MEMORANDUM TO: Shana Helton, Acting Director  
Division of Fuel Cycle Safety, Safeguards, and Environmental Review  
Office of Nuclear Material Safety and Safeguards  

FROM: DyLanne Duvigneaud, Fuel Cycle Operations Engineer /RA/  
Programmatic Oversight and Regional Support Branch  
Division of Fuel Cycle Safety, Safeguards, and Environmental Review  
Office of Nuclear Material Safety and Safeguards  

SUBJECT: SUMMARY OF MARCH 16, 2016, MEETING WITH THE INDUSTRY AND STAKEHOLDERS TO DISCUSS FUEL CYCLE REGULATORY ACTIVITIES AND CUMULATIVE EFFECTS OF REGULATION  

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 March 16, 2016, in Atlanta, Georgia. The purpose of the meeting was to discuss the status of several topics of mutual interest, including updates to the Cumulative Effects of Regulation (CER) Integrated Schedule, Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting Defects and Non-Compliance" guidance development, NEI 14-14, "Regulatory Issue Resolution Protocol," Revised Fuel Cycle Oversight Process significance determination process, and Generic Letter 2015-01, "Treatment of Natural Phenomena Hazards in Fuel Cycle Facilities" closeout process. The meeting announcement is available in the Agencywide Documents Access and Management System (ADAMS) under the accession number ML16064A315.  

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 stated that it requested Commission approval to discontinue a number of planned or proposed rulemaking activities (ADAMS Accession No. ML15336A324) including 10 CFR Part 26, "Fitness for Duty" rulemaking activities. The NRC staff is waiting for Commission direction. The NRC staff also discussed SECY-16-0009, "Recommendation Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities" (ADAMS Accession No. ML16028A189).  

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This paper provides the staff's proposal for re-baselining agency activities and requests Commission approval to implement recommendations on work to be shed, de-prioritized, or performed with fewer resources. 10 CFR Part 20, "Standards for Protection against Radiation" and 10 CFR Part 21 rulemaking are some of the items discussed in this paper. The NRC staff proposes to discontinue the 10 CFR Part 21 rulemaking activities but still continue to work on the guidance. On April 13, 2016, the Commission issued a Staff Requirements Memoranda accepting the staff's recommendation (ADAMS Accession No. ML16104A158).

The NRC staff and industry also discussed non-rulemaking activities associated with the integrated schedule. The Material Control and Accounting Regulatory Guides (RGs) schedule is pushed back by 4 months. The industry stated that it would be helpful to have a list of all upcoming RG revisions applicable to fuel cycle facilities to better facilitate its public comment responses. Also, the NRC staff and industry discussed reducing the frequency of the CER meeting from quarterly to semi-annually. It was agreed that semi-annually meetings will be sufficient.

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.

10 CFR Part 21, "Reporting Defects and Non-Compliance" Guidance Development"

The NRC staff provided a presentation on the development of regulatory guidance for the implementation of 10 CFR Part 21 at non-reactors. The NRC staff shared text from Draft Guide (DG)-3049, "Reporting of Defects and Noncompliance for Fuel Cycle, Materials, Waste Disposal, Packaging and Transportation, Independent Storage, and Non-Power Reactor Licensees," for discussion. DG-3049 text for thresholds associated with Substantial Safety Hazard, examples of basic components for fuel facility, and the commercial grade dedication sections were discussed and the stakeholders provided feedback. The public comment period for the draft guide is tentatively scheduled for Fall 2016. The staff presented how the DG will address non-reactor and non-power reactors licensees. Present challenges regarding NUREG-0302, "Remarks Presented at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," and the current lack of consolidated guidance for non-reactors regarding the implementation of 10 CFR Part 21 were discussed.

NEI 14-14, “Regulatory Issue Resolution Protocol”

The NRC staff provided the status of the staff’s efforts to apply the screening phase as outlined in NEI 14-14, “Regulatory Issue Resolution Protocol: A Methodology for Resolving Regulatory Issues with Generic Implications for Fuel Cycle Facilities,” dated December 2014. 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 40.60 and 10 CFR 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 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 staff shared with NEI and industry that a response letter had been drafted and was being routed for internal NRC concurrence. NEI and industry provided comments on the protocol process and made observations on how the issues raised under the protocol affected respective fuel cycle facilities. The meeting was useful in exchanging dialogs with the NEI and industry representatives. No NRC staff decisions were made during the meeting.

Revised Fuel Cycle Oversight Process

The staff and industry representatives discussed the draft Fuel Cycle Significance Determination Process (FCSDP) framework, to include cornerstone-specific tools, and proposed options to reduce core inspection resources for facilities with an approved Corrective Action Program (CAP). During the FCSDP discussion the staff and industry reached alignment on the definition of performance deficiency and discussed the overall structure of the FCSDP and some high-level examples using some of the cornerstone-specific tools. The staff noted that after the draft cornerstone-specific guidance has been developed another public meeting will be scheduled sometime in the summer of 2016 to discuss the specific criteria and thresholds associated with the proposed tools. The staff and industry also discussed reducing core inspection requirements that focus on programmatic items for licensees with an approved CAP. The staff noted that the overall reduction of programmatic items from the core inspection procedures is expected to be greater than the additional inspection resources for the CAP inspection. Furthermore, it was suggested that the CAP inspection could be implemented on an as needed basis dependent upon the licensee's performance in implementing the approved CAP.

Generic Letter 2015-01, “Treatment of Natural Phenomena Hazards in Fuel Cycle Facilities” Closeout Process

Staff provided a presentation on the closure process of Generic Letter 2015-01. The staff shared the tasks identified in the "Closure Strategy for Generic Letter 2015-01" (ADAMS Accession No. ML15195A474). In addition, the staff discussed the scope of Temporary Instruction (TI) 2600/016, "Inspection Activities Associated with NRC Generic Letter 2015-01" (ADAMS Accession No. ML111030453). The purpose of the TI is to perform inspections to verify that the justification provided by licensees in their Generic Letter 2015-01 responses are implemented adequately in the facility. The staff also stated that the results of TI inspections will serve as a basis for closure of Unresolved Items related to natural phenomena hazards and as a basis for closure of Generic Letter 2015-01.

Enclosures:
1. Cumulative Effects of Regulation Presentation (ML16070A276)
2. Fuel Cycle Integrated Schedule of Regulatory Activities Supporting CER (Mar 2016) (ML16070A256)
4. Part 21 "Reporting Defects and Non-Compliance" Presentation (ML16070A217)
5. Part 21 "Reporting Defects and Non-Compliance" Presentation Handout (ML16070A266)
6. NEI 14-14, “Regulatory Issue Resolution Protocol” Presentation (ML16116A409)
7. Revised Fuel Cycle Oversight Process Presentation (ML16070A291)
8. Natural Phenomena Hazards Presentation (ML16070A285)
9. List of Attendees (ML16112A161)
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