

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) published the final rule for Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" on March 19, 2013. The rule was effective on March 19, 2014. It established physical protection requirements for all NRC licensees in possession of aggregated category 1 or category 2 quantities of radioactive material listed in Appendix A of Part 37. The rule applies to any person who possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

The requirements promulgated in Part 37, in large part, are based on the Increased Control Orders that NRC had issued to over 1400 material licensees in the post-September 11, 2001, threat environment. The Increased Control Orders addressed security for numerous types of licensees. NRC chose to use an international isotope/activity approach consistent with international standards (category 1 and category 2 of the International Atomic Energy Agency (IAEA) "Radionuclides of Concern") for the Increased Control Orders (and consequently Part 37) as opposed to writing a specific rule for each type of licensee. Developing separate rules for the numerous and divergent types of affected licensees would have been a difficult, if not impossible task.

After the final Part 37 rule was published on March 19, 2013, questions were raised regarding how Part 37 should apply to large components that contain category 1 or category 2 quantities of radioactive material stored in robust structures. Following interaction with stakeholders in public meetings and internal discussions, the NRC determined that there were unintended regulatory consequences to Part 50 and 52 licensees as a result of the requirements of Part 37. However, the unintended regulatory consequences did not result in any public health and safety effects, and were related to unnecessary security requirements added at reactor sites. In addition, for the vast majority of the licensees covered by Part 37, the rule is implementable as written and no further clarification was required. In a memorandum dated March 24, 2014, the Acting Director of the Office of Federal and State Materials and Environmental Management Programs (FSME) approved the charter of a working group (WG) to assess NRC's process, including communications and coordination both internally and externally, as it pertained to the provisions of Part 37 specific to the unintended regulatory consequences for large components that contain category 1 or category 2 quantities of radioactive material stored in robust structures at facilities licensed under 10 CFR Parts 50 and 52 (See appendix A of this report or ADAMS Accession No. ML14070A473 for the WG Charter).

OBSERVATIONS

Part 37 was promulgated primarily to codify the Increased Control Orders. These orders were issued only to materials licensees. The staff and management involved in developing of the Part 37 rule did not fully recognize the potential impact of Part 37 on reactor licensees. This contributed to the following:

1. The technical analyses associated with Part 37 did not fully consider security requirements for radioactive material at operating reactor sites and reactor sites under construction.
2. The specific exemptions in 10 CFR 37.11 in the final rule were not sufficiently clear and resulted in challenges for stakeholders in determining how Part 37 would affect them.
3. Communication issues during the Part 37 rulemaking development included:
 - a. The Part 37 rulemaking, that extended over 3 years, had many participants, among numerous working groups which hampered communications.
 - b. The rulemaking working and steering groups did not consistently have appropriate representation from all affected offices.
4. The Part 37 final rule could have more effectively addressed the comments provided by power reactor licensees on the proposed rule.

RECOMMENDATIONS/ENHANCEMENTS

1. Endorsement of the Cumulative Effects of Regulation (CER) process enhancements to increase interaction with external stakeholders early in the rulemaking process where applicable on significant rulemakings. Specifically, the CER process now encourages public meetings earlier in the rulemaking process.
2. Endorsement of NRC's commitment for a follow-up rulemaking to include:
 - a. clarification of the three exemptions: 37.11(a), (b) and (c); and
 - b. an updated regulatory analysis which ensures that all radioactive material storage configurations are considered at NRC licensee facilities.

3. Revise Management Directive 6.3, “The Rulemaking Process” to ensure that:
 - a. the number of WGs that are used in the rulemaking process is optimized;
 - b. members on the WGs from all Offices impacted consistently participate throughout the entire working group process; and
 - c. the Steering Group for the WG includes Senior Managers from all Offices impacted and that they consistently participate throughout the rulemaking process; and
 - d. the rule’s applicability is clearly defined and communicated to internal and external stakeholders throughout development of the rule.
4. Ensure thorough and complete responses to public comments on significant rulemakings; consider public meetings to discuss comments and resolution.