secure use of sealed sources. The sealed sources that Nordion ships and installs in the US-based production irradiators are used daily to ensure that medical equipment is sterilized to prevent unnecessary and dangerous infections in patients, food is irradiated to aid in improved food quality, distribution and selection nation-wide, and other scientific and research areas that provide huge value to the economy.

Nordion has always taken its security responsibilities very seriously and fully implemented a security program under the previous Orders. The transition to 10 CFR Part 37 has been a mostly positive experience. Some general comments we have are as follows;

- We note that the openness of the regulations and guidance materials makes it much easier for training and assessment. This has a positive impact, since now, there is less confusion about security processes, improved work instructions and communications. For example, they provide for easier communication with suppliers and transport providers regarding their responsibilities and obligations under the regulations.
- It is also much easier to stay aware of changes in the regulations through the Federal Register system which did not occur with the security orders.
- The transition from the security orders to the regulations required minimal changes to Nordion processes with respect to Trustworthy and Reliability Designation and also to shipment notifications.
- The recent change in the regulations modifying the requirements for SGI-M are also a welcomed improvement. This is a good example of practical regulations.
- We experienced some challenges in working through the License Verification System. These were mostly linked to the readiness of the software and the population of current licenses - specifically licenses issued by Agreement States.



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I would also like to provide responses to specific questions listed in the Federal Register notice.

Subpart A—General Provisions:

1. Are the definitions (in 10 CFR 37.5, "Definitions") clear, unambiguous, and consistent with their usage in other parts of the regulations?

Response – Nordion finds the definitions in 10 CFR 37.5 to be acceptable

2. Is the rule clear as to when a licensee can use physical barriers to render aggregated sources below the category 2 aggregated quantity?

Response – this is not applicable to Nordion as we do not handle Category 2 or below sources.

Subpart B—Background Investigations and Access Control Program:

3. Are the requirements of subpart B clear for use in determining individuals to be trustworthy and reliable?

Response – These requirements are clear and Nordion has implemented a robust trustworthy and reliable program.

4. While the regulations provide the type of information that must be gathered before making a Trustworthiness and Reliability (T&R) determination, NUREG-2155 provides additional guidance on determining whether someone is T&R. Is the information in Annex A to NUREG-2155 adequate in helping a Reviewing Official make a T&R determination?

Response – Although we did not use this information, the information provided in the Annex provides additional details to consider when making a T&D determination.

Subpart D—Physical Protection in Transit:

9. Do the requirements of subpart D clearly define what is needed to support the physical protection of licensed category 1 and category 2 quantities of radioactive material in transit?

Response – Yes, requirements are clear and Nordion has fully implemented the requirements.

10. Are the requirements in 10 CFR 37.81, "Reporting of events," clear in defining the licensee's responsibility to notify LLEA and the NRC's Operations Center within 1 hour when a determination is made that a shipment of a category 1 quantity of radioactive material is lost or missing?

Response – Yes, requirements are clear



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Implementation Guidance Documents:

Please specify the sections of NUREG-2155 and NUREG-2166 in your responses to the extent practicable.

11. How have you utilized NUREG-2155 to implement the 10 CFR part 37 regulatory requirements in order to protect your licensed category 1 and category 2 quantities of radioactive material? If utilized, are there certain areas of NUREG-2155 that you have found to be particularly useful? Are there areas of NUREG-2155 that you think could be clarified or supplemented to make it a more useful tool?

Response – Nordion found the content of NUREG-2155 to be very helpful when transitioning from the former security orders to the new regulations. We incorporated this into our initial staff training. The Q&A structure of the guidance was supportive for this transition. Now that the regulations have been in place for some time, it could be beneficial to provide more textual information in the guidance.

12. How have you utilized NUREG-2166 to implement the 10 CFR part 37 regulatory requirements in order to protect your licensed category 1 and category 2 quantities of radioactive material? If utilized, are there certain areas of NUREG-2166 that you have found to be particularly useful?

Response – Nordion did not use NUREG-2166 during implementation of 10 CFR Part 37. Nordion is only involved in the transportation of Category 1 sources in the US and had already implemented robust security measures that meet the requirements of 10 CFR Part 37.

Nordion appreciates the opportunity to comment on the regulatory requirements in 10 CFR Part 37. Should you have any questions, or require additional information, please do not hesitate to contact me.

Sincerely,

Greg Fulford
Nuclear Transportation Specialist
Nordion (Canada) Inc.