

November 16, 2016

MEMORANDUM TO: Craig G. Erlanger, Director
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Office of Nuclear Material Safety
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SUBJECT: SUMMARY OF OCTOBER 12, 2016, MEETING WITH THE
INDUSTRY AND STAKEHOLDERS TO DISCUSS THE
CUMULATIVE EFFECTS OF REGULATION AND FUEL CYCLE
REGULATORY ACTIVITIES

The staff of the U.S. Nuclear Regulatory Commission (NRC) met with representatives of the Nuclear Energy Institute (NEI), fuel cycle industry, and members of the public on October 12, 2016, in Rockville, Maryland. The purpose of this Category 2 public meeting was to discuss the status of several topics of mutual interest, including updates to the Cumulative Effects of Regulation Integrated Schedule; Generic Letter 2015-01, "Treatment of Natural Phenomena Hazards in Fuel Cycle Facilities" closeout status; chemical safety audits; fuel cycle inspection efficiencies; reporting requirements related to medical treatment of personnel and unplanned contamination events for fuel cycle facilities (FCFs); lessons learned related to NEI 14-14, "Regulatory Issue Resolution Protocol;" Project AIM; and cyber security rulemaking cost estimates. The meeting announcement is available in the Agencywide Documents Access and Management System (ADAMS) under the Accession No. ML16278A340.

Cumulative Effects of Regulation

The NRC staff provided updates to the various rulemaking and regulatory activities involving the fuel cycle industry listed in the Integrated Schedule of Regulatory Activities for Fuel Cycle. The NRC staff communicated that the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 74, "Material Control and Accounting of Special Nuclear Material" rulemaking activities resumed in October 2016. The schedule has been revised to extend the completion date by 1 year.

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Therefore, the draft final rule is due to the Commission in November 2017. The staff also communicated that they are awaiting Commission direction for the 10 CFR Part 73, "Physical Protection of Plants and Materials," rulemaking regarding security-related regulations for special nuclear material and FCFs.

The NRC staff and industry also discussed non-rulemaking activities associated with the integrated schedule. The Material Control and Accounting Regulatory Guides (RGs) revision schedule has been pushed back by 2 months. The NRC staff and industry discussed the upcoming Fuel Cycle Information Exchange (FCIX) and possible session topics. The FCIX is tentatively scheduled for June 2017.

The NEI suggested adding the two issues under NEI 14-14, "Regulatory Issue Resolution Protocol" to the integrated schedule. By letter dated July 27, 2015 (ADAMS Accession No. ML15217A487) NEI submitted a request to the NRC to clarify the requirements contained in 10 CFR Sections 40.60 and 70.50. In particular, NEI stated that the industry is seeking clarification of the terms "medical treatment" and "medical facility" as they pertain to the event reporting requirement in 10 CFR Paragraph 40.60(b)(3) and 10 CFR 70.50(b)(3). NEI is also seeking clarification of "spreadable radioactivity" and "unplanned" as they pertain to the event reporting requirements in 10 CFR 40.60(b)(1) and 10 CFR 70.50(b)(1). The NRC staff stated that it would discuss the NEI's suggestion internally and provide a response. Following the meeting, NEI submitted a letter on October 27, 2016, stating that the NRC should not expend further resources to clarify these terms.

The NRC staff committed to review the information on the integrated schedule and supplement, and to post these documents on the public website available at <http://www.nrc.gov/materials/fuelcycle-fac/regs-guides-comm.html#cumeffects>. The ADAMS Accession numbers for the presentations, attendees list, the fuel cycle integrated schedule and the supplement to that schedule are enclosed. No regulatory decisions or commitments were made during the meeting.

Natural Phenomena Hazards Update

The NRC staff discussed the status of the closure activities related to Generic Letter (GL) 2015-01, "Treatment of Natural Phenomena Hazards In Fuel Cycle Facilities" (ADAMS Accession No. ML14328A029). The staff presented the expected schedule for completion of the milestones for each licensee. At the time of the meeting, the NRC staff issued closure letters to Westinghouse and AREVA. For the remaining licensees, the GL closure activities are scheduled to be completed by June 2017. The staff also discussed challenges and lessons learned that have been identified so far during the closure process of the GL.

Chemical Safety Audits

NRC staff discussed the results of the chemical safety audits conducted at FCFs during the months of June and July 2016. The purpose of the audits was to gather information on the evaluation and mitigation of acute chemical exposures. The audits allowed the NRC staff to determine the safety significance of this issue and whether there needs to be any additional regulatory action. The NRC staff explained the process used to conduct the audits. The audits were conducted during a 1-day or 2-day site visit. The scope of the audits involved: operations covered by the integrated safety analysis (ISA), evaluation of acute chemical exposures, standards used to classify consequences, and worker protection programs. Based on the

audits observations, the NRC staff has initially determined that there is no immediate safety concern. There are no major unanalyzed hazards as it relates to licensee's analysis of exposure pathways. The NRC staff has reasonable assurance that licensees are in compliance with 10 CFR 70.61. One licensee's ISA methodology does not consider all exposure pathways. This represents a weakness in their safety program when managing chemical hazards. This would be a safety issue if they were processing licensed material with a non-inhalation hazard (e.g. HF). NRC staff is developing audit summary reports for each licensee documenting the audits' observations and results. All audit reports are expected to be completed and issued by the end of November 2016. The NRC staff briefly discussed the next steps associated with the Commission paper and ISG.

Fuel Cycle Inspection Efficiencies

NEI provided a presentation on industry's suggestions to enhance NRC inspections at FCFs and make them more efficient. NEI expressed industry's appreciation for receiving NRC's inspection schedule early, which allows industry to support site visits accordingly. NEI suggested that the NRC consider bundling more of the inspection modules to decrease site visits. NEI stated that industry views the electronic document reading rooms, for facilities authorized to use them, as an efficient tool for the inspectors. Industry observed that the NRC's use of the reading room varies by facility and inspection team. In addition, the industry would prefer each inspection module to have a standardized document request, since there are sometimes multiple requests for the same document and requests for large documents when only a section is needed. NEI suggested reducing the inspection frequency of some modules. Some examples provided were: reducing operational safety to annual inspections; reducing fire protection inspection frequency from annual to triennial; and conducting emergency preparedness module during the biennial observed exercise week. NEI expressed that the industry finds that the inspection team composition generally works well and that the NRC inspection team lead aids in communication and provides daily de-briefs. The industry would like to see more consistency in inspection team size, since the size varies between sites and for the same inspection module. In regards to programmatic efficiency opportunities, NEI suggested that resident inspectors perform routine inspections instead of regional inspectors. Industry would also like for the NRC to consider sharing NRC observations with industry on a periodic basis and modifying licensee performance review meeting format (e.g., use of a webinar and open house).

Reporting Requirements Related to Medical Treatment of Personnel and Unplanned Contamination Events for Fuel Cycle Facilities

The staff presented the proposed resolution of and path forward for the two issues raised by industry under the NEI 14-14, "Regulatory Issue Resolution Protocol". Both issues are related to clarifying the reporting requirements contained in 10 CFR 40.60 and 10 CFR 70.70. Regarding the reporting requirements for unplanned contamination events, contained in 10 CFR 40.60(b)(1) and 10 CFR 70.50(b)(1), the staff discussed providing more clarity through the development of a Regulatory Issue Summary (RIS), which will be tracked on the integrated schedule. During the development of the RIS the staff will engage the industry and public stakeholders by means of the public comment period as well as public meetings. Industry representatives expressed concern with the length of time it can take to develop and issue a RIS, and stated they may be interested in developing criteria that can be used to apply for an exemption from the requirements. The staff indicated they would review any proposed criteria submitted by industry.

Regarding the reporting requirements for medical treatment of an individual with spreadable contamination, contained in 10 CFR 40.60(b)(3) and 10 CFR 70.50(b)(3), the staff position was presented. The staff acknowledged that a licensee may elect to submit a request for exemption from these requirements and highlighted minimum criteria to be addressed in the request. The staff indicated that a clarification regarding spreadable radioactive contamination is under development but has broader implications requiring coordination with other NRC offices.

Meeting attendees agreed that the formal closure of the two issues would be documented by means of a letter accompanied by the appropriate forms contained in NEI 14-14.

NEI 14-14, “Regulatory Issue Resolution Protocol” Lessons Learned

The NRC staff shared initial lessons learned on using the NEI 14-14 protocol for the two issues raised by NEI. Meeting participants agreed that the amount of resources needed to bring the two issues to resolution exceeded both NRC's and NEI's expectations. NRC staff and industry agreed that a public pre-meeting would be useful prior to any future submittals under the protocol. Meeting prior to the formal submission may allow more clarity in the problem statement and a fuller understanding by the NRC staff. The NRC staff stated that the timeline associated with bringing issues to closure using the protocol should account for changes in schedule as a result of external factors and varying work priorities. In addition, the staff stated that the NEI 14-14 closeout process should be reevaluated to establish what type of documentation is appropriate for various stages of the protocol including closure, (closure form versus standard letter) and what level of detail it should contain.

Project Aim

Project Aim is the NRC's strategic initiative to enhance the agency's ability to plan and execute its mission while adapting in a timely and effective manner to a dynamic environment. In June 2015, the Commission approved the 19 Project Aim recommendations that related to the NRC's need to right-size, while retaining appropriate skill sets to accomplish its mission, and streamline processes. As of the time of this meeting, 16 of the 19 Project Aim tasks were completed, with several of them moving into the implementation phase, which may continue for a number of years in the future. The 16 completed tasks include common prioritization and re-baselining activities, NRC's assessment of risks within IT systems, strategic workforce planning, and centers of expertise.

The staff also presented the C-list reductions identified in Enclosure 1 to SECY-16-0009, “Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities,” (ADAMS Accession No. ML16028A189) specific for the Fuel Facilities Business Line. The staff provided status updates on the implementation of these activities, indicating that these activities were completed within 6 month of issuance of the Staff Requirements Memoranda.

Cyber Security Cost Estimates

The NRC discussed the costs associated with the proposed cyber security rulemaking for FCFs, NEI presented cost estimates for implementing the proposed rulemaking and related draft RG (ADAMS Accession No. ML16273A130).

NEI's Cost Estimates and Additional Considerations:

The NEI indicated that the cost estimates in their slides were provided by multiple fuel cycle facilities. The numbers ranged from \$900,000 to \$2.8 million with an average of \$1.8 million per facility. Industry stated that they recognize cyber security is important to safe and secure operations. One facility indicated that they divert up to 1000 cyber attacks per day (most of these are unauthorized attempts to access the plant network). This was stated in the context that industry has undertaken voluntary efforts to protect against cyber attacks.

NEI asked the NRC staff to consider the impacts that their petition for rulemaking PRM-73-18 (ADAMS No. ML14184B120, and www.regulations.gov docket number Docket ID NRC-2014-0165) may have on the proposed cyber security rule. This proposal would limit the cyber security requirements to those facilities that have a design basis threat. In addition, they requested the NRC staff keep management and the Commission informed on the relation between the PRM and the cyber security proposed rulemaking.

NEI and industry expressed concern that the rule is not cost justified. Although they recognize that cyber security is important at fuel cycle facilities, they reiterated their position that their voluntary efforts are adequate. NEI also expressed concern that the current rule would encourage facilities to replace digital assets with administrative controls.

NEI requested the NRC consider holding additional public meetings. Industry proposed that one of these meetings should include working through some specific examples of identifying digital assets, applying controls, defining the system boundary, grouping VDAs by type, etc.

NRC Staff Considerations:

The NRC presented the staff estimates of costs to implement the proposed rulemaking. The NEI and Industry cost estimates exceed the NRC's by a factor of 6. The NRC plans to use feedback from stakeholders to inform the cyber security regulatory analysis. NRC staff also gained insight into Industries interpretation of the proposed rule language and related guidance. The NRC staff reminded stakeholders that the next public meeting opportunity will be the staff's briefing to the Advisory Committee on Reactor Safeguards, scheduled for November 2, 2016.

Enclosures:

1. Cumulative Effects of Regulation Presentation (ML16288A690)
2. Fuel Cycle Integrated Schedule of Regulatory Activities Supporting CER (Oct 2016) (ML16292A432)
3. Supplement to Fuel Cycle Program Integrated Schedule (Oct 2016) (ML16292A433)
4. Generic Letter 2015-01, "Treatment of Natural Phenomena Hazards (NPH) in Fuel Cycle Facilities" Update Presentation (ML16288A667)
5. Chemical Safety Audits Presentation (ML16288A686)
6. NEI Inspection Efficiency Presentation (ML16288A685)
7. Reporting Requirements Related to Medical Treatment of Personnel and Unplanned Contamination Events for Fuel Cycle Facilities Presentation (ML16288A672)
8. NEI 14-14, "Regulatory Issue Resolution Protocol" Lessons Learned Presentation (ML16288A681)
9. Project Aim Update Presentation (ML16288A696)
10. Fuel Facilities Budget Line C-List Reductions Presentation (ML16288A702)

11. NEI Fuel Cycle Cyber Security Implementation Costs Presentation (ML16288A661)
12. NRC Fuel Cyber Security Cost Estimates Presentation (ML16288A711)
13. List of Attendees (ML16306A051)

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13. List of Attendees (ML16306A051)

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ADAMS Accession No.: ML16306A050 Package No.: ML16288A646

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