



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
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June 17, 2009

Mr. Felix M. Killar, Jr.
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SUBJECT: TRANSMITTAL OF DRAFT REVISED FUEL CYCLE OVERSIGHT PROCESS
BASIS DOCUMENT

Dear Mr. Killar:

The purpose of this letter is to provide you a draft copy of the Revised Fuel Cycle Oversight Process (RFCOP) basis document. In our last public meeting conducted in the Nuclear Regulatory Commission's (NRC) Region II Office in Atlanta, GA, on June 4 - 5, 2009, both you and industry representatives requested that this document be shared with you in order to effectively prepare for the next public meeting scheduled for June 22, 2009, in NRC headquarters (reference public meeting notice dated June 10, 2009 - ADAMS accession number ML091590316).

The enclosed basis document represents the NRC's initial attempts to produce a document that will describe the basis for the significant decisions reached by the NRC staff during the development and implementation of the RFCOP for operating nuclear fuel cycle facilities. This document shall serve as the source information for all applicable program documents such as inspection manual chapters (IMCs), significance determination process guidance, performance indicator guidance, and assessment guidance. The current version enclosed primarily provides an outline of the central elements of the RFCOP and provides some discussion relative to the proposed regulatory framework for the RFCOP with initial discussion of cornerstones for the Safety and Security Strategic Performance Areas.

To facilitate a discussion of the emergency preparedness (EP) cornerstone at the June 22 meeting, language was extracted from the Reactor Oversight Process Basis Document, IMC 308, and modified to accommodate differences between oversight of commercial power reactors and fuel cycle facilities.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions concerning the information provided, please contact me at (404) 562-4806 or at (301) 492-3120.

Sincerely,



Russell A. Gibbs, Team Leader
Fuel Cycle Oversight Process
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Enclosure: Draft Revised Fuel Cycle Oversight
Process Basis Document

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3

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MANUAL CHAPTER 0XXX

**FUEL CYCLE OVERSIGHT PROCESS (FCOP)
BASIS DOCUMENT****0XXX-01 PURPOSE**

To describe the basis for the significant decisions reached by the U.S. Nuclear Regulatory Commission (NRC) staff during the development and implementation of the revised Fuel Cycle Oversight Process (FCOP) for operating nuclear fuel cycle facilities. This document shall serve as the source information for all applicable program documents such as manual chapters (MCs), performance indicator (PI) guidance, and assessment guidance.

0XXX-02 OBJECTIVES

02.01 To discuss significant developmental steps and decisions reached.

02.02 To describe in general how the processes work and why they are setup the way they are.

02.03 To summarize the history of the development of and reasons for significant changes made to the oversight processes.

0XXX-03 DEFINITIONS

Later.

0XXX-04 RESPONSIBILITIES AND AUTHORITIES

Later.

0XXX-05 GENERAL DISCUSSION**05.01 Introduction**

On Month Day, 2-XX, the NRC implemented a revised FCOP at all operating nuclear fuel cycle facilities. The objectives of the staff in developing the various components of this revised oversight process were (1) to provide tools for

inspecting and assessing licensee performance in a manner that used the risk insights of licensees' Integrated Safety Analyses (ISAs) and Safety Analysis Reports (SARs), and (2) to develop a process that was more risk-informed and performance based, objective, predictable, transparent, and understandable than the previous oversight processes. The revised FCOP was also developed to meet the two agency Strategic Goals to: (1) ensure adequate protection of public health and safety and the environment, and (2) ensure adequate protection in the secure use and management of radioactive materials. The FCOP was also developed to meet the Organizational Excellence Objectives of Openness, Effectiveness, and Operational Excellence in support the Strategic Goals.

In developing the revised FCOP, many aspects of the previous oversight process, such as the inspection program, assessment process, and enforcement policy were revised to meet the Strategic Plan Objectives and Goals and to be better integrated and streamlined. Additionally, several revised oversight processes were developed, such as Measures and Metrics (and/or Performance Indicators (PIs)) and a fuel cycle significance determination process (FCSDP) for inspection findings. An overview of the FCOP and how the individual processes interact is shown in Exhibit 1.

Additional detail regarding the development and basis for each of the individual oversight processes is included as separate attachments to this document. Attachment 1 describes the Inspection Program and discusses the concepts of the Baseline and Supplemental Inspections. Attachment 2 discusses the basis for the different FCSDPs that have been developed to evaluate the safety significance of inspection findings. Attachment 3 discusses the PIs and describes the bases for selecting the initial set of PIs and their thresholds, and how the PIs were benchmarked. Attachment 4 discusses how the Assessment Program was developed to identify the appropriate NRC actions to take based on the PIs and inspection findings generated. Attachment 5 will describe the significant changes made to the Enforcement Policy to support the FCOP.

05.02 Background.

The following discussion provides the background for how the FCOP was developed and the basis for many of the key attributes of the revised oversight process.

More will be added.

05.03 Regulatory Framework.

The foundation of the revised FCOP is the Regulatory Framework. The staff used a top-down, hierarchical approach to develop the concept for a revised regulatory oversight framework that addresses the agency's regulatory principles. This approach started with a desired outcome, identified performance goals to

achieve this outcome, and then identified specific objectives and information needs to meet each performance goal. The regulatory framework is shown in Exhibit 2.

This framework starts at the highest level, with the NRC's overall mission to ensure that nuclear fuel cycle facilities are operated in a manner that provides adequate protection of public health and safety and the environment and ensure adequate protection in the secure use and management of radioactive materials. The staff then identified those aspects of licensee performance that are important to the mission and therefore merit regulatory oversight. The February 2008 NRC Strategic Plan (NUREG-1614, Vol. 4) identifies the performance goals to be met for ensuring nuclear fuel cycle facility safety and security and include the following:

- Prevent the occurrence of any inadvertent criticality events
- Prevent the occurrence of any acute radiation exposures resulting in fatalities
- Prevent the occurrence of any releases of radioactive materials that result in significant radiation exposures
- Prevent the occurrence of any releases of radioactive materials that cause significant adverse environmental impacts
- Prevent any instances where licensed radioactive materials are used domestically in a manner hostile to the United States

In addition to the radiation-related goals above, because of the hazardous chemicals at fuel cycle facilities, and through a memorandum of understanding with the Occupational Safety and Health Administration (OSHA), NRC regulations require licensees to control the potential impacts on workers and the public of certain chemicals used at their facilities that are associated with processes involving radioactive materials.

These performance goals reflect those areas of licensee performance for which the NRC has regulatory responsibility in support of the overall agency mission. These performance goals were represented in the framework structure as the strategic performance areas of Safety and Security and formed the second level of the regulatory framework. The Safety strategic performance area was divided into facility operational safety and radiological materials safety in order to make a clear distinction between facility and radiological safety relative to their distinct cornerstones.

With a risk-informed perspective, the staff then identified the most important elements in each of these key performance areas that form the foundation for

meeting the overall agency mission. These elements were identified as the cornerstones of safety and security in the third level of the regulatory framework structure. These cornerstones serve as the fundamental building blocks for the revised FCOP, and acceptable licensee performance in these cornerstones should provide reasonable assurance that the overall mission of adequate protection of public health and safety would be met.

For the fourth level of the regulatory framework, cross-cutting areas were added. Cross-cutting areas include: (1) safety conscious work environment; (2) human performance; and (3) problem identification and resolution. A detailed discussion of cross-cutting areas is provided in Section 05.06 of this MC.

Once the regulatory framework was established, the staff developed the defining principles that formed the strategy and rules for the further development of the details of the revised FCOP. These defining principles established the relationship between elements of the oversight processes, such as enforcement and inspection, and include:

- There will be a risk-informed baseline inspection program that establishes the minimum regulatory interaction for all licensees.
- Thresholds can be set for licensee safety performance, above which increased NRC interaction (including enforcement) would be warranted.
- Adequate assurance of licensee performance at the cornerstone level requires assessment of both PIs and inspection findings.
- Both the PIs and results of inspections used to assess a cornerstone will have risk-informed thresholds, when possible.
- Crossing a PI threshold and an inspection threshold will have the same meaning with respect to safety significance and directly define the level of NRC involvement and follow-up action.
- The baseline inspection program will cover those risk-significant attributes of licensee performance not adequately covered by PIs.
- The baseline inspection program will also verify the accuracy of the PIs and provide for event response.
- Enforcement actions taken (e.g., the number of cited violations, the amount of a civil penalty) should not be an input into the assessment process. However, the issue that led to the enforcement action will continue to be considered in the assessment.

- Assessment process results might be used to modify enforcement actions (although assessment results would not affect the determination of violation severity level).
- Guidelines will establish criteria for identifying and responding to unacceptable licensee performance.

It is important to note that the intent of these defining principles was to result in an oversight process that would provide adequate margin in the assessment of licensee performance so that appropriate licensee and NRC actions could be taken before unacceptable performance occurred.

05.04 Cornerstones of Safety and Security

The staff used a top-down, hierarchical, risk-informed approach for each cornerstone in an effort to:

- provide a general description of the cornerstone;
- identify the objective and scope of the cornerstone;
- identify the desired results and key attributes of the cornerstone;
- identify what items should be measured to ensure that the cornerstone objectives are met;
- determine which of the areas to be measured can be monitored adequately by metrics and/or measures or PIs;
- determine whether inspection or other information sources would be needed to supplement the measures and/or metrics or PIs; and
- determine the thresholds of performance for each measure and/or metric or PI, which would trigger additional NRC actions.

Where possible, the staff sought to identify measures and/or metrics or PIs as a means of measuring the performance of key attributes in each of the cornerstones. Where such a measure and/or metric or PI could not be identified, or where one was identified but was not sufficiently comprehensive, the staff identified a baseline inspection activity. The staff also identified the inspections necessary to verify the accuracy and completeness of the reported PI data. Additional detail and discussion on the baseline inspection program and the PI program for each cornerstone can be found in IMC XXXX, Attachments 1 and 2, respectively.

For the Safety strategic performance area, the chosen cornerstones of facility

operational safety were: (1) emergency preparedness; (2) chemical process safety; (3) fire protection; and (4) criticality safety. The chosen cornerstones of radiological material safety were: (1) public radiation safety; and (2) occupational radiation safety. The chosen cornerstones for the Security performance area were: (1) information security; (2) physical security; and (3) material control and accounting. [These cornerstones were selected because they best represent the baseline inspection program requirements which overall were determined to be sufficient in meeting the Agency's mission and were best suited to make the framework understandable to stakeholders].

A general description of each cornerstone is provided below.

Safety Strategic Performance Area

Facility Operational Safety

- Emergency preparedness – verifies the licensee's ability to respond to events that could threaten the facility to protect workers, the public and the environment.
- Chemical process safety – ensures that chemical process upsets do not affect the safe handling of licensed materials and that workers, the public, and the environment are protected chemical hazards from radioactive materials and hazardous chemicals produced from radioactive materials
- Fire protection – ensures that fire events are prevented or do not affect the safe handling and storage of radioactive materials.
- Criticality safety – ensures that inadvertent nuclear criticality events are prevented.

Radiological Materials Safety

- Public radiation safety - ensures the public and the environment are protected from unintended exposure to radioactive material that could adversely affect public health.
- Occupational radiation safety - ensures the protection of workers from unintended exposure to radioactive material that could adversely affect worker health.

Security Strategic Performance Area

- Information security – verifies that the licensee effectively controls classified and restricted material and information, unclassified controlled

nuclear information, and safeguards information to prevent unauthorized disclosure, modification, loss of theft.

- Physical security – ensures that the radioactive material is protected from sabotage or theft.
- Material control and accounting (MC&A) – ensures that the licensee knows the location, form, and amount of special nuclear material under their control.

A more detailed discussion of each cornerstone is provided below.

Facility Operational Safety

Emergency Preparedness – The objective of this cornerstone is to ensure that emergency plan actions taken by the emergency response organization would provide protection of the public health and safety during a radiological or chemical emergency. Licensees can ensure that the emergency plan would be implemented correctly by conducting drills and training. This would give reasonable assurance that the licensee can effectively protect the public health and safety in the event of an actual radiological emergency.

More will be added.

Chemical Process Safety

Later.

Fire Protection

Later.

Criticality Safety

Later.

Radiological Materials Safety

Public Radiation Safety

Later.

Occupational Radiation Safety.

Later.

Security Strategic Performance Area

Information Security

Later.

Physical Security

Later.

Material Control and Accounting (MC&A).

Later.

05.05 Performance Indicators

Later.

05.06 Cross-Cutting Issues, Substantive Cross-Cutting Issues, and Safety Culture Oversight.

Later.

a. Cross-Cutting Areas

1. Safety Conscious Work Environment

Later

2. Human Performance

Later.

3. Problem Identification and Resolution Program

Later.

b. Substantive Cross-Cutting Issues

Later.

c. Safety Culture Oversight

Later.

05.07 Risk-Informed Scale.

Later.

05.08 Commission Commitments

During the development of the revised FCOP, the Commission provided significant direction to the staff. This direction came, for the most part, from Commission Staff Requirements Memoranda (SRMs) that were issued in response to papers written and briefs given during the development of the FCOP. A summary of the more significant items that influenced the development of the FCOP are outlined below.

More to be added.

0XXX-06 ACRONYMS AND REFERENCES

06-01 Acronyms.

Later.

06-02 References

Later.

END

Exhibits:

1. Fuel Cycle Oversight Process (06/16/2009)
2. Regulatory Framework – Cornerstones and Cross Cutting Areas (06/16/2009)

Attachments:

1. Inspection Program (Later)
2. Significance Determination Process (Later)
3. Performance Indicators (Later)
4. Assessment (Later)
5. Enforcement Policy (Later)

Appendices:

- A. Technical Basis for Emergency Preparedness Significance Determination Process (Later)
- B. Technical Basis for Chemical Process Safety Significance Determination Process (Later)
- C. Technical Basis for Fire Protection Significance Determination Process (Later)

- D. Technical Basis for Criticality Safety Significance Determination Process (Later)
- E. Technical Basis for Public Radiation Safety Significance Determination Process (Later)
- F. Technical Basis for Occupational Radiation Safety Significance Determination Process (Later)
- G. Technical Basis for Information Security Significance Determination Process (Later)
- H. Technical Basis for Physical Security Significance Determination Process (Later)
- I. Technical Basis for Material Control and Accounting Significance Determination Process (Later)

Exhibit 1

Fuel Cycle Facility Oversight Process

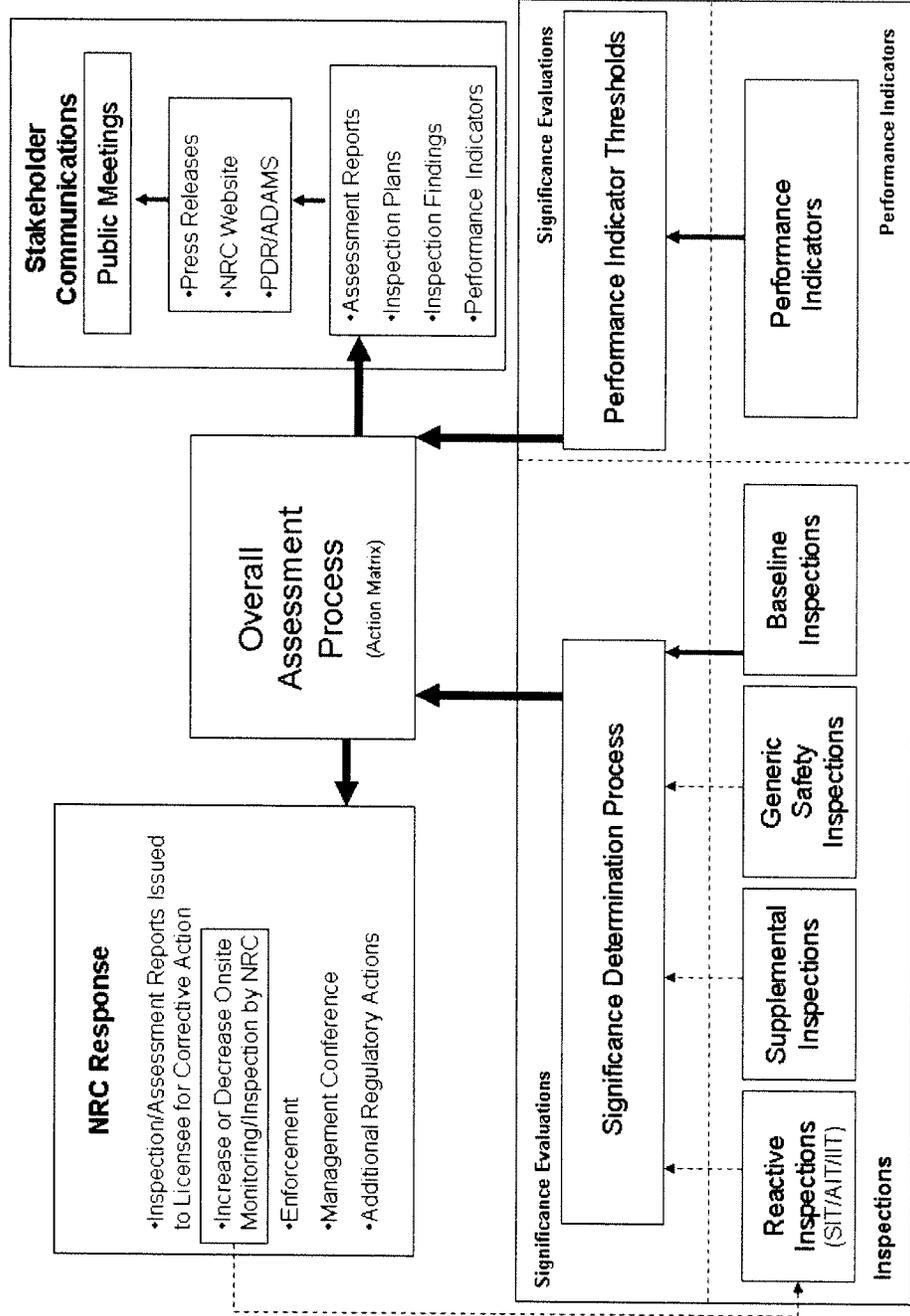
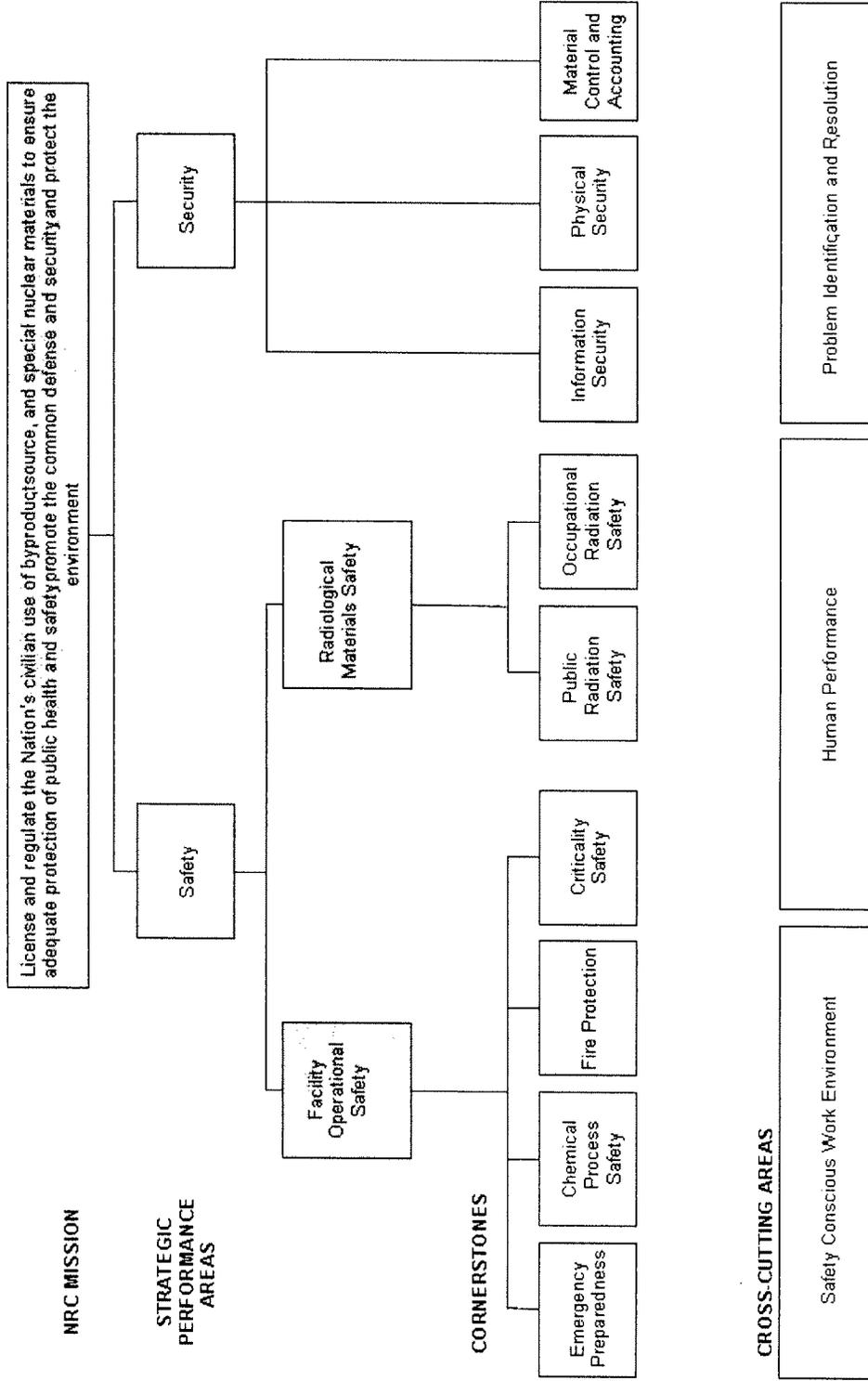


Exhibit 2

Regulatory Framework – Cornerstones and Cross Cutting Areas



Revision History for IMC 0XXX

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number