



NUCLEAR ENERGY INSTITUTE

9/13/09

74FR 45657

2

November 2, 2009

Felix M. Killar, Jr.  
SENIOR DIRECTOR  
FUEL SUPPLY/MATERIAL LICENSEES  
NUCLEAR GENERATION DIVISION

Mr. Michael T. Lesar  
Chief, Rules and Directives Branch  
Office of Administration  
U.S. Nuclear Regulatory Commission  
TWB-05-B10M  
Washington, D.C. 20555-0001

REMOVED

NOV 03 AM 11:54

RULES AND DIRECTIVES  
BRANCH  
F-REDS

**Subject:** Industry Comments on the Notice of Availability of Revised Fuel Oversight Process issued in 74FR45657 dated September 3, 2009

**Project Code:** 689

Dear Mr. Lesar:

On behalf of the fuel cycle industry, the Nuclear Energy Institute<sup>1</sup> (NEI) appreciates the opportunity to comment on efforts by the U.S. Nuclear Regulatory Commission (NRC) staff to revise the current oversight process for fuel cycle facilities. Specifically, we support enhancements to the current oversight process to the degree that such modifications make it more risk-informed, objective, transparent and predictable for stakeholders, the NRC, licensees and certificate holders (hence referred to as licensees). As such, we consider such program attributes as our mutual goals. We appreciate the opportunity to provide the following general comments and the enclosed specific comments in response to the subject *Federal Register* notice for the staff's consideration as it proceeds to develop the fuel cycle oversight process (FCOP).

First and most importantly, it should be recognized that the current regulatory oversight process is adequate for the protection of people and the environment. As such, there is no "burning platform" for immediate change, and any efforts to modify it should be conducted in a well-coordinated, integrated and step-wise manner that will take a few years to fully develop and implement properly, just as the NRC's Reactor Oversight Process required. With an interest in improving the current process, industry formed a working group in October 2008 to begin considering the matter. To this

<sup>1</sup> The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

SONSI Review Complete

F-REDS = ADM-03

Template = ADM-013

add = B. Gibbs (RAG1)

end, a well developed detailed plan to receive all stakeholder feedback and then initiate a revised oversight process with appropriate indoctrination and training is vital for a successful step forward. This must be done in recognition of the existing and planned additional initiatives by the agency and industry to continue to assure safety in our operations and the need to fully implement the new Part 70 changes still underway. To date, industry has been responsive to NRC staff requests for information and has supported the four public workshops held since June of this year.

Secondly, from industry's perspective, efforts to develop the revised FCOP appear to be schedule-driven, which is negatively impacting the time available to discuss key concepts and the quality of the draft procedures issued to date. More discussion on key concepts include the "significance determination process" (SDP), the definition of "performance deficiency," which is the entry point into the SDP process, and the risk metrics that will be used to evaluate the significance of the findings and categorize them relative to the risk (or lack thereof) posed by the diverse set of fuel facilities. Also, the lack of a detailed project plan with specific milestones that demonstrate interdependencies and a realistic resource-loaded schedule at the beginning of the project in June 2009 has made it difficult for industry and, we suspect, the NRC to effectively apply its limited resources to support our mutual goals for the revised FCOP.

In that regard, industry provided the NRC with a comprehensive list of current NRC regulatory initiatives, in addition to the FCOP, which industry is supporting in parallel with expending resources to support routine and reactive inspections as well as major license amendments including renewals. An updated version of that list is attached. It should also be noted that development of the FCOP represents an unbudgeted activity at present, both at the NRC and licensees. We understand that NRC staff is taking this information into consideration as it prioritizes its resources and requests of industry, and we look forward to receiving feedback on the effort to get alignment on regulatory priorities.

Third, the NRC should take full advantage of the vast amount of information in each facility's specific Integrated Safety Analysis when determining how to risk-inform the oversight or inspection process for fuel facilities and how that information might be used on-site during an inspection. The ISAs were required by Part 70 (which became effective in 2000), were developed in a timely manner, and the ISA Summaries have been accepted by the NRC. While the ISAs are maintained as living documents at the facility, an annual update of the ISA Summary is submitted to the NRC each January as required by Part 70 and provides a wealth of information. Industry is willing to meet with the NRC to identify how the ISAs might risk inform the inspection and oversight programs.

Fourth, an equally important fact is that the operating fuel facilities, unlike operating commercial nuclear power reactors, do not represent a uniform set of operations and processes. Specifically, the regulatory basis is different for the Part 40, 70 and 76 facilities (vs. the reactors all Part 50-based) and, within this fleet, there are five Category III plants, three Category I plants and four enrichment plants (not all operational), which collectively represent a highly diverse group of operations that do not lend themselves to a "cookie cutter" approach and are not a mirror image of the reactors. Understanding these distinctions is critical when designing a revised FCOP, a concept that may not be well understood by some at the NRC. Such plant diversity drives up the complexity of revising the

Mr. Michael T. Lesar  
November 2, 2009  
Page 3

current reactor oversight process to be used for the fuel facilities while the economy of scale decreases its conceptual or derived benefits immensely, a fact that continues to raise questions within industry on the need for, or priority of, addressing the FCOP in the complex manner described by NRC staff to date and on the apparent accelerated schedule.

Finally, once the key issues, such as the ones described above, are more fully discussed and resolved, and a workable project plan and schedule are rationalized and prioritized with other ongoing regulatory initiatives, the NRC and industry will be in a better position to converge on the guiding principles, processes and related procedures to implement a revised FCOP.

In summary, industry supports our mutual goals of implementing a revised FCOP that is more risk-informed, objective, transparent and predictable for everyone, and reflects the distinct nature and variety of the fleet of fuel facilities. This goal needs to be performed within the realistic resources available to both the NRC and industry and our collective capabilities. Anything less would be counterproductive and distract limited resources from day-to-day safety management of the facilities, which is the primary goal of facility personnel. The initial NRC efforts to apply appropriate project management to the FCOP are to be applauded and need to be further developed by considering the priority of all regulatory initiatives underway and proceeding accordingly.

We appreciate the opportunity to provide these comments and trust you will find them useful. If you would like to discuss them further, please contact me (202.739.81267; fmk@nei.org) or Janet Schlueter (202.739.8098; jrs@nei.org). For your information, the Commission offices are copied on this letter since the FCOP was a topic of discussion for the industry visits originally scheduled for November 12, 2009 but are being rescheduled.

Sincerely,



Felix M. Killar, Jr.

Attachment

- c: The Honorable Gregory B. Jaczko, Chairman, U.S. Nuclear Regulatory Commission
- The Honorable Dale E. Klein, Commissioner, U.S. Nuclear Regulatory Commission
- The Honorable L. Kristine Svinicki, Commissioner, U.S. Nuclear Regulatory Commission
- Ms. Annette Vietti-Cook, Secretary, U.S. Nuclear Regulatory Commission
- Mr. Russell Gibbs, U.S. Nuclear Regulatory Commission
- Mr. Joseph Shea, U.S. Nuclear Regulatory Commission

**CURRENT REGULATORY INITIATIVES REQUIRING INDUSTRY SUPPORT**  
**November 2, 2009**

<b>Project</b>	<b>Status</b>	<b>Mtg/Wkshp</b>	<b>Input to NEI</b>	<b>Input to NRC</b>
PRM Part 70, Appendix A	Comment Cycle; waiting on resolution of petition and proposed rule			8/18/09
ISG – Reporting Safety Event (Part 70, Appendix A)	Comment Cycle; Waiting on final ISG			8/10/09
DG-3037 – Facility Change Process in 70.72	Comment Cycle; Waiting on final RG; may send 2 <sup>nd</sup> comment ltr	? guidance to be re-issued		8/17/09
ISG – Digital I & C	Comment Cycle; waiting on final guidance	10/29/09		9/02/09
Soluble Uranium Intake	Input to NRC Waiting on draft Guidance Doc	?	?	5/09
Enforcement Policy Update	Comments Submitted; waiting on final		?	7/22/09
Dermal Exposure	NRC Letter, Public meeting to be scheduled	11/12/09	10/15 call 10/30 call 11/10/09 mtg	11/12/09
Depleted Uranium Workshop & Qs&As	Meetings Qs&As in FRN	9/2-3/09 9/23-24/09	10/23/09	10/30/09
Chemical Security Gap Analysis	Awaiting NRC		?	?
Chemical Security Site Visits to at least 3 FCFs	Oct – November Ongoing		?	?
D-5034 Revised 73.21 SGI & SGI-M	Comment Cycle; waiting for final		9/24/09	10/01/09
Draft NUREG 1520	Workshop and Public Comment; waiting for final	10/8/09	10/19/09	10/23/09
DG-3038, SRP for Pu Processing Plants	Comment Cycle; waiting for final			9/21/09
Safety Culture Policy (SECY-09-0075)	SRM issued		?	?

Design Features versus IROFS	Industry Bi-wkly call; NRC to issue draft guidance	10/8/09	9/24/09 call 10/2/09 call 11/10/09 mtg	?
DG-5029, Seals used in MC&A	Comment Cycle; waiting on final		10/6/09	10/13/09
Proposed Rule on Export/Import of nuclear equipment and material	Comment Cycle; waiting on final rule			9/08/09
Comments on NRC Revision to the Fuel Facility Oversight Program & Document Review; Respond to FRN	Comment Cycle Meeting  Comments Due  Respond to FRN	6/4-5 6/24 7/28-30 10/6-7/09 Wk of 11/19		9/30/09    10/28/09 11/02/09
FRN on RIS 2005-02 regarding process for making changes to Emergency Plans	Comment Cycle extended from 10/8 to 10/23		10/13/09	10/23/09
DG-8039 on Determining EDE for External Exposures	Comment Cycle		11/9/09	11/26/09
DG-XX on Designating IROFS (vs Design Features)	Comment Cycle; waiting on draft guidance		?	?
Draft Inspection Procedure on SGI rule	Comment Cycle		10/23/09	10/30/09
Implementation of Part 73 final Weapons Rule	Implementation of final rule			04/12/10
Update and submit ISA Summary	Currently on-going			01/31/2010

Note: This list does not reflect the significant licensee resources needed to support other regulatory initiatives. These include but are not limited to: 1) ongoing support for baseline, reactive or other special inspections at fuel cycle facilities; 2) submittal of licensing actions such as major amendments and renewals, and response to Requests for Additional Information from NRC; and 3) the numerous Draft Regulatory Guides discussed by NRC officials at the 2009 FCIX that are expected to be issued in the near term for stakeholder comment.

**Industry Responses to the Topics Described in 74FR45659 on the Revised Fuel Cycle Oversight Process dated September 3, 2009**

The following comments in response to the topics and questions identified in the Federal Register notice should be considered in conjunction with the general comments provided in the cover letter for this enclosure.

**A. The Regulatory Oversight Framework, Cornerstones, Significance Determination, Action Matrix, Performance Indicators and Their Thresholds.**

**1. Graphic Description of the Oversight Framework and Process**

Contrary to the language and its implications in the *Federal Register* notice, industry believes that NRC *is* currently meeting its regulatory mission through its current oversight process of ensuring that fuel facilities are operated in a manner that provides adequate protection of the public health and safety and the environment, and protects against radiological sabotage and the theft or diversion of special nuclear materials. As with any process, improvements can be made, but fundamentally the current program is adequate. During the meetings to date, industry has informed the NRC that, conceptually, it supports the overall framework and process, as depicted on the graphics distributed to date, as one that could conceivably result in a more risk-informed, objective, transparent and predictable revised fuel cycle oversight process (FCOP). That being said, the proof is in the design of the FCOP and its full implementation which is, in industry's opinion, a few years away. As such, we would note that the graphics do not, in and of themselves, accomplish what is stated in this section of the FRN, e.g., "facilitate greater regulatory attention;" "give timely and understandable assessments."

**2. Cornerstones**

During the four meetings to date, the potential set of cornerstones has been discussed in a relatively limited manner. However, clear alignment has not been reached, in part, because until such time that we collectively work through examples of how the significance of inspection findings would be determined in each cornerstone and whether performance indicators are indicated, final decisions on the appropriate set of cornerstones cannot be made. For example, there is not alignment on the "information security" cornerstone. In addition, it is conceivable that during initial implementation of revised FCOP, modifications to the cornerstones might be indicated. At this time, we reserve judgment on whether the NRC has identified the most appropriate set of cornerstones for the FCOP and trust there will be more dialogue on this topic in the coming months. There has also been some acknowledgement that in fact not all the cornerstones necessarily apply to all the fuel facilities due to their diversity, scope of activities and regulatory basis. An example of this is whether a facility even requires an emergency plan for their operations.

**3. Significance Determination Process**

The Significance Determination Process (SDP) and its related definition of "performance deficiency" are key attributes of any revised FCOP. While the NRC has introduced the concept, had some discussions with industry on the SDP, and drafted the shell of corresponding guidance for industry comment, much discussion is needed on the SDP by using specific examples of potential inspection findings and applying the SDP to gain a fuller understanding of where the findings would be categorized on the action matrix. Conceptually, industry supports a revised process whereby findings that are not risk-significant are dispositioned to the licensee for action within its own corrective

action program and the finding is not escalated for NRC action. However, the definition of performance deficiency which is the "trip wire" for entering into the SDP has been discussed but alignment has not been reached. We understand that the NRC plans to issue additional guidance documents that will further illustrate the SDP, and that it has offered to conduct a public meeting where potential inspection findings would be subjected to the SDP to allow industry the opportunity to more fully understand the process and its potential outcomes.

#### **4. Performance Indicators and Associated Thresholds**

Based on the limited discussion to date with the NRC on formulation of performance indicators and previous experience working with the NRC during the 1999-2002 timeframe to develop indicators, industry is not convinced that performance indicators can or should be developed for use in the revised FCOP. Specifically, it is not clear that the diverse and limited set of fuel facilities lends themselves to a common set of performance indicators or warrants this level of complexity given their radiation safety risk profile compared to those operating commercial nuclear power reactors. The notice states that the indicators would be "indicators of facility performance that, when thresholds are crossed, reveal adverse trends that warrant increased regulatory oversight." This purpose appears to be redundant with that of the inspection and SDP. It is not clear what additional information or insights would be gained from a performance indicator process that would not already be apparent through a licensee's own management measures, corrective action program, monitoring of self-imposed standards or limits or other processes or procedures that are used daily to ensure plant and personnel safety. At this time, industry does not support the development of performance indicators due to the diversity of scope and regulatory basis for the fuel facilities and their diverse absolute risk profiles and such efforts could diminish the quality and timeliness of the core oversight process improvements. However, industry is willing to engage NRC in further discussion on this matter.

#### **5. Action Matrix**

Based on discussions to date, industry agrees that the concept of an action matrix where the NRC's response to a finding, and resulting action, is determined by the risk significance of the inspection findings and the NRC relies more heavily than it does today on a licensee's corrective action program has merit. However, additional discussion on the matrix, its step-wise approach, the NRC's expectation for and reliance on a licensee's corrective action program and other elements is needed. It should also be recognized that a licensee's CAP is a voluntary initiative and is not required by NRC regulations. Also, discussing how sample inspection findings would be processed through the SDP and categorized on the action matrix will be useful in increasing industry's understanding of this proposed approach. As such, we look forward to learning more about the action matrix concept.

#### **B. Risk-Informed Baseline Inspections**

As this section of the *Federal Register* is written, someone could infer that the NRC does not have an inspection program in place today that provides the NRC reasonable assurance that the agency's safety and security missions are being met, when in fact they are being met. The NRC should not consider "throwing the baby out with the bath water." Instead, the NRC should work with industry to identify key insights and risk information, available in the NRC-accepted site-specific Integrated Safety Analyses, which would inform the NRC's current baseline inspection to make it more risk-informed and to help the NRC prioritize its inspection resources. At present, fuel facilities are subject to hundreds of hours of baseline inspections without regard to whether this is an appropriate amount for any one site. By year's end, some facilities have experienced inspection hours which exceed four months, even at sites with resident inspectors or without a significant event or reactive

inspection. The baseline inspection hours are then supplemented by reactive inspections, operational readiness reviews or other NRC reviews. Given the relative low public health and safety risk from licensed material at these sites, this amount of inspection hours seems excessive. As such, industry assumes that a more risk-informed approach would result in more targeted inspections that focus on the most risk significant processes and operations so that the NRC and facility resources are used more effectively to ensure plant safety and security.

## **C. Assessment Process**

### **1. Frequency of Assessments**

The Federal Register notice states that licensees would be subject to continuous, semi-annual, annual and biennial reviews of licensee performance and asks for feedback on this frequency. It is important to note that such an approach represents a significant increase over current practice in NRC resources which corresponds to a significant increase in licensee resources needed to support an increased NRC assessment effort. There is no evidence to suggest that the current state of fuel cycle facilities or inspection findings in recent years warrants this level of increased assessments. In fact, such an approach appears overly burdensome in the absence of a health and safety or security problem at a particular facility or a generic issue across the industry that needs to be addressed in a comprehensive and near term manner. At present, the staffing level at fuel cycle facilities would likely not be able to support such an increased burden without taking critical resources from oversight of day-to-day licensed activities.

### **2. Communicating Assessment Results**

The notice describes a process where licensees and stakeholders would receive more information more routinely on the licensee's performance. We applaud NRC efforts to make its process and findings more transparent to all stakeholders including licensees. In this regard, industry suggests that, even under today's oversight program, the NRC should consider including in its periodic reports and public meetings more balanced information that would reveal the positive aspects of a licensee's program as well as any inspection findings. If the public were provided more information with regard to the extensiveness of NRC's inspections, it is possible that their confidence would increase regarding the licensee's performance and NRC's credibility might increase if the rigor of its regulatory processes were more comprehensively discussed and represented during public meetings and documented in its final reports.

## **D. Implementation**

The Federal Register notice does not provide a timeline with milestones for implementation of the revised FCOP. Industry suggests that the NRC engage with stakeholders including the industry on development of a detailed resource loaded project plan that would include the milestones necessary to fully develop and implement a revised process and demonstrate the interdependencies of the activities, so that both the NRC and industry could support this effort in a meaningful and realistic manner while still operating the facilities in a safe and secure manner.