



Council on Radionuclides and Radiopharmaceuticals, Inc.

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September 6, 2011

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Subject: CORAR Comments to NRC on Prompt Remediation of Residual Radioactivity During Operations. Docket ID NRC-2011-0162.

Reference: Federal Register Vol.76, No 137, July 18, 2011, Page 42074. Consideration of Rulemaking To Address Prompt Remediation of Residual Radioactivity During Operations. Notice of public Webinar and request for comment.

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹. CORAR submitted comments on to the NRC on May 7, 2008 which included this topic, and is now providing the attached additional comments in response to NRC's specific questions.

CORAR appreciates the opportunity to submit comments on this important subject and would be glad to provide clarification or additional information.

Yours Sincerely,

Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety.

Enclosure: CORAR comments to NRC on Consideration of Rulemaking to Address Prompt Remediation of Residual Radioactivity During Operations. September 6, 2011.

1. CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

SUNSE Review Complete

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September 6, 2011

**CORAR COMMENTS TO NRC ON CONSIDERATION OF RULEMAKING TO ADDRESS
PROMPT REMEDIATION OF RESIDUAL RADIOACTIVITY DURING OPERATIONS.**

1. Should the NRC conduct rulemaking to address remediation of residual radioactivity during the operational phase? Why or why not?

CORAR recommends that the NRC does not need to conduct rulemaking to address remediation of residual radioactivity during the operational phase because current regulations already obligate licensees to conduct these activities. 10CFR20 and equivalent Agreement State regulations require that licensees control licensed material and reduce contamination and radiation exposure to ALARA. These activities are key elements of what licensees and licensing agencies consider to be an adequate radiation protection program. Regulations require that a licensee has an adequate radiation protection program. Also licensees to possess radioactive materials routinely commit licensees to comply with these regulatory requirements.

It is also the experience of CORAR members that radionuclide and radiopharmaceutical manufacturer and distributor licensees have never in the past 50-60 years left a contaminated legacy site. This implies that both current and previous regulations and license conditions have been adequately protective for this group of licensees. If the NRC decides that new rulemaking is necessary to address the activities of other licensees we recommend that manufacturers and distributors and any other groups of licensees that have a perfect compliance record be exempt from these additional new requirements.

CORAR is aware that there are a few material licensees that caused contaminated legacy sites. These are facilities that processed uranium and transuranics. CORAR has recommended that such operations should be identified by licensees and their regulatory agencies and the necessary controls specified as license conditions. The NRC response to this comment asserts that it is more efficient to make a rule change than apply license conditions. However, CORAR recommends that it is much more efficient and effective to establish specific license conditions for a few licensees to accommodate their unusual practices than for the entire licensed community to be obligated to conduct unnecessary, extensive and invasive surveillance.

2. If the NRC implements a rule that requires prompt remediation of radioactive spills and leaks, what concentration, dose limits, or other threshold limits should trigger prompt remediation? Should the thresholds differ for soil versus groundwater contamination? For example, should the NRC screening criteria be used to establish threshold levels for soil contamination? Should the EPA's maximum contaminant levels be used for drinking water?

If the NRC implements a rule that requires prompt remediation, this can be done without specifying concentration, dose limits or other threshold limits to prompt remediation. CORAR does not recommend such limits in the rule because appropriate limits would depend critically on the actual conditions which could be complex, variable and difficult to determine. Instead, CORAR recommends that threshold limits would be more usefully conveyed in a guidance document describing various potential scenarios and acceptable ways to address them. CORAR recommends that thresholds should be based on current assessment tools that ISCORS has developed using up-to-date ICRP recommended dose conversion and weighting factors in conjunction with the ALARA principle.

3. Should the NRC allow licensees to justify delaying remediation under certain conditions when the contaminant level exceeds the threshold limit? If yes, then what conditions should be used to justify a delayed remediation?

Each situation should be evaluated by appropriately qualified individuals and the decision made to promptly remediate or delay remediation. The decision should be justified and documented.

Conditions that may warrant delaying remediation include:

Quantity, chemical form and potency of the contaminants

Degree of containment of the contaminants

Mobility of the contaminants and potential conditions that could affect these

Ability to monitor and track the contaminants

Cause of the contaminants, and whether historic, ongoing or potential

Radioactive decay and benign dispersion

Potential environmental and public impact

Ongoing operational and remediation considerations including: occupational exposure, safety, security, and cost-effectiveness

4. Should factors such as safety, operational impact and cost be considered for delaying remediation?

Yes. These considerations, and those in the above answer to question 3, are similar to those made by licensees in controlling all radiation and contamination sources.

5. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, then what should the licensee's analysis cover? For example, what kind of dose assessment, risk-assessments and/or cost-benefit analyses should be performed to justify delayed remediation? What other types of analyses are relevant?

This question is difficult to answer concisely because the specific analysis that is required will depend on the actual circumstances. For manufacturers and distributors, the radiation protection program will normally have a surveillance schedule and a requirement for employees to promptly report unusual occurrences. When a situation potentially requiring remediation is detected, the licensee staff is likely to implement emergency procedures and/or an investigation. Response teams will typically include operations management and their staff and facility, safety and radiation protection specialists. Like other emergency conditions we expect there would commonly be a need to make rapid assessments and analysis to define the situation and ensure prompt notifications, isolation, safety and any necessary mitigation.

When the situation has stabilized, the emergency phase is ended and more comprehensive investigation and analyses done to determine the cause, corrective and preventive actions. These are documented and reviewed by appropriate staff, modified as necessary and the actions implemented. In a complex situation there could be a succession of investigations and remediation until a satisfactory outcome is achieved. The timing of corrective and preventive actions is determined and could include a decision to delay remediation.

6. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, what role should the cost of prompt remediation versus remediation at the time of decommissioning play in an analysis to justify delayed remediation?

The cost of prompt remediation would normally be considered as a contingency in planning new operations with licensed materials, in decommissioning cost estimates and when residual contamination is determined. Usually a licensee will be prepared to spend more to promptly remediate if this is necessary to prevent a significant impact, adverse perception or a business interruption.

7. If the NRC implements a rule that allows licensees to analyze residual radioactivity to justify delaying remediation, what standards or criteria should a licensee use to demonstrate to the NRC that a sufficient justification to delay remediation has been met?

Again, this will depend on the situation. Any attempt to establish detailed criteria for all potential situations is unlikely to be practical. However, we would expect that any analysis would determine potential dose to operations staff and the potentially affected community.

8. Are there any other alternatives beyond those discussed in the Draft Proposed Technical Basis document that the NRC should have considered to address prompt remediation?

The NRC might want to consider the role that licensing agency licensing, inspection and enforcement played and should play in determining vulnerable sites and practices.

9. What other issues should the NRC staff consider in developing a technical basis for a rulemaking to address prompt remediation of residual radioactivity during site operations?

We do not think there are any other significant issues for rulemaking but recommend the following consideration for guidance. NRC guidance should show how it is cost-effective and risk-informed for many groups of licensees who have never created a contaminated legacy situation to routinely use limited resources to make hydro-geologic evaluations to determine effective sampling and analysis.