

10 CFR 40.60 and 10 CFR 70.50 Reporting Requirements – Issue Closure and Path Forward

Office of Nuclear Material Safety and Safeguards
Division of Fuel Cycle Safety, Safeguards and Environmental Review
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Issues for Resolution

Two issues were submitted under the NEI 14-14 Regulatory Issue Resolution Protocol related to the reporting requirements contained in the Code of Federal Regulations (CFR)

- Clarification on the definitions of “medical facility (onsite vs. offsite)” and “with spreadable contamination” under 10 CFR 40.60(b)(3) and 70.50(b)(3).
- Clarification on the definition of “unplanned” under 10 CFR 40.60(b)(1) and 70.50(b)(1).

Issues for Resolution

During a May 2016 public meeting, industry representatives provided additional comments in support of their original submission, including the desire to be treated consistent with 10 CFR Part 50.

Staff position

The regulations in 10 CFR Part 50 apply to production and utilization facilities (example: power reactors), and are not applicable to 10 CFR Part 40 and 10 CFR Part 70 licensees (example: fuel cycle facilities).

Reporting Requirements for Unplanned Contamination Events

10 CFR 40.60(b)/70.50(b) Twenty-four hour report: Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

- 40.60(b)(1)/70.50(b)(1) An unplanned contamination event that:
 - (i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area
 - (ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of section 20.1001-20.2401 of 10 CFR part 20 for the material, **and**
 - (iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination

Resolution and Path Forward - Unplanned Contamination Events

To ensure clear and consistent understanding of the regulatory requirements, the staff plans to issue a Regulatory Issue Summary (RIS) to clarify the NRC position.

- Concerns raised in previous meetings will be addressed in the RIS, including:
 - “planned” v. “unplanned”
 - Is there a threshold of significance?
 - Are radiologically controlled areas allowed flexibility?
- The staff will seek additional comments through public interactions (comment period/meetings as needed)

Reporting Requirements for Medical Treatment of Personnel

10 CFR 40.60(b)/70.50(b) Twenty-four hour report:
Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

- 40.60(b)(3)/70.50(b)(3): An event that requires unplanned medical treatment at a *medical facility* of an individual with *spreadable radioactive contamination* on the individual's clothing or body.

Staff Position – Medical Treatment of Personnel

Clarification of a *medical facility*:

The Statements of Consideration (SOC) for the rulemaking make clear that events involving contaminated patients treated at onsite medical facilities – even such facilities that only administer first aid – are subject to the reporting requirements.

* Federal Register, Vol 56 No. 159, page 40762 (b)(3) response to Comment 34

Resolution and Path Forward – Medical Treatment of Personnel

The NRC staff will consider, on a case-by-case basis, requests seeking relief from the reporting requirements involving the treatment of contaminated workers at onsite medical facilities, in accordance with 10 CFR 40.14(a) and 70.17(a).

At a minimum, the staff considers the following criteria to be important components of any such exemption request:

1. The onsite medical facility is in a restricted area and not accessible to members of the public;
2. An injured worker can reach the onsite medical facility without traversing any areas accessible to the public;
3. Radiation safety personnel, who have been trained and qualified in contamination control, are readily available;
4. Equipment and facilities that may be needed for contamination control are readily available; and
5. The licensee commits to establish and maintain a log of contaminated workers treated at the onsite medical facility, and provides this information for NRC inspection upon request.

Resolution and Path Forward – Medical Treatment of Personnel

Clarification of “spreadable” radioactive contamination:

The staff is developing an appropriate clarification and believes this issue has broader implications requiring coordination with multiple NRC offices.

Questions? Comments?