POLICY ISSUE
NOTATION VOTE

March 19, 2010 SECY-10-0031

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: REVISING THE FUEL CYCLE OVERSIGHT PROCESS

PURPOSE:

To request Commission approval of the staff's plan to develop a fuel cycle oversight process (FCOP) that is more risk-informed and performance-based. The goal is to provide a more objective, predictable, repeatable, and transparent assessment of licensee or certificate holder (licensee) performance.

SUMMARY:

Currently, the U.S. Nuclear Regulatory Commission's (NRC's) oversight of fuel cycle facilities consists of both planned and reactive inspections, with enforcement and periodic assessments based on the findings of those inspections. This existing oversight process is effective and ensures safety and security. A proposed revised performance-based inspection process could incorporate risk-informed assessments measured against predetermined thresholds for integrated safety analysis (ISA) or other risk assessment related findings. This will include findings in nuclear criticality safety, chemical process safety and worker and public radiation dose from accidents. Significance determinations for findings in other areas, such as security, emergency preparedness and transportation safety, could be more deterministic. The staff considered two options for incorporation of risk assessment results, one quantitative and one qualitative. From these objective thresholds, the NRC can determine with greater predictability whether a licensee with declining performance warrants additional oversight. By differentiating inspection findings to identify those of very low safety or security significance, the proposed process will allow licensees to resolve deficiencies of very low safety or security significance through their own corrective action programs (CAPs) without additional oversight from the NRC. This will permit both licensees and the NRC to focus their resources on more risk-significant activities.

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The NRC staff considered including performance indicators (PIs) in the FCOP in a manner similar to that used in the Reactor Oversight Process (ROP); however, the diversity of processes and hazards among the fuel facility licensees impairs the effectiveness of generic PIs. Instead the staff proposes to develop site-specific, quantitative performance metrics for use in the inspection and assessment programs.

The NRC staff does not intend for the revised oversight process to create new regulatory requirements; instead, it will institute a well-defined process for NRC action. Specifically, the NRC staff proposes to conduct supplemental inspections (i.e. above and beyond the number and type that are normal for a well-performing facility) for licensees whose performance shows risk-significant deficiencies based on objective criteria.

The ultimate deliverables will include: (1) risk-informed program-level documents presented in Inspection Manual Chapters (IMCs); (2) specific inspection procedure guidance for activities not currently contained in the fuel cycle oversight process; (3) a revised Enforcement Policy; and (4) a more objective and predictable performance assessment process. To achieve these goals, the staff proposes to develop a FCOP during fiscal year (FY) 2011 through FY 2014 as described in the enclosure. A successful revised FCOP will allow NRC actions and conclusions to be more objective, predictable, and transparent to all stakeholders, and repeatable for findings of comparable significance.

The NRC staff plans to continue internal and external stakeholder involvement (NRC staff and management, licensees, members of the public, etc.) throughout the program development. This includes publication of draft work products for public comment, public meetings, use of the www.regulations.gov web site, and internal NRC staff communications.

BACKGROUND:

Regulatory Principles and the Need for Change

Since 1999, the NRC has undertaken several initiatives to examine its oversight process for fuel cycle facilities. These examinations included all facilities either licensed or certified under the provisions of the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, “Domestic Licensing of Special Nuclear Material”; conversion facilities licensed under Part 40, “Domestic Licensing of Source Material”; or Part 76, “Certification of Gaseous Diffusion Plants.” The goal of these initiatives has been to establish a fuel cycle facility oversight process that is more risk-informed, performance-based, predictable, consistent, and objective, based on the agency’s positive experience with the 1999 revision to the Reactor Oversight Process.

Over the last decade, the staff implemented incremental revisions to inspection procedures and limited changes to the oversight process. While the staff has made progress by incorporating ISA insights into the current inspection and enforcement processes, the overall process continues to have substantial subjectivity in the determination of enforcement actions, assessment of licensee performance, and consequent staff decisions regarding levels of inspection. Therefore, the staff concluded that a comprehensive effort to develop a revised process was warranted to achieve the stated objectives.

Previous Commission Guidance and Direction

On August 16, 1995, the NRC published its "Final Policy Statement for Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" in the *Federal Register* (60 FR 42622). It stated the following, in part:

> This statement presents the policy that the NRC will follow in the use of probabilistic risk assessment (PRA) methods in nuclear regulatory matters. The Commission believes that an overall policy on the use of PRA methods in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that will promote regulatory stability and efficiency. In addition, the Commission believes that the use of PRA technology in NRC regulatory activities should be increased to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach.

The staff interprets this to mean that, where practical, it should use PRA methods to promote regulatory stability and efficiency. When the NRC revised 10 CFR Part 70 in 2000, the NRC did not require licensees to develop PRAs, but rather it required them to develop more qualitative ISAs and identify items relied on for safety (IROFS). Licensees and the NRC use the fuel cycle facility's ISAs or safety analysis reports (for licensees without ISAs) to gain risk insights regarding credible events with significant safety consequences, and the NRC will build on these insights in the development of the FCOP. For the conversion facility licensed under 10 CFR Part 40, and for the Gaseous Diffusion Plans certified under 10 CFR Part 76 which do not have ISAs, the NRC will utilize the risk assessment in their safety analysis reports.

In 1999, following the initial success of the ROP, the Commission prompted the NRC staff to determine whether the fuel cycle facility oversight process could be improved using elements similar to those in the ROP. In 2000, the NRC revised 10 CFR Part 70 to require ISAs and the resultant IROFS for fuel cycle facilities. At the same time, the NRC staff also began to consider a risk-informed FCOP, using selected elements from the ROP. In Staff Requirements Memorandum (SRM) 00-0222, dated January 17, 2001, the Commission directed the staff to proceed with the proposed new FCOP, cautioning that it should not negatively affect implementation of the revised 10 CFR Part 70. The staff engaged stakeholders, including the Nuclear Energy Institute (NEI), fuel facility licensees, and members of the public, in developing a new FCOP. In a March 18, 2002, memorandum to the Commission, the Executive Director for Operations recommended deferring development of the new FCOP until after the licensees had completed the ISAs and submitted their ISA summaries and the NRC had reviewed and approved them. Licensees had also expressed a need to focus resources on completing the ISAs, and some were concerned about the costs and benefits of a new oversight process.

In the SRM dated June 30, 2005, in response to the briefing on the Agency Action Review Meeting, the Commission directed the staff to evaluate the feasibility of developing objective, transparent, risk-informed, and performance-based facility-specific PIs for the NRC's oversight process for fuel facilities. In May 2006, the staff provided an update on the feasibility of developing such PIs. The Commission, in June 2006, directed the staff to discontinue PI development for fuel cycle facilities.

On January 10, 2007, the Office of the Inspector General (OIG), in OIG-07-A-06, "Audit of the NRC's Regulation of the Nuclear Fuel Cycle Facilities," recommended that the staff fully implement a framework for fuel cycle oversight, consistent with a structured process, such as the ROP. In a February 13, 2007, memorandum in response to the audit, the Deputy Executive

Director for Materials, Research, State, and Compliance Programs stated that, as the staff gained more experience with the ISA process, it will make appropriate enhancements to the inspection and licensing procedures, to establish a more structured program, similar to the ROP. The memorandum also noted that, because various fuel cycle facilities possess different operational characteristics and under different regulations, the ultimate structure of the FCOP will use more qualitative, rather than quantitative, assessments of performance. Since February 2007, the staff has completed several actions outlined in the response to the OIG report. Attachment 1 to the enclosure describes these actions.

Following a March 17, 2008, briefing of the Commission on the state of NRC technical programs, the Commission issued an SRM dated April 3, 2008, "Staff Requirements – Briefing on State of NRC Technical Programs, 1:00 p.m., Monday, March 17, 2008, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)" (M080317B) (ML0809404390). This memorandum directed the NRC staff to "continue to make the fuel cycle performance review process more transparent and risk-informed. In making the improvements to the process the staff should consider developing performance measurements or metrics leveraging the integrated safety assessments completed by licensees that were recently approved by the NRC."

Following a February 5, 2009, briefing of the Commission on uranium enrichment, the Commission issued an SRM dated February 17, 2009, "Staff Requirements Memorandum – Briefing on Uranium Enrichment, 9:30 a.m. and 1:30 p.m., Thursday, February 5, 2009, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)" (M090205) (ML094900320). This memorandum directed that the staff should "continue its review of the FCOP and evaluation of whether that quantitative measures of performance will be applicable."

In response, the staff initiated a comprehensive effort to develop a new oversight process, one with improved objectivity, predictability, transparency, and consistency, and one that incorporates risk-informed and performance-based tools.

Staff Activities in 2009

In March 2009, the staff formed a steering committee to initiate and oversee the FCOP project. A *Federal Register* notice announced this initiative on September 3, 2009. The NRC used the www.regulations.gov web site to solicit comments on this project and to publish proposed guidance as it was developed. During 2009, the staff conducted five full days of public meetings to engage and inform NEI, industry representatives, and the public on a conceptual framework for the FCOP. The purpose of the meetings was to present the staff's vision of the FCOP revisions, explain how the process revisions will benefit the public, the NRC, and the industry, and seek stakeholder feedback on selected draft program documents. The public meetings resulted in the issuance of several major program documents for comments, and the staff had prepared 10 more for release when the NRC suspended project activities, in response to SRM-COMGBJ-09-0005 dated November 20, 2009.

In addition, the NRC staff began work with Brookhaven National Laboratory (BNL) to develop the technical basis for establishing quantitative risk-informed thresholds, for significant safety findings, that could be used in the revised FCOP. NRC risk experts have provided guidance to BNL and have developed the foundation for using quantitative risk thresholds. To ensure consistency, and to build on lessons learned throughout the NRC, the staff also held internal meetings on threshold development with risk experts from other NRC offices.

The thresholds and their basis documents will undergo extensive internal review, and the staff plans to brief the Advisory Committee on Reactor Safeguards and the Commission offices before their final adoption.

Staff Requirements Memorandum for COMGBJ-09-0005

The SRM associated with COMGBJ-09-0005 limited the FCOP revisions to 0.5 full-time equivalent (FTE) in the Office of Nuclear Material Safety and Safeguards (NMSS) and 0.5 FTE for Region II in FY 2010. It also directed the staff to gather and evaluate risk insights from ISAs and to prepare a plan for developing an integrated and phased approach to risk-informed fuel cycle facility oversight. The SRM directed the staff to provide the plan for Commission approval within four months. The staff's plan is enclosed.

DISCUSSION:

Objectives and Approach

Proposed Regulatory Oversight Framework

The revised oversight framework will build on a foundation of two strategic performance areas, safety and security. These areas will be supported by multiple cornerstones of safety and security (cornerstones), such as nuclear criticality safety, chemical safety, radiation safety, and physical security. Attachment 2a to the enclosure contains a graphic of the suggested framework, showing the proposed cornerstones. Within this defined framework, the staff proposes to assess licensee performance in a more objective and predictable manner using the results of a baseline inspection program coupled with published thresholds for action.

The key to the proposed FCOP revisions is that the NRC will be able to objectively and predictably determine appropriate levels of agency response to events and inspection findings informed by the risk-significance. Risk-significance would be defined by a significance determination process (SDP). Inspection findings would be measured against risk-informed thresholds for ISA-related findings, or more deterministic thresholds, for the findings not related to the ISA. Exceeding thresholds will produce a predictable agency response (e.g., additional inspection efforts, confirmatory action letters, and orders). This achieves a major objective of defining both licensee and NRC actions in a transparent and predictable way. Specifically, an "action matrix" to be developed for the fuel cycle facilities will establish predictable levels of agency response for a given level of performance. These individual components are described in more detail in the following paragraphs, and shown graphically in Attachment 2b to the Enclosure.

Proposed Risk-Informed Baseline Inspection Program

The foundation of the proposed oversight process is the baseline inspection program. The baseline inspection program will be applied to each facility regardless of performance consistent with the scope of licensed activities. It consists of a defined level of inspection effort in each cornerstone. The level of effort should be focused on the areas of greatest risk and on assessing safety and security performance over programmatic implementation. Because of the variability among fuel facilities, a broader set of baseline definitions is needed for fuel facilities than for operating reactors.

The existing core inspection procedures do not consistently identify inspection hours and sample sizes, allowing some inspector discretion to address the variations in facility processes and safety or security significance. In addition, risk insights from ISA implementation have not been systematically incorporated into a sample selection process.

The staff proposes to develop the technical basis for identifying the most risk-significant IROFS and structures, systems, and components to inform the sample selection process for baseline and, as necessary, supplemental inspections. During preparation for the operational readiness reviews of new enrichment facilities, for example, the staff performed a risk ranking of IROFS for the Louisiana Enrichment Services and U.S. Enrichment Corporation gas centrifuge enrichment facilities. The staff proposes to incorporate insights from that experience into a broader effort to develop facility-specific IROFS risk-ranking at a level sufficient to inform sample selection by inspectors. As the core inspection procedures are revised to incorporate these risk insights, the staff proposes to holistically evaluate the allocation of inspection effort and samples among the baseline procedures to ensure that the baseline inspection program will be implemented at each facility in a manner that is risk-informed, predictable, and transparent. The staff will also consider the safety-security interface as they revise the procedures, although to fully address this interface, the NRC will need to establish a requirement to consider this analogous to the requirement in 10 CFR Part 73.

Finally, the staff expects that the FCOP revision will include changes to the Enforcement Policy to allow for the adjudication of inspection findings in a manner more similar to the ROP than traditional enforcement. Forgoing elements of the traditional process, such as written responses to notices of violations, will be based on a demonstration that the licensee has an effective program for problem identification and resolution. Therefore, the staff will include a problem identification and resolution procedure in the baseline inspection program.

Assessment Process

The assessment process begins when an event or inspection finding is identified and evaluated for risk-significance. Similar to the ROP, the staff expects that this population of issues may include any risk-significant condition related to licensed activities, whether or not the condition may be tied to violation of a specific regulatory requirement. The assessment process will include an SDP, an action matrix for determining regulatory response, and a performance assessment process to clearly communicate to licensees and other stakeholders.

The proposed SDP would include risk-informed tools for the ISA-related cornerstones and more deterministic methods, similar to those for certain ROP cornerstones, for the non-ISA cornerstones (e.g., security and emergency preparedness). Short-term actions in the enclosed FCOP plan are focused on technical basis development for the SDP, including defining risk thresholds for characterizing inspection findings. These thresholds will also inform the action matrix. The staff considered two alternatives for the assessment of ISA-related and other risk assessments findings in developing the risk thresholds for the SDP, one qualitative and one quantitative. Both options would use qualitative tools for findings of very low safety significance, but the quantitative option would include development of enhanced quantitative tools for evaluation of more significant findings.

The qualitative option would be aligned with the qualitative nature of most ISAs and would build on the results of staff work to risk-inform enforcement for fuel cycle facilities. Recently, the NRC staff developed a revision of the Enforcement Policy that relies on qualitative risk assessment based on ISAs. The staff is awaiting Commission review of the Policy before finalizing an

implementing procedure. In the qualitative option for the risk assessment of ISA-related findings, the staff would use the qualitative tools developed to implement the revised Enforcement Policy in developing risk-significance of findings, thresholds, and the SDP. Risk determinations would be based on the qualitative likelihood of the degraded condition as provided in the ISA or safety analysis report, the consequences defined in the ISA or safety analysis report, and the duration of the degraded condition. For findings involving an unanalyzed condition, the staff would perform an analysis of the finding using the qualitative methods in NUREG-1520, "Standard Review Plan for the Review of License Applications for a Fuel Cycle Facility," dated March 2002. Recognizing the differences in ISAs and risk assessments, the staff will examine outcomes to ensure that, when judged against similar findings among similar processes at the different licensees, the results are predictable, objective, and reasonable.

In the quantitative option, the staff would use qualitative risk assessment tools to determine if an ISA-related or other risk assessment finding was of potentially greater than very low safety significance. For a finding potentially greater than very low safety significance, the staff would develop a quantitative risk assessment methodology to determine changes in risk as a result of the finding. The staff would have to develop human reliability and equipment reliability tools to provide a more quantitative probability of an occurrence. This probability would be used with the consequences for the affected scenarios in the ISA and the duration of the degraded condition. For findings involving an unanalyzed condition, the staff would use the more quantitative probabilities in conjunction with the qualitative methods for consequence determination consistent with the guidance in NUREG-1520.

The "Pros" and "Cons" for the two options for risk assessment of ISA-related inspection findings are:

Option 1: Qualitative risk determination process

Pros: Risk assessment will be closely linked to risk as shown in ISAs or safety analysis reports which were generally qualitative assessments.

A qualitative process will meet the goals of developing the revised FCOP in that it will result in risk-informed, objective, predictable, and transparent risk determinations and thresholds of significance.

Stakeholders and other members of the public have already reviewed the underpinning of the process during the revision to the Enforcement Policy.

Fewer resources will be required to develop FCOP tools based on this process.

Cons: The risk assessments might not necessarily be directly comparable among licensees for the same finding because of differences in ISAs or other risk assessments.

The risk assessment results might indicate higher than actual risk due to conservatisms and margins in the development of the ISA that are not documented in the ISA.

Option 2: Quantitative risk determination process

Pros: The process will result in a more precise estimation of relative risk and risk degradation. The results will be based on standard tools for quantifying human and equipment

reliability and thus will be objective and repeatable among licensees for similar findings.

Cons: The process will be based on numerical analyses using human and equipment reliability tools and thus will be more complex and less transparent.

Development of the process will require more resources than the qualitative approach.

This enhanced process would be applied to a small number of findings each year and the outcome of dispositioning the findings will likely not be significantly enhanced.

A proposed action matrix will be used to determine the appropriate regulatory response to findings that have not screened out of the SDP as having very low significance. Incorporating the SDP risk thresholds and considering all open inspection findings, the action matrix will provide a transparent, predictable, and repeatable process for identifying the regulatory response to a licensee's performance. Potential regulatory actions will include supplemental inspections, management meetings, and issuing confirmatory action letters or orders. The structure of the action matrix will provide for a predictable agency response that is based on a licensee's performance.

Finally, the proposed performance assessment process will use the output of the action matrix to provide transparent and predictable communication of the staff's assessment of licensee performance and associated regulatory response to the licensee and other stakeholders. This communication will include a web site where members of the public could review assessment results and include periodic public meetings to discuss assessment results. This will replace the current licensee performance review process with a process that is more objective, predictable, and efficient.

Enforcement Process

The staff plans to rewrite the Enforcement Policy to be more like the ROP process than traditional enforcement for licensees with CAP that meet certain criteria. In the revised process, the NRC first assesses a potential finding to determine if there were: (1) actual safety or security consequences; (2) potential safety or security consequences; (3) the potential for affecting the NRC's ability to perform its regulatory function; or (4) any willful aspects of the violation. In the rare instances where the violation is willful or affects the NRC's ability to perform its regulatory function, the NRC would impose traditional enforcement measures.

All other violations will be evaluated in the SDP to determine the level of safety or security significance. Licensees must correct findings of very low safety or security significance, but given the limited significance of the findings, the licensees will not be subject to formal enforcement action. Also, if these findings are entered into and dispositioned by the licensee's CAP, they will only be listed as non-cited violations in inspection reports. This revised process results in a significant reduction in both regulatory and administrative burdens for the NRC and the licensees. The staff considers this improvement, alone, to be a major benefit of the FCOP revision.

Performance Indicators

The ROP uses a broad sample of data from risk-informed inspections and PI data in risk significant areas to assess licensee performance. Power reactor licensees continue to measure and voluntarily report PI data to NRC. The PIs are not intended to provide complete coverage

of every aspect of plant design and operation, but they are intended to be an effective indicator of licensee performance in the measured areas. In developing the FCOP, the NRC staff was aware that fuel cycle licensees use a variety of internal corporate performance measures to monitor safety, security, and facility performance. Licensees also already provide a variety of routine and event reports to the NRC, although the thresholds for such reports are not necessarily risk informed or consistent. With this in mind, and given the successful use of PIs in the ROP, the staff thought it reasonable to plan to include PIs as a component of the FCOP.

However, during meetings in 2009, licensee representatives indicated that they were not sure how to designate a PI or develop the associated thresholds. Concerns were also expressed regarding the ability of fuel cycle facilities to develop an effective PI system due to the significant differences in the operations and risk among facilities, as well as their lack of experience with using PIs. The licensee representatives raised concerns about the difficulty that members of the public would have in attempting to compare the performance at one facility to that of another, leading to potentially inaccurate perceptions of relative risk. In addition, the licensee representatives expressed the view that the benefits from PIs were small compared to the costs associated with PI development, implementation, and maintenance. These concerns generally aligned with the staff's analysis of PIs for fuel cycle facilities, which led to the June 2006 Commission directive to discontinue the development of PIs.

The staff agrees that the diversity of processes within a given facility and among facilities complicates the development of statistically significant PIs. Although the diversity among fuel cycle facilities does not preclude applying a uniform set of PIs, further investigation of this issue may reveal the need to develop PIs unique to each facility or types of facilities. The staff notes that this approach would represent a departure from the current application of PIs in the ROP.

Given the challenges associated with the development and use of PIs in the FCOP, the staff considered the merits of developing a revised FCOP without PIs. In particular, the staff assessed whether a risk-informed, performance based fuel cycle facility inspection and assessment program could meet the goals of the FCOP (more objective, predictable, repeatable and transparent). The staff concluded that these goals could be met through the development and application of revised fuel cycle facility inspection procedures focused on safety- and security-significant license activities, an SDP with thresholds based on objective criteria, and with an Action Matrix to support predictable NRC actions.

As a result, the staff recommends placing a lower priority on the development and implementation of PIs because: (1) the goals of the FCOP can be met without including PIs, at this point; (2) the administrative process required to develop and use PIs is substantial (see attachment 3 to the enclosure) ; (3) the staff anticipates PI development to be a lengthy and resource intensive effort based on ROP experience; and finally (4) absent rulemaking, PIs will remain a voluntary aspect of the FCOP. Thus, given the lack of industry interest in, and the complexity of, developing PIs, the staff proposes to defer the development of PIs, and to focus its initial efforts on developing the bases for the SDP and other elements of the FCOP. The staff will continue to evaluate various quantitative measures of performance for potential development and future incorporation into the FCOP.

Knowledge Capture for Efforts to Date

In 2009, the staff made a significant effort to discuss with stakeholders concepts of a risk-informed oversight process. In parallel, the staff provided draft versions of selected revised FCOP basis documents and IMCs for review and comment. As discussed earlier, the NRC

issued several major documents for comment and had prepared 10 more for release when it suspended the current effort in response to Commission direction in the SRM for COMGBJ-09-0005. These documents and the comments received provide a foundation for future work. They are cataloged and stored and will be reviewed as part of a future development phase, following Commission direction on the proposed plan for revising the FCOP.

Program Office Role in FCOP Development and Implementation

The staff plans to follow the directives of IMC 2600, "Fuel Cycle Facility Operational Safety and Safeguards Inspection Program," dated January 27, 2010, which assigns overall program direction (policy) for the fuel cycle inspection program NMSS and assigns general responsibility for implementation of the inspection program elements to Region II. Two components of the inspection program, criticality safety and material control and accounting, have been implemented from NRC Headquarters for many years based on decisions made in 1995 and the late 1980s, respectively. As part of FCOP development, NMSS will review the basis for those earlier decisions in light of the consolidation of fuel facility oversight in Region II and the general principle that the regions generally are best suited organizationally to conduct inspections and implement the oversight process, with support from Headquarters. The staff will provide any resulting recommendations to the Commission. NMSS (Division of Fuel Cycle Safety and Safeguards or, FCSS) will lead the continued development of the FCOP and will be the focal point of contact for internal and external stakeholders. However, the Office of Nuclear Security and Incident Response, the Office of Enforcement, and Region II will provide key support and, under NMSS project management, may be responsible for developing individual components.

Finally, as the FCOP is developed and implemented, the staff will build the processes and procedures for ongoing self-assessment, periodic evaluation for re-alignment of baseline procedures and associated resources, and oversight of program implementation. These functions are not currently funded, but in the future will reside in NMSS/FCSS.

RECOMMENDATION:

Approve the attached plan to develop an FCOP using the qualitative option for risk assessment of ISA-related and risk assessment findings with potentially greater than very low safety significance. In light of the upcoming Commission meeting on this topic, the staff recommends making this paper publicly available in advance of the meeting.

The staff's plan for revising the FCOP is premised on the central theme of making the oversight process more closely aligned with the NRC's ROP. As such, the options described in this paper are minor variations on this theme. The staff recognizes that the Commission has a broader range of alternatives available, including maintaining the current FCOP, as well as making more modest adjustment to enhance the effectiveness and efficiency of the current oversight process without the more significant modifications that would be necessary to adopt the attributes of the ROP. This also includes other alternatives, such as phasing the revisions to the oversight process, such as by making more modest enhancements to the Licensee Performance Review process and the enforcement policy in the near term, followed by more substantive revisions that adopt the ROP approach in the intermediate and longer term. The NRC staff is prepared to implement Commission direction in an open and transparent manner with stakeholders.

The plan, schedule, and resources to support the FCOP revisions will be adjusted in response to Commission direction.

RESOURCES:

Resources for developing the proposed revised FCOP are described in the Enclosure. For the staff's recommended option, resources are included in the FY2011 President's Budget. Resources for FY2012 through FY2014 will be included in future budget requests.

COORDINATION:

The Office of the General Counsel has no legal objection to the FCOP revision. The Office of the Chief Financial Officer reviewed this Commission paper for resource implications and has no objections.

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosure: FCOP Project Plan and
Resource Estimates

FUEL CYCLE OVERSIGHT PROCESS
PROJECT PLAN AND RESOURCE ESTIMATE
Revision 0

Executive Summary

In 2000, the U. S. Nuclear Regulatory Commission (NRC) revised its rules to establish Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," to the Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," and require certain fuel facility licensees to develop an integrated safety analysis (ISA) and identify items relied on for safety (IROFS) to manage the risk of certain high- and intermediate-consequence events. In the intervening decade, the staff has implemented limited revisions to inspection and enforcement guidance to incorporate ISA insights; however, the processes applied by the staff for evaluating licensee performance, determining the need for reactive and supplemental inspections, and communicating licensee performance to stakeholders continue to lack consistent application of risk insights and are overly subjective.

This plan provides a blueprint for a multi-year effort to systematically revise the fuel cycle oversight process (FCOP) to make it more risk-informed, performance-based, objective, predictable, repeatable and transparent. The products of this effort will be: (1) a risk-informed, repeatable significance determination process (SDP) to assess the risk significance of inspection findings and events; (2) an improved baseline inspection program incorporating risk insights into a sample selection and providing a more predictable and transparent level of effort; (3) an action matrix to provide a transparent, objective and repeatable method for staff decisions regarding increasing inspections above the baseline based on licensee performance; (4) a revised Enforcement Policy to incorporate ISA insights and provide credit for an effective corrective action program (CAP) as appropriate; (5) a new problem identification and resolution (PI&R) or CAP baseline inspection that provides an ongoing basis for crediting licensee corrective actions in the enforcement process; and (6) a program for ongoing oversight of the new FCOP to ensure effective implementation and continuous improvement.

In addition to developing and implementing the products described above, the staff will work to develop risk-informed quantitative performance metrics and potentially performance indicators to enhance the objective assessment of licensee performance and, where possible, reduce inspection efforts. Finally, the staff will re-examine the basis of previous staff decisions to conduct portions of the fuel facility inspection program (i.e., criticality safety and material control and accounting) from the program office rather than the region and make a recommendation regarding potential consolidation of the inspection program.

This plan describes program development through fiscal year (FY) 2013, with full implementation in FY 2014. The staff has estimated the resources needed to support this plan and schedule and will request these resources through the normal budget process.

Enclosure

I. Short-Term Actions (FY 2010-FY 2011)

Short-term actions focus on the development of the technical bases for the key elements of the FCOP. These technical bases will serve as the foundation for further development of the regulatory oversight process.

a. Option 1- Technical Basis Development for Qualitative Risk Assessment for Areas Related to ISA.

The ISAs include the areas of nuclear criticality safety, chemical process safety, radiation dose to the public from accidents, and radiation dose to workers from accidents.

i. Develop a tool to identify findings of very low safety significance.

(a) Task: Develop a flow chart screening tool for inspection staff to use to determine which ISA-related findings are of very low safety significance.

(b) Action: Licensees generally performed qualitative risk assessments as they developed their ISAs to meet the requirements of Subpart H of 10 CFR Part 70. The staff revised the Enforcement Policy, to focus on qualitative risk assessment based on these ISAs in determining the Severity Level of violations. (This revised Enforcement Policy is awaiting Commission approval.) The staff has developed an implementing procedure in the form of an Inspection Manual Chapter (IMC) that uses a qualitative risk assessment tool. This proposed IMC is undergoing internal NRC review. The staff plans to use the qualitative tools developed for the revised Enforcement Policy as a basis in the FCOP for development of a screening method and tool for inspection staff to use to identify inspection findings of very low safety significance. The staff plans to base this tool on each licensee's ISA and/or safety analysis report. The process will be based on the qualitative likelihood of the degraded condition as provided in the ISA, the consequences from the ISA, and the duration of the degraded condition. For findings involving an unanalyzed condition, the staff plans to perform an analysis of the finding using the risk assessment methods in NUREG-1520, "Standard Review Plan for the Review of License Applications for a Fuel Cycle Facility."

(c) Deliverables: A flowchart to be used by inspectors to identify findings of very low safety significance.

ii. Develop SDP flowcharts.

(a) Task: Develop SDP flow-charts for ISA-related findings.

(b) Action: In addition to the screening tool for inspection findings of very low safety significance, the staff will also develop a flowchart that could be used in an SDP that will establish thresholds for safety significant findings. This flowchart will, as above, use the tools developed as part of the Enforcement Policy revision, based on the ISA, as a basis.

This tool will be used to determine the safety significance of findings that were screened as being potentially greater than very low safety significance.

(c) Deliverables: A flowchart for use in an SDP for ISA-related inspection findings.

iii. Compare findings using the SDP and the traditional process.

(a) Task: Test SDP flow chart against previous findings and violations

(b) Action: The staff will use the screening tool and SDP flowchart to determine the safety significance of recent (within the past 5 years) inspection findings to evaluate the results against findings whose risk significance was established using traditional enforcement. The staff will evaluate the results to determine what changes, if any, should be made to the screening tool and SDP flowchart, and then make any needed changes.

(c) Deliverables: Evaluation of the screening tool and SDP flowchart to prepare a final draft screening tool and flow chart suitable for incorporation into IMCs and procedures.

iv. Evaluate potential performance metrics.

(a) Task: Evaluate the use of performance metrics in the oversight program.

(b) Action: The staff plans to evaluate information reported by licensees under existing requirements (e.g., effluents, worker dose) to assess its potential use in assessing and communicating licensee performance.

(c) Deliverable: Report on potential performance metrics.

v. Include non-ISA facilities (i.e., gaseous diffusion plants).

(a) Task: Assess issues in applying the FCOP to non-ISA facilities.

(b) Action: The staff will review and document the status of risk-related information at fuel cycle facilities that do not perform ISAs. The staff will assess the feasibility and other issues if the FCOP were to be applied to these facilities. This assessment will occur in two stages: an initial quick look and a more thorough examination that includes some test cases of risk-significance determination. A preliminary report will include information from the initial quick look. The currently proposed FCOP only uses ISA information to supplement the information needed by the NRC risk analyst to perform assessments. The staff will determine if barriers exist that will prevent independent risk assessments for inspection findings of potentially greater than low significance.

(c) Deliverables: Preliminary report on risk-related information and issues at non-ISA facilities; report on issues in applying the fuel cycle oversight program to non-ISA facilities.

b. Option 2 - Technical Basis Development for Quantitative Risk Assessment for Areas Related to ISA

i. Review ISA methodologies used by licensees.

(a) Task: Review ISA methodologies.

(b) Action: The staff has already completed a preliminary summary of the status of ISA methods used by licensees and needs to document it as a reference guide for NRC risk analysts. The staff will include Agencywide Documents Access and Management System (ADAMS) accession numbers for documents describing current licensee ISA methods. The guide will include only top level descriptions of methods, likelihoods, and consequence criteria, not detailed descriptions of licensee procedures. This project will require a small level of NRC staff effort. This information will not be included in IMC guidance on significance determination but kept as a separate reference.

c) Deliverables: Memorandum summarizing ISA methods.

ii. Document and further review of qualitative risk-significance determination screening criteria for inspectors.

(a) Task: Document qualitative risk-significance determination screening criteria and guidance for inspectors, and review of existing assessment of actual inspection findings by NRC inspection staff.

(b) Action: The staff has completed preliminary work on developing a qualitative significance determination screening process and criteria for application by inspectors. The staff tested these criteria by applying them to past inspection findings. This application was hypothetical in that insufficient information was available to assess actual situations, so assumptions were made. The staff has prepared draft guidance documentation. Additional review is needed for these criteria. The inspection staff needs clear screening criteria and guidance so a wider group of inspectors should review the documents, which likely will lead to additional clarification in the guidance. This guidance will appear in the SDP section of an IMC. The agency will discuss the guidance at a public meeting, issue it for public comment, and revise it as appropriate.

(c) Deliverables: Final draft input to IMC SDP guidance on qualitative risk-significance determination screening by inspectors.

iii. Establish a basis for risk-informed significance determination thresholds.

(a) Task: Develop and document the basis for SDP risk-significance metrics and thresholds.

(b) Action: The objective is to develop and document the basis for SDP risk-significant metrics and thresholds. The staff has already completed initial documentation of trial thresholds and their bases. These have been reviewed but responses to comments and documentation remain. Metrics may also be supplemented by qualitative criteria, based on the review of actual inspection findings. The product will consist of preliminary SDP risk-significance metrics, thresholds, and criteria, to be made available for a trial application to actual inspection findings.

(c) Deliverables: Final draft SDP quantitative risk-significance basis document.

iv. Test risk thresholds against a limited set of inspection findings.

(a) Task: Conduct a limited test of the risk-significance determination process.

(b) Action: Brookhaven National Laboratory (BNL), with input from the NRC staff have selected eight fuel cycle events and prepared preliminary parts of their risk analysis. They will calculate the trial SDP risk metrics for these events and compare them to the trial thresholds to determine levels of significance. The NRC staff, with input from BNL, will make determinations regarding the usefulness of thresholds; the need for other criteria; and the need for further methods, data, and guidance to support such risk-significance analyses. Contractors will primarily perform the work with staff review.

(c) Deliverables: Initial report on the trial test of risk-significance determination thresholds.

v. Test risk thresholds against a wider set of actual and hypothetical inspection findings.

(a) Task: Test risk thresholds and significance determinations.

(b) Action: There is a need to test the trial risk significance determination metrics, thresholds, and process against a set of past actual and hypothetical inspection findings that represents a wide spectrum of possible findings. Such tests will result in a spectrum of examples, each rated in significance levels for public and worker metrics. The frequency of occurrence of each sample type of finding may be estimated to determine how often each level of significance may occur in practice. This will communicate the practicality of the trial thresholds and criteria. Hypothetical test cases are needed, because actual findings that are of greater than very low safety significance are too few to be representative. NRC staff, including inspectors, will develop these hypothetical findings.

(c) Deliverables: Report on tests of trial risk thresholds and significance determinations.

vi. Prepare the preliminary Risk-Significance Assessment Handbook for fuel cycle facilities.

(a) Task: Prepare final draft quantitative risk-significance assessment guidance for fuel cycle facilities.

(b) Action: This guidance will provide procedures, guidance, and references for the NRC inspectors and risk analysts to use in assessing the quantitative risk significance of inspection findings for fuel cycle facilities.

(c) Deliverables: Outline of guidance and final draft guidance on quantitative risk-significance determination for fuel cycle facilities.

vii. Develop and validate human-reliability risk-assessment tools and data applicable to fuel cycle processes.

(a) Task: Develop human reliability tools for fuel cycle risk-significance assessment.

(b) Action: The majority of fuel cycle inspection findings involve human errors, such as a lack of current procedures, absence of postings, failure to follow procedures, or unauthorized process changes. Events have occurred involving human errors that were not analyzed in ISAs. The types of human error situations often do not fit the few categories for which error probabilities are available in the Savannah River Site Human Error Database. Thus, the NRC needs a simple tool analogous to that database that fits past experience at fuel cycle facilities. The NRC currently has simplified tools used in the Reactor Oversight Process (ROP) for human reliability analysis failure rates, but the agency will have to validate the tool for the new use. Based on staff scoping in FY 2010, it will conduct a small project in FY 2011 to develop an initial guidance document tool. This document may require supplementation to incorporate experience gained from applying the preliminary SDP to actual inspection findings in FYs 2012 - 2013.

(c) Deliverables: Fuel cycle human reliability tool.

viii. Develop and validate hardware-reliability risk-assessment tools and data applicable to fuel cycle processes.

(a) Task: Confirm the use of hardware risk-assessment tool for fuel cycle facilities.

(b) Action: Hardware failure data relevant to many fuel cycle processes already exists in WSRC-TR-93-262, “Savannah River Site Generic Database Development,” dated May 1998, and its successors. The staff should review this document to assess the reasonableness of its data for use in evaluating change in risk caused by deficiencies in process equipment in NRC-regulated fuel cycle facilities. The product will be an

NRC staff memorandum recommending the use of these data in the implementation phase in FY2012 – 2013. The agency will present this recommendation at a public meeting for comment.

(c) Deliverables: Memorandum with recommendations on hardware reliability data.

ix. Develop performance metrics.

(a) Task: Evaluate the use of performance metrics in the oversight program.

(b) Action: The staff plans to evaluate information reported by licensees under existing requirements (e.g., effluents, worker dose) to assess its potential use in assessing and communicating licensee performance.

(c) Deliverable: Report on potential performance metrics.

x. Assess risk-related information for non-ISA facilities (i.e., gaseous diffusion plants).

(a) Task: Assess issues in applying the FCOP to non-ISA facilities.

(b) Action: The staff will review and document the status of risk-related information at fuel cycle facilities that do not perform ISAs. The staff will assess the feasibility and other issues if the FCOP were to be applied to these facilities. This assessment will occur in two stages: an initial quick look and a more thorough examination that includes some test cases of risk-significance determination. A preliminary report will include information from the initial quick look. The currently proposed FCOP only uses ISA information to supplement the information needed by the NRC risk analyst to perform assessments. The staff will determine if barriers exist that will prevent independent risk assessments for inspection findings potentially greater than low significance.

(c) Deliverables: Preliminary report on risk-related information and issues at non-ISA facilities; report on issues in applying the fuel cycle oversight program to non-ISA facilities.

c. Technical Bases for Significance Determination for Non-ISA Areas.

The areas not included in the ISAs are emergency preparedness, occupational radiation protection (nonaccident), public radiation protection (nonaccident), physical security, and material control and accounting. (Information security will be considered for inclusion at a later date.)

i. Task: Develop a technical basis for significance determinations.

ii. Actions: The NRC staff plans to develop significance determination tools and a process for areas not included in the ISAs. The staff plans to use available non-ISA risk insights, such as radiation dose limits for workers and members of

the public, that are based on the health risk from radiation doses. Nonetheless, several of the SDP tools will be deterministic, as they are in the ROP. The staff plans to evaluate the SDP tools used in the ROP to determine if they provide insights on how to proceed with the fuel cycle SDP. For example, under public radiation protection, the FCOP process for evaluating findings in transportation safety might be very similar to that used in the ROP, given that the ROP significance determination is based on risk from radiation or contamination from, or on, shipping packages. The regulatory limits and public safety impacts for certain issues related to packages shipped by power reactors will relate directly to a similar shipment from a fuel cycle facility.

iii. Deliverables: Draft SDP flow charts for non-ISA areas suitable for incorporation into an SDP IMC in the medium-term phase.

d. Technical Basis for Baseline Inspections.

The baseline inspection program will apply to ISA-related and non-ISA-related areas. These technical bases will be developed in FY 2011.

i. Task: Develop technical bases for baseline inspections.

ii. Actions: The NRC staff plans a baseline inspection program that is risk informed and performance-based and that identifies the minimum level of inspection required for a licensee (regardless of performance) to give the NRC sufficient information, (1) to determine whether licensee performance is acceptable and the licensee is operating safely and securely in accordance with NRC requirements, and (2) to allow the NRC to identify indications of declining licensee performance before it affects public safety or security.

The staff plans to establish an expert panel of NRC technical staff to develop a baseline inspection program. Starting with the objective for a cornerstone, the expert panel will use ISA risk insights, operational experience, and regulatory requirements to develop key attributes that reflect whether each cornerstone's objectives are met. For example, the key attributes of an effective emergency response might include the readiness and availability of the emergency response organization (ERO), the reliability of appropriate facilities and equipment, appropriate ERO procedures, and adequate ERO training and testing. Based on key attributes, the expert panel will develop methods to monitor the licensee's performance regarding these key attributes, considering the use of performance metrics, performance indicators, and inspections. The expert panel will define what should be inspected, the scope of inspection, and methods of inspection (inspectable areas) to determine if all of the key attributes are adequate at a licensee's facility.

The expert panel will recommend the number of samples for inspectable areas. For example, it might recommend that an inspection procedure (IP) require between three and five scenario walkthroughs of emergency actions with a licensee's emergency directors to determine the effectiveness of their training. The expert panel might recommend the use of performance metrics in determining samples and sample sizes. For example, it might specify a lower sample number for walkthroughs for a facility that conducts quarterly emergency

drills with effective critiques.
The expert panel will also identify potential performance metrics for consideration in the future.

iii. Deliverables: A list of inspectable areas by cornerstone, recommended sample sizes, and potential performance measures in a form suitable for the development of IMCs and IPs as well as basis summary sheets (inspectable area, cornerstone, scope, basis, and performance metrics) for each inspectable area.

e. Technical Bases for PI&R Inspections.

i. Task: Develop a technical basis for PI&R inspections (CAP inspections)

ii. Actions: The staff intends the PI&R inspection to be a key part of the baseline inspection program. The staff plans to develop an IP for reviewing the PI&R, using, as acceptance criteria, basic well-established elements of effective PI&R programs. The staff will not expect licensees to have programs that meet the criteria in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities," except for those few facilities for which compliance with Appendix B is a requirement. For those licensees with effective PI&R programs, the staff plans to apply a revised Enforcement Policy that allows licensees to place NRC findings of very low safety or security significance in their CAPs for resolution. For these licensees, the NRC will not require descriptions of the proposed corrective actions for violations of low safety or security significance to be sent to the NRC and will not inspect corrective actions for each violation of low safety or security significance.

The IP will recognize that fuel cycle licensees have a range of PI&R programs and processes, many of which go beyond regulatory requirements. The staff plans that the IP will be one of the few to evaluate both program content and process, as well as program implementation. The IP will review the elements of a licensee's PI&R program, as well as a sample of items in a licensee's CAP, to determine if items are being properly identified, assessed for significance, and corrected. This inspection will include consideration of cross-cutting and other safety culture elements when a licensee has difficulty resolving issues in the CAP. The staff recognizes that the Commission has issued a draft safety culture policy statement for public comment and will not complete cross-cutting or other safety culture aspects of the IP until after Commission action on the draft policy statement. Because this IP will be central to the FCOP, the staff plans to develop a full draft of the IP in the short-term phase, recognizing that safety culture aspects will be completed later, in the medium-term phase.

iii. Deliverables: A draft PI&R IP that includes criteria for an effective CAP

f. Technical Bases for Supplemental Inspections.

i. Task: Develop technical bases for supplemental inspections.

ii. Actions: The staff plans to develop the objectives for supplemental

inspections to apply NRC resources in a graded manner when a licensee or the NRC identifies risk-significant performance issues. The staff plans two or three supplemental IPs that will be based on the risk-significance and breadth of identified performance issues. The IPs could range from a review of a licensee's root cause investigation, to expansion of the baseline samples, to a focused team inspection, or to a broad-scope team review of multiple cornerstone areas that will include an independent evaluation of root causes of licensee performance issues. The staff plans that the type of inspection will be based on objective measures of licensee performance.

iii. Deliverables: Objectives for supplemental inspection types that should be suitable for developing IPs in the medium-term phase

g. Technical Basis for Reactive Inspections.

i. Task: Develop a technical basis for reactive inspections.

iii. Actions: The staff plans to develop the technical bases to revise Management Directive (MD) 8.3, "NRC Incident Investigation Program," dated March 27, 2001, to provide more risk-informed criteria (based on ISAs or other risk insights) for determining the type of inspection or investigation of operational events. The staff plans to provide criteria for a range of inspections, based on the seriousness of an event. These reactive inspections include incident investigation teams, augmented inspection teams (AITs), and special inspections (SIs). The staff will use these criteria in the medium term to revise the IPs for reactive inspections. The staff does not plan for licensee or other stakeholder comment on the development of the revised MD 8.3 criteria during the short-term phase.

iii. Deliverables: Criteria to be used to revise MD 8.3 for reactive inspections.

h. Technical Basis for Assessment of Licensee Performance.

i. Task: Develop the basis for a more risk-informed, objective, predictable and transparent process for assessing safety and security performance to replace the licensee performance review (LPR).

ii. Actions: The NRC staff plans to develop a more objective process to assess licensee safety and security performance. The process will include periodic internal meetings within the NRC to evaluate planned inspections and interfaces with licensees in light of their performance, periodic letters to licensees documenting the conclusions for NRC assessments, and periodic public meetings to discuss those conclusions. The staff plans to develop criteria for classifying performance in a cornerstone (for example, two safety-significant findings in an assessment period might result in defining a cornerstone as degraded). These criteria will be based on the safety or security significance of inspection findings (and on exceeding thresholds for performance indicators, if applicable).

The staff also plans to develop a process for integrating licensee performance across cornerstones to performance categories columns in the ROP action

matrix (for example one degraded cornerstone, multiple degraded cornerstones). In addition, the staff plans to develop NRC actions and expected licensee actions for levels of degraded licensee performance. The staff expects that the keystone of the assessment will be an action matrix to categorize licensee performance and define NRC actions and expected licensee actions, based on this categorization. The staff recognizes that the action matrix might result in a tool that looks similar to that of the ROP action matrix, but the staff expects that the risk differences between power reactors and fuel cycle facilities will result in different thresholds of significance, performance columns, and NRC actions and expected licensee actions.

iii. Deliverables: An assessment process flow chart for internal NRC actions and NRC public actions, a method to determine when a cornerstone is degraded, a method to integrate performance across cornerstones, performance categories, types of reviews at different levels of degraded performance, and NRC actions and expected licensee actions for levels of degraded performance all of which should be suitable for developing an action matrix and supplemental IPs in the medium-term phase.

1. Framework Development.

i. Task: Develop an oversight framework.

ii. Actions: The NRC staff plans to further develop the oversight framework, making changes as needed as it develops the components of the framework. Attachment 2 provides current versions of the draft FCOP framework and process.

iii. Deliverables: A framework to be updated, as necessary, as its components are developed.

j. Stakeholder Communication.

i. Task: Develop a process to ensure that stakeholders have access to, and are informed of, the results of the oversight program, once it is implemented.

ii. Actions: The staff plans to develop a process to ensure that stakeholders could review the results of inspections and assessment. The NRC will continue to make inspection reports available to the public in its ADAMS, except for those reports containing security-related or proprietary information. The staff plans to post summaries of performance results on its Web site. The staff also plans to post assessment reports on the Web and to hold periodic assessment meetings with licensees that are open to the public.

iii. Deliverables: Outline of information that will be available on the Web site (other than through ADAMS) and other processes (such as assessment) that should involve the public, such as meetings open to the public; information will be suitable for incorporation into IMCs and will include a list of items that should be available on the Web site and their format.

II. Medium-Term Actions (FY 2012–FY 2013)

The medium-term tasks are, for the most part, actions to integrate the technical bases that were developed in the short-term phase into program documents (attachment 4) and procedures.

a. Oversight Process Development

i. Improve the inspection program.

(a) Task: Revise the fuel cycle facility inspection program documents and IPs, based on the technical bases developed above.

(b) Actions: The staff plans to revise the inspection program documents to incorporate the FCOP framework. Attachment 2 lists the documents that the staff expects to revise. The staff plans to use the technical bases developed in the short-term phase to revise IMCs and IPs. During these revisions, the staff will delete previous inspection areas that were not identified as inspectable areas from the baseline IPs. Based on recommendations from the expert panel and line management decisions, the staff might incorporate these deleted areas into supplemental IPs. In addition, the staff will revise any other IPs that could be used as part of the supplemental program. The staff will develop supplemental IPs and revise reactive IPs (AITs, SIs).

(c) Deliverables: Revised inspection program documents (IMCs) and revised IPs.

ii. Develop the SDP.

(a) Task: Incorporate the screening tool and SDP flow charts drafted in the short-term phase into an SDP IMC and procedures.

(b) Actions: During the medium-term phase, the staff plans to use the screening tool and SDP flow charts developed during the short-term phase to develop the SDP IMC and any implementing procedures, while coordinating the revision of the Enforcement Policy. The staff plans a parallel test of the SDP process with the legacy process to gain lessons learned to use in completing the FCOP SDP process.

(c) Deliverables: A final SDP IMC and implementing procedures.

iii. Develop performance metrics.

(a) Task: Incorporate quantitative performance metrics into IPs and assessment, as appropriate. Identify any performance measures that might be appropriate as performance indicators.

(b) Actions: The staff plans to integrate performance metrics developed in the short-term phase into oversight process documents, as appropriate. For example, if meeting a certain performance metrics will result in a

reduction in the number of samples in an area of inspection, the IP will include this guidance for sample selection.

(c) Deliverables: Inspection program documents and procedures that incorporate performance metrics developed in the short-term phase.

iv. Develop a safety and security assessment process.

(a) Task: Develop an assessment process.

(b) Actions: The staff plans to use the technical bases developed in the short-term phase to develop an action matrix, an assessment IMC, and any implementing procedures. During the medium-term phase, the NRC staff plans to conduct parallel tests of the proposed and legacy processes to incorporate lessons learned and feedback into the final IMC.

(c) Deliverables: A final assessment IMC that integrates the action matrix into an IMC and the necessary implementing procedures.

v. Develop a revised Enforcement Policy.

(a) Task: Develop a revised Enforcement Policy that incorporates the fuel cycle SDP and recognizes effective licensee CAPs.

(b) Actions: The staff plans to develop, issue for formal comment, and implement a revised Enforcement Policy. The staff plans to conduct parallel tests of the draft revised Enforcement Policy and the legacy processes to develop lessons learned and feedback into the proposed Enforcement Policy.

(c) Deliverables: Revised Enforcement Policy and necessary implementing procedures.

vi. Action matrix.

(a) Task: Complete the action matrix and integrate it into the assessment process.

(b) Actions: The staff intends to develop an action matrix based on the technical bases developed in the short-term phase. The action matrix will include thresholds of significance, performance columns, and NRC and expected licensee actions.

(c) Deliverables: Action matrix integrated with the assessment process.

b. Transition Plan

i. Revise the communications plan and develop a training plan.

(a) Task: Revise the communications plan to include details on

implementing the FCOP, including reference to a training plan for staff and a plan for informing stakeholders.
(b) Actions: The staff plans to implement a revised communications plan and update it, as necessary. The staff plans to develop a training plan for the NRC staff that will recognize the different needs of the NRC staff, given their different roles. It will include basic modules for all staff, and other modules customized to a staff member's specific assignments. The staff also plans to revise the qualification journals for new staff training and qualification.

(c) Deliverables: An updated communications plan, a staff training plan, and stakeholder briefing materials.

ii. Conduct initial implementation.

(a) Tasks: Evaluate each licensee's CAP to determine if it meets the criteria for an effective CAP. Test part of the FCOP at selected licensee facilities.

(b) Actions: The staff plans to evaluate each licensee's CAP using the PI&R IP during calendar year 2012. These inspections will determine if the licensee has a CAP that will support implementation of the FCOP.

The staff plans an initial implementation of selected parts of the FCOP at selected licensee facilities that have effective CAPs or for all licensees. This "test" implementation will be for one calendar year, beginning in January 2013. (For those licensees without a CAP, the staff plans to continue to implement a legacy oversight process that meets the criteria for the FCOP). The test use of the FCOP will take the place of the legacy oversight in the areas tested. The staff plans to develop a transition plan that will include licensee staff and stakeholder orientations before its initial implementation. During initial implementation, the staff will use a process that will require NRC staff feedback and encourage stakeholder feedback. The staff will evaluate this feedback and use it to revise the FCOP before its full implementation at the beginning of 2014.

(c) Deliverables: Reviews of all licensees' CAPs; test of certain parts of the FCOP at certain licensee facilities; and revised FCOP, based on the test use.

iii. Conduct full implementation.

(a) Task: Implement the FCOP.

(b) Actions: The staff plans to fully implement the FCOP starting in January 2014. To do this, it will complete all processes, documentation, and training by the end of calendar year 2013.

(c) Deliverables: Final program documents and procedures, trained staff, and program management tools.

iv. End the LPR program.

The NRC will terminate the legacy LPR process at the end of FY2013 and replace it with the assessment process.

c. Stakeholder Involvement

i. Task: Ensure stakeholder involvement in the development of the FCOP.

ii. Actions: The NRC staff intends to continue to implement and revise, as appropriate, a communications plan that provides information and plans to stakeholders.

iii. Deliverables: Implementation of a communications plan.

d. FCOP Oversight

i. Task: Implement a process to ensure FCOP oversight during implementation.

ii. Action: The staff will establish program oversight functions in the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Nuclear Security and Incident Response (NSIR). This oversight will include the role of revising oversight processes and procedures, as needed, and developing temporary instructions and generic issue inspections, as needed. The staff plans to develop the FCOP self-assessment process, considering in this development the ROP self-assessment process used as part of the preparation for the Agency Action Review Meeting (AARM) (MD 8.14, "Agency Action Review Meeting," dated March 16, 2009).

iii. Deliverables: Oversight organizations, with roles, responsibilities, and processes, and a self-assessment process for the FCOP.

III. Long-Term Actions (FY 2014 and beyond)

a. Conduct stable implementation.

i. Task: Fully implement the FCOP, beginning in January 2014, including a feedback process like that used in the ROP.

ii. Action: The staff will implement the program.

iii. Deliverables: Ongoing program.

b. Implement an alignment process.

i. Task: Develop and implement a periodic review to ensure the most effective overall application of resources.

ii. Action: The staff plans to use the ROP realignment process as a guide to develop a simplified alignment process for the FCOP.

iii. Deliverables: An IMC and the necessary procedures to implement an alignment process and the FCOP.

IV. Public Process, Industry Engagement, Federal Advisory Committee Act Considerations

The NRC staff plans to continue stakeholder involvement in the development of the FCOP that began in the initial stage of development in 2009. This involvement included a *Federal Register* notice to the public requesting input and the establishment of a Web page at www.regulations.gov for stakeholders to provide comments. In addition, the staff plans to continue to hold periodic meetings, open to the public, to discuss with licensees proposed FCOP processes and draft documents. The staff plans to continue to offer participation in these meetings through teleconference calls and the "Go to Meeting" Web tool. Program office and regional office staff will review draft documents to be discussed at these meetings and then provide them to licensees and the public and post them on www.regulations.gov, before the public meetings during which they are discussed. The NRC staff plans to collect public and internal staff comments and consider each in developing the FCOP.

The process for oversight of and participation in FCOP development is based on the Working Group process defined in MD 5.3, "Agreement State Participation in Working Groups," dated August 22, 2007. Under this process, a steering committee made up of senior managers from NMSS, Region II, NSIR, the Office of Enforcement, and Office of Nuclear Reactor Regulation directs staff actions. This steering committee establishes a charter for the staff developing the FCOP and provides continuing direction, guidance, and support. The staff considered whether it will be appropriate to place FCOP development under the provisions of the Federal Advisory Committee Act, but, in consultation with the Office of the General Counsel, the staff determined that it best fit under MD 5.3 oversight, because the process and work products were best developed by the NRC staff, with stakeholder and other public comments, rather than by a committee of NRC and non-NRC experts. The evaluation of FCOP governance appears at ADAMS Accession No. ML092310052.

V. Schedule and Resources

The staff estimates that, given the resources shown below, it could fully implement the FCOP in January 2014. Short-term actions involve developing the technical bases for FCOP elements and the staff will complete them from mid-FY 2010 through the end of FY 2011. Medium-term actions involve developing the formal processes and procedures to implement the FCOP and are planned for FY 2012 through FY 2013. Such actions include parallel testing of certain new processes with the legacy processes. Long-term actions are those in FY 2014 and beyond. They involve full implementation of the FCOP and the development and use of tools to evaluate the FCOP (self-assessment and realignment). Long-term actions could also include the development of performance indicators for the FCOP.

For FY 2011, the staff estimates it will require 3.7 full time equivalents (FTE) to complete the short-term tasks for the qualitative option. The staff estimates it will require 3.7 NRC FTE and $810,000 in contract support to complete the short-term tasks for the quantitative option.

The staff estimates it will require 9.2 FTE and $500,000 to complete the medium-term tasks for either the qualitative or quantitative option.

On a fiscal year basis, the resources are:

	Qualitative		Quantitative	
FY	FTE	Contract Dollars	FTE	Contract Dollars
11	3.7	0	3.7	810
12	4.6	250	4.6	250
13	4.6	250	4.6	250
Total	12.9	500	12.9	1,310

VI. Status Reports to Commission

The staff will provide status reports to the Commission every 6 months, beginning 6 months after the staff requirements memorandum providing initial Commission approval and direction on this plan.

Attachments:
1. Staff Actions in Response to OIG Audit of Fuel Cycle Oversight (OIG-07-A-06)
2. Oversight Framework – Cornerstones and Cross Cutting Areas
3. Administrative Considerations in the Development of a Performance Indicator Program
4. Documents that may be Updated as Part Of the Revision to the Fuel Cycle Oversight Process

STAFF ACTIONS IN RESPONSE TO OIG AUDIT OF FUEL CYCLE OVERSIGHT (OIG-07-A-06)

On January 10, 2007, the Office of Inspector General (OIG), in OIG-07-A-06, "Audit of the NRC's Regulation of the Nuclear Fuel Cycle Facilities," provided Recommendation 1, "that the staff fully implement a framework for fuel cycle oversight, consistent with a structured process, such as the Reactor Oversight Process (ROP)." In a February 13, 2007, memorandum in response to the audit, the Deputy Executive Director for Materials, Research, State, and Compliance Programs stated that, as the U.S. Nuclear Regulatory Commission (NRC) staff gains more experience with the integrated safety analysis (ISA) process, it will make appropriate enhancements to the inspection and licensing procedures, to establish a more structured program, similar to the ROP. The memorandum also noted that, because various fuel cycle facilities possess different operational characteristics, the ultimate structure of the fuel cycle oversight process (FCOP) will use more qualitative, rather than quantitative, assessments of performance. Since February 2007, the staff has completed several actions outlined in the response to OIG and provided status reports to OIG every 6 months.

The initial status report to OIG regarding Recommendation 1 discussed five corrective actions related to improving fuel cycle oversight: (1) structured evaluation of ISA annual updates; (2) consolidation of the fuel cycle inspection program at Region II; (3) revision of the NRC Enforcement Policy; (4) development of structured event-processing guidance; and (5) completion of a safety culture pilot plan. In a memorandum dated June 29, 2007, OIG noted that the proposed corrective action addressed the intent of OIG's recommendation and that it will close Recommendation 1 when the NRC provides evidence that it has fully developed and implemented a framework for the Fuel Cycle Facility Oversight Program.

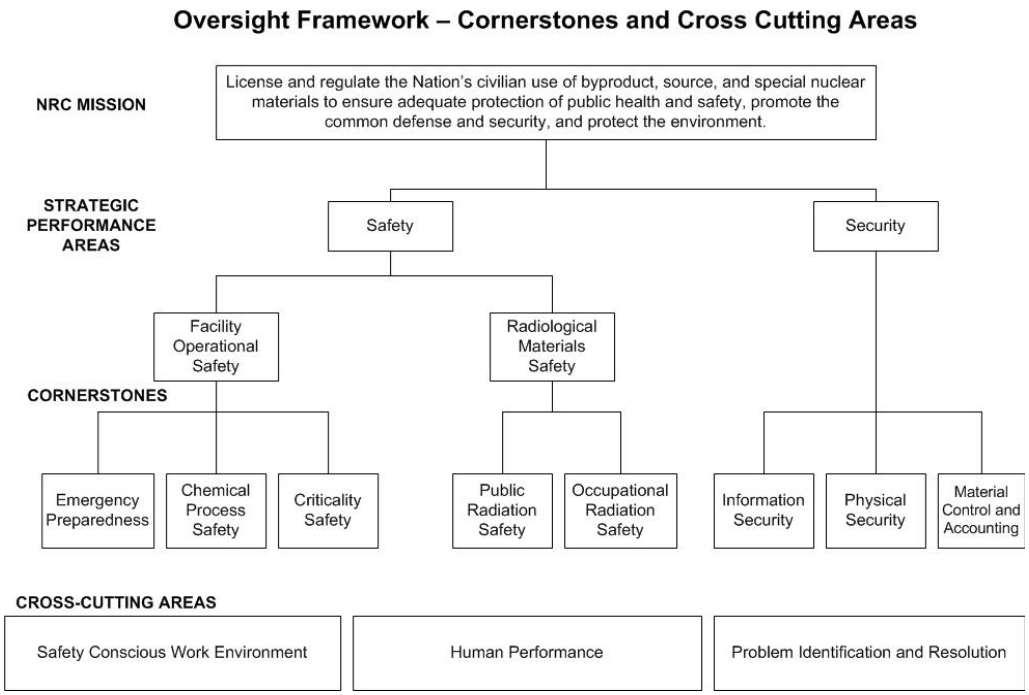
Regarding item (1), the Division of Fuel Cycle Safety and Safeguards (FCSS) staff developed and implemented a process and procedure for the structured evaluation of ISA summary annual updates provided to the NRC by licensees. This process benefited from a lessons-learned evaluation of the process that was used to review ISA summary updates initially resulting in improved change-screening criteria and a new internal review schedule. This item is closed.

With regard to item (2), regional responsibility for fuel cycle inspections has been consolidated in Region II for several years. This item is closed.

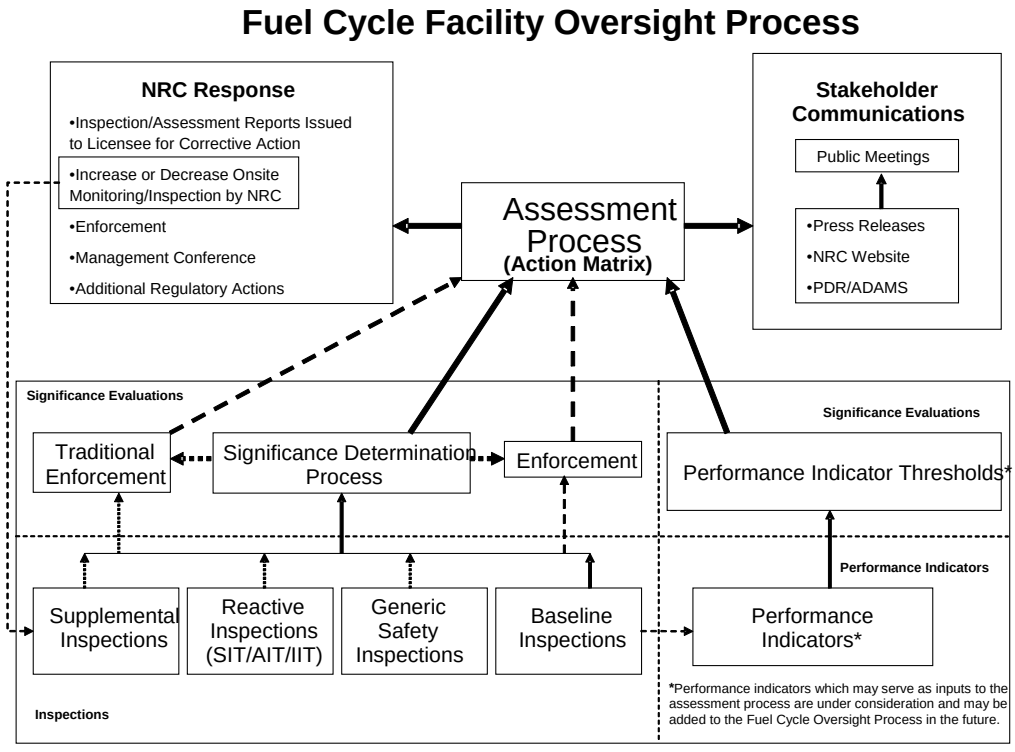
Regarding item (3), the proposed Enforcement Policy revision, which has completed a public comment period, includes new fuel cycle supplement examples that use ISA criteria and results. The final revised Enforcement Policy, including resolution of public comments, is currently with the Commission pending final approval.

Regarding item (4), the Office of Nuclear Material Safety and Safeguards (NMSS) developed and is implementing a structured event processing procedure. This item is closed.

Regarding item (5), NMSS has: (1) reviewed and gathered information on NMSS' inspection procedures and programs relative to the 13 components of Safety Culture identified in RIS 2006-13; (2) identified gaps; and (3) proposed actions to address these gaps. The report on this effort (internal non-public), documenting the progress to date is available in the Agencywide Document Access and Management System (ML100680249). The staff will incorporate the results of this effort into the new fuel cycle oversight process.



Attachment 2a



Attachment 2b

Administrative Considerations in the Development of a Performance Indicator Program

The following actions must be completed before the staff can either request or use new information from the licensees. This restriction applies even if the information is voluntarily provided; however, the U.S. Nuclear Regulatory Commission (NRC) can use historical data as input to the action matrix until this process is completed.

Assumption: On a parallel path with the development of the fuel cycle oversight process (FCOP), the Nuclear Energy Institute (NEI) will produce a document similar to NEI 99-02 "Regulatory Assessment Performance Indicator Guideline," Revision 6, October 2009, that includes the fuel cycle performance indicator (PI) program and the NRC will review and endorse the end product.

1. Industry supplies its proposed PIs; starts the approval process

2. The staff reviews and obtains concurrence on a supporting statement; thus, subject to public comment, the NRC will be able to endorse the industry proposal. The staff will produce a *Federal Register* notice (FRN) for the PI program and send it to the Office of Information Security (OIS) for publication to start the Office of Management and Budget (OMB) clearance process: **90 days**

3. OIS publishes the FRN for comment: **84 days** (dependent on 2)

4. The staff dispositions of all comments and drafts OMB submission ready for dispatch: **45 days** (dependent on 3)

5. Concurrent with the above, the staff produces a letter to industry announcing concurrence with the proposed PIs: **45 days** (dependent on 2)

6. OIS publishes a second FRN for comment announcing the OMB Submittal (30 days mandatory): **30 days** (dependent on 4)

7. Begin holding public meetings near each fuel cycle facility: (dependent on 5) These must be completed before roll out (9)

8. Concurrent with (6), OIS will provide a "Supporting Statement" to OMB seeking the clearance to collect the PI data: **180 days** (dependent on 4**)**

9. Issue regulatory issue summary to roll out the program to all stakeholders: **30 days** (dependent on 8, but can start early)

10. Prepare management directive that covers the entire program

- Results in a **<u>minimum</u>** of **429 days** (8 is outside NRC control) from the submission of the PIs <u>by industry</u> until they can be implemented as part of the FCOP.

DOCUMENTS TO BE UPDATED AS PART OF THE REVISION TO THE FUEL CYCLE OVERSIGHT PROCESS

Inspection Manual Chapters

IMC - 2604		**Fuel Cycle Facility Assessment Program**
IMC - Basis		**Fuel Cycle Oversight Process Basis Document**
Attachment	1	Technical Basis for Inspection Program
Attachment	2	Significance Determination Process (SDP) Basis Document
Attachment	3	Technical Basis for Performance Indicators
Attachment	4	Technical Basis for Assessment
Attachment	5	Technical Basis for Enforcement
Appendix	A	Technical Basis for Criticality Safety and Chemical Process Safety SDP
Appendix	B	Technical Basis for Emergency Preparedness SDP
Appendix	C	Technical Basis for Occupational Radiation Safety SDP
Appendix	D	Technical Basis for Public Radiation Safety SDP
Appendix	E	Technical Basis for Physical Security SDP
Appendix	F	Technical Basis for MC&A SDP
IMC - 0309		**Reactive Inspection Decision Basis for Fuel Facilities**
IMC - 0350		**Oversight of Fuel Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns**
IMC - 0608		**Performance Indicator Program**
IMC - SDP		**Fuel Cycle Significance Determination Process**
Attachment	1	Determination of Finding of Greater than Minor Significance
Attachment	2	Minor Issues
Attachment	3	Significance and Enforcement Review Panel Process
Attachment	4	Process for Appealing of the NRC Characterization of Inspection Findings (SDP Appeal Process)
Attachment	5	Senior Fuel Facility Analyst Support Expectations
Appendix	A	Criticality Safety, and Chemical Process Safety
Appendix	B	Emergency Preparedness
Appendix	C	Occupational Radiation Safety Situations
Appendix	D	Public Radiation
Appendix	E	Physical Security
Appendix	F	MC&A
Appendix	G	Information Security

IMC - 0616 Fuel Cycle Safety and Safeguards Inspection Reports

Exhibit	1	Standard Fuel Cycle Facility Inspection Report Outline
Exhibit	2	Inspection Report Documentation Matrix
Exhibit	3	Sample Fuel Cycle Inspection Report
Exhibit	4	Sample Cover Letters
Appendix	A	Acronyms Used in Inspection Manual Chapter 0616
Appendix	B	Issue Screening
Appendix	C	Guidance for Supplemental Inspection Reports
Appendix	D	Guidance for Documenting Inspection Procedure 88152, Identification and Resolution of Problems
Appendix	E	Examples of Minor Issues
Appendix	F	Examples of Cross-Cutting Aspects

IMC - 2600 Fuel Cycle Facility Inspection Program—Operations Phase

Appendix	A	Risk-Informed Baseline Inspection Program
Appendix	B	Supplemental Inspection Program
Appendix	C	Special and Infrequently Performed Inspections
Appendix	D	Plant Status
Appendix	E	Inspection Program Modifications during a Pandemic
Appendix	F	Physical Protection and Transport of Special Nuclear Material (SNM) and Irradiated Fuel Inspections of Fuel Facilities
Appendix	G	MC&A Inspection of Fuel Cycle Facilities

IMC - 2681 - Physical Protection and Transport of SNM and Irradiated Fuel Inspections of Fuel Facilities

IMC - 2683 - MC&A Inspection of Fuel Cycle Facilities

Management Directives

MD - 8.3 NRC Incident Investigation Program

MD - 8.14 Agency Action Review Meeting

Inspection Procedures

The staff will review all safety, physical security, and material control and accounting (MC&A) inspection procedures and likely revise or delete them. In addition, the staff expects to develop limited number of new procedures. The following are key potential new procedures.

IP - 88151 Performance Indicator Verification (if performance indicators are adopted)

IP - 88152 Identification and Resolution of Problems

IP - 950X1 a first level supplemental procedure

IP - 950X2 An intermediate level supplemental procedure

IP - 950X3 A comprehensive, in-depth supplemental procedure