



Meeting to Discuss the Revised Fuel Cycle Oversight Process

NRC Headquarters
Rockville, Maryland
October 6 - 7, 2009

Agenda

October 6, 2009

- 8:30 a.m. Introductions and Opening Remarks - U.S. Nuclear Regulatory Commission (NRC)
- 8:50 a.m. Nuclear Energy Institute (NEI) Opening Statement - NEI
- 9:00 a.m. Meeting Protocol - NRC
- 9:10 a.m. Begin discussion on theme-related comments:
- Safety Culture including Cross-Cutting Issues – NRC and NEI/Industry
 - Performance Deficiency – NRC and NEI/Industry
 - Significance Determination Process Thresholds and Risk-informed Scale – NRC and NEI/Industry
 - Action Matrix – NRC and NEI/Industry
 - Project Plan (October and beyond) – NRC and NEI/Industry
- 11:30 a.m. Questions and Discussion with Members of the Public
- 12:00 p.m. Lunch
- 1:00 p.m. Continuation of Discussion - NRC and NEI/Licensees
- 4:30 p.m. Questions and Discussion with Members of the Public
- 5:00 p.m. Adjourn

Agenda

October 7, 2009

- 8:30 a.m. Introductions and Opening Remarks - NRC
- 8:40 a.m. Nuclear Energy Institute (NEI) Opening Statement - NEI
- 8:50 a.m. Meeting Protocol - NRC
- 9:00 a.m. Begin discussion on specific comments on the documents:
- IMC-RFCOP-SDP, Appendix B – Emergency Preparedness SDP - NRC and NEI/Industry
 - IMC-RFCOP-Basis Document – NRC and NEI/Industry
 - IMC-RFCOP-Inspection Program - NRC and NEI/Industry
 - IMC-RFCOP-SDP – NRC and NEI/Industry
 - IMC-RFCOP – Assessment Program - NRC and NEI/Industry
- 11:30 a.m. Questions and Discussion with Members of the Public
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- 4:00 p.m. Next Steps and Other Issues - NRC and NEI/Industry
- 4:30 p.m. Questions and Discussion with Member of the Public
- 5:00 p.m. Adjourn



DAY 1
OCTOBER 6, 2009

Key Objectives for Today

- Reach common understanding of Industry comments provided by NEI on theme-related areas
- Discuss in detail and help stakeholders understand the concepts supporting the revised oversight process related to theme-related areas

Status of Program Development – Resolution of Comments

- Five key program documents issued for public comment on 8/28. Documents included:
 - Basis Document, Inspection Program, Significance Determination Process (SDP), Assessment Program, and SDP for Emergency Preparedness
- Industry comments received 10/1. Comments associated with following area of revised process
 - Safety culture and cross-cutting issues, definition of performance deficiency, SDP thresholds and risk-informed scale, action matrix and process project plan

Safety Culture and Cross-Cutting Issues

June Cai
October 6, 2009

NMSS Safety Culture Pilot (2007-2008)

- Purpose: determine how to enhance Fuel Cycle Inspection and Oversight Program for addressing safety culture
- Findings:
 - Safety culture components apply to fuel cycle facilities and are comprehensive
 - Some details should be modified to be specific for fuel cycle environment
 - All safety culture components are implicitly addressed by existing oversight programs
 - Level of coverage varied

2008 FCIX session slides for more info: <http://www.nrc.gov/about-nrc/regulatory/enforcement/fcix-safety-culture.pdf>

Phased Approach for Revised Oversight

- Initial implementation – incorporate safety culture elements into:
 - Problem identification and resolution inspection procedure (IP 88152)
 - Supplemental inspection procedures (IP's 950X1 and 950X2)

Phased Approach (con'd)

- Longer term – implement cross-cutting issues process
 - Will be informed by results from relevant agency safety culture activities
 - Development of Commission Policy Statement
 - Initiative to engage with stakeholders to develop common terminology for the nuclear industry
 - Cross-cutting areas are based on safety culture components
 - Revise safety culture components for specific application to fuel cycle environment
 - Engage with stakeholders and provide opportunity for review and comment

Advantages of Phased Approach

- Allows near term focus on more fundamental elements of revised process
- Addresses safety culture considerations in near term for two important inspection areas
- In longer term, implement one consolidated set of changes to safety culture components, in alignment with relevant agency activities

Performance Deficiency

Russell Gibbs
October 6, 2009

Performance Deficiency

- **ROP Definition of Performance Deficiency:** An issue that is the result of a licensee not meeting a requirement or standard where the cause was reasonably within the licensee's ability to foresee and correct, and that should have been prevented. A performance deficiency can exist if a licensee fails to meet a self-imposed standard or a standard required by regulation.
- **Licensee Proposed Definition of Performance Deficiency:** An occurrence at or the state of a licensed facility that is the result of a licensee not meeting a regulatory requirement or license commitment. If the occurrence or state is of low to no safety significance and the licensee identified (including events) the occurrence or state and is managing them in accordance with their Corrective Action Program this would not constitute a Performance Deficiency.

Performance Deficiency Attributes

- Risk-informed - risk is considered first, not regulatory requirements or commitments
- Performance based - grounded in deficient licensee performance
- Recognizes a “baseline risk” that includes degraded conditions not resulting from deficient licensee performance
- Focuses on the cause of degraded condition, not the condition itself
- Defines the point where NRC and licensee resources are applied to the evaluation of the safety or security significance of an inspection issue
- Should not be a disincentive to continuous improvement
- Uses clear language, consistent with current use to the degree reasonable
- Supplemented by clear explanation where needed in basis document

Remarks on Industry-Proposed Definition

- Definition should be risk-informed (start with change in baseline risk) and performance-based (what did licensee do or not do that caused the increase in risk)
- Who identifies issue does not factor in whether an increase in the baseline risk has occurred - risk is not sensitive to identification
- Regulations and commitments by themselves may not address all significant safety or security risk aspects of facility operations
- Proposed language would be inconsistent with a fundamental definition for the same type of “starting point” in the reactor oversight process - a process used successfully for several years
- NRC intends to engage licensees for issues of very low safety significance but not for issues that are of minor or negligible risk.

Proposed Performance Deficiency Definition

- An issue that is the result of a licensee (or certificate holder) not meeting a requirement or standard where the cause was reasonably within the licensee's ability to foresee and correct, and that should have been prevented. A performance deficiency can exist if a licensee fails to meet a self-imposed standard or a standard required by regulation. *Issues which do not have a more than minor impact on safety or security are not to be pursued as inspection findings and are not included in the assessment of overall licensee performance.*



SDP Thresholds and Risk-Informed Scale

Rudy Bernhard

Dennis Damon

October 6, 2009

Why an SDP?

- Findings need to be communicated to decision makers in a way that is consistent, and expresses the significance of the finding, to aid in the decision-making process.

Risk-Informed Process

- The agency is using concepts of risk as inputs in the decision making process. The agency does not base its decisions solely on a calculated risk value, but instead uses risk as one of many inputs. Therefore the decision making process is "Risk-Informed", not "Risk-Based."

Two Methods for SDP

- Two approaches to determine significance are proposed.
 - One approach is for Cornerstones that have some basis for estimating the risk using the ISAs. This method will probably use significant input from calculated values of change in risk.
 - Second method assesses findings for Cornerstones not well represented in the ISAs. SDPs for these cornerstones will use a more deterministic approach and the thresholds were developed using risk concepts.

Risk

Risk = Probability * Consequence

- Calculations can be used to compare different conditions' level for risk.
- This concept can also be used to inform decisions without precise numerical values being assigned, using expert elicitation.

Expert Elicitation

- Expert elicitation was used in the development of the non-ISA type cornerstones' thresholds.
 - thresholds were established based on the experience gained in the ROP.

Numerical Methods

- For ISA-related Cornerstones, a change in risk from a baseline (that was judged to be acceptable) is one way to measure significance of findings.
- Another way would be to look at the remaining barriers or controls that prevent the consequence, with the deficiency present, and judge their value.
- In each case, the consequence would have to be defined.

Phase 1 Screening

- A Phase 1 process is being developed for the Criticality and Chemical Safety Cornerstones. Guidelines for the inspector to execute this first level of significance screening will be issued for comment in October.
 - Guidelines based on expert elicitation using past inspection findings.
 - Thresholds set to allow an inspector, without a risk analyst, to characterize certain findings to be of very low safety significance.

Phase 2 Determination

- Items exceeding very low significance threshold will go to Phase 2.
 - Risk analyst will use best available information to make an estimate of the change in risk.
 - Based on the change in risk from a baseline, recommendations will be made on the finding's significance.

Phase 2 (continued)

- The Phase 2 process is not a ‘true’ calculation of risk - instead is a method to characterize a finding.
- Often a series of numerical upper bound calculations/assumptions can lead to a characterization without large effort - especially true with items of very low significance.

Risk Comparisons?

- Again, the purpose of the SDP is to risk-inform NRC actions in response licensee performance deficiencies.
- Caution must be used when comparing risks for various processes with extremely different consequences.

Thresholds of Significance

- Thresholds need to be established for the analyst to make recommendations in a consistent manner. NRC has not yet developed the value of, or how much weight should be used, to risk inform the process for the findings that will be more numerically based.

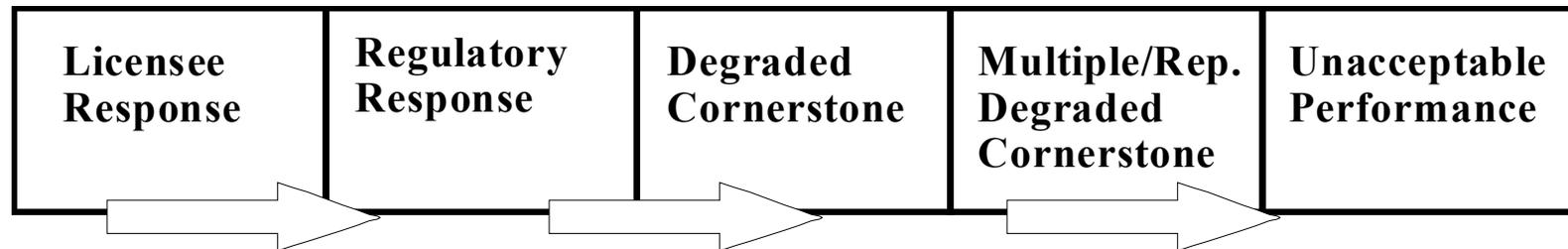
Risk-Informed Scale

- Risk-informed thresholds will be developed for ISA-related cornerstones.
- Numerical risk thresholds will be developed to inform the significance of the findings.
- Development of these thresholds is underway internally and results will be available for public review.
 - Deterministic criteria may be used to modify the numerical thresholds for the final characterization of the finding.

Action Matrix

Steven J. Vias
October 6, 2009

Assessment and Response Concept



Increasing Safety Significance

Increasing NRC Inspection Efforts

Increasing NRC/Licensee Management Involvement

Increasing Regulatory Actions

IMC-RFCOP Assessment

- Replacement for the LPR Process
- Only uses inspection findings
- Uses Action Matrix as the center of assessment
- Process is based on use of thresholds
- Considers performance for a 24-month rolling window
- Provides a graded approach

Process Activities

Level of Review	Frequency/ Timing	Participants (* indicates chairperson)	Desired Outcome	Communication
Continuous	Continuous	SRI, RI, regional inspectors, SRAs	Performance awareness	None required, notify licensee by an Assessment Follow-Up letter <u>only</u> if thresholds crossed.
Periodic (Quarterly or Semi-annually)	Once per quarter/semi-annual - Five weeks after end of quarter	DRP: BC*, PE, SRI, RI	Input/verify PIM data, detect early trends	Update data set, notify licensee by an Assessment Follow-Up letter <u>only</u> if thresholds crossed.
Mid-Cycle	At mid-cycle/ Seven weeks after end of second period	DFFI and FCSS DD*, DFFI, FCSS and security BCs	Detect trends, plan inspection	Mid-cycle letter with an inspection plan of approximately 15 months.
End-of-Cycle	At end-of-cycle/ Seven weeks after end of assessment cycle	DFFI and FCSS DD, RA*, BCs, principal inspectors, SRAs, HQ offices as appropriate.	Assessment of plant performance, oversight and coordination of regional actions	Annual assessment letter with an inspection plan of approximately 15 months.
End-of-Cycle Summary Meeting	The end-of-cycle summary meeting will be scheduled within one week after the completion of the last regional end-of-cycle review	DIR NMSS, RA, BCs, OE, OI, other HQ offices as appropriate.	Summarize results of the end-of-cycle review	Information to be discussed at Agency Action Review Meeting.
Agency Action Review	Annually/ Several weeks after issuance of the assessment letters	EDO*, DIR NMSS, RA DFFI and FCSS DDs, OE, OI, other HQ offices as appropriate.	Review of the appropriateness of agency actions	Commission briefing, followed by public meetings with individual licensees to discuss assessment results, as appropriate.

		Licensee Response Column	Regulatory Response Column	Degraded Cornerstone Column	Multiple/ Repetitive Degraded Cornerstone Column	Unacceptable Performance Column	Restart Process
RESULTS		All Inspection Findings) Green; Cornerstone Objectives Fully Met	One or Two White Inputs (in different cornerstones) in a Strategic Performance Area; Cornerstone Objectives Met	One Degraded Cornerstone (2 White Inputs or 1 Yellow Input) or any 3 White Inputs in a Strategic Performance Area; Cornerstone Objectives Met with Moderate Degradation in Safety and security Performance	Repetitive Degraded Cornerstone, Multiple Degraded Cornerstones, Multiple Yellow Inputs, or 1 Red Input; Cornerstone Objectives Met with Longstanding Issues or Significant Degradation in Safety and security Performance	Overall Unacceptable Performance; Facilities Not Permitted to Operate Within this Band, Unacceptable Margin to Safety and security	Facilities in a shutdown condition with performance problems placed under the IMC Restart process
RESPONSE	Regulatory Performance Meeting	None	Branch Chief (BC) or Division Director (DD) Meet with Licensee	Regional Administrator (RA) (or Designee) Meet with Senior Licensee Management.	EDO/DEDO (or Designee) meet with Senior Licensee Management	EDO/DEDO (or Designee) Meet with Senior Licensee Management	RA/EDO (or Designee) Meet with Senior Licensee Management
	Licensee Action	Licensee Corrective Action	Licensee Root cause Evaluation and corrective action with NRC Oversight	Licensee cumulative root cause evaluation with NRC Oversight	Licensee Performance Improvement Plan with NRC Oversight		Licensee Performance Improvement Plan / Restart Plan with NRC Oversight
	NRC Inspection	Risk-Informed Baseline Inspection Program	Baseline and supplemental inspection procedure 950X1	Baseline and supplemental inspection procedure 950X2	Baseline and supplemental inspection procedure 95003		Baseline and Supplemental as Practicable, Plus Special Inspections per Restart Checklist.
	Regulatory Actions ²	None	Supplemental inspection only	Supplemental inspection only Plant Discussed at AARM if Conditions Met	-10 CFR 2.204 DFI - CAL/Order Plant Discussed at AARM	Order to Modify, Suspend, or Revoke Licensed Activities Plant Discussed at AARM	CAL/Order Requiring NRC Approval for Restart. Plant Discussed at AARM
COMMUNICATION	Assessment Letters	BC review/sign assessment report (w/ inspection plan)	DD review/sign assessment report (w/ inspection plan)	RA review/sign assessment report (w/ inspection plan)	RA review/sign assessment report (w/ inspection plan)		N/A. RA Review/ Sign Restart-Related Correspondence
	Annual Involvement of Public Stakeholders	SRI or BC Meet with Licensee	BC or DD Meet with Licensee	RA (or Designee) Discuss Performance with Senior Licensee Management	EDO/DEDO (or Designee) Discuss Performance with Senior Licensee Management		N/A. Region II Conduct Public Status Meetings Periodically
	Commission Involvement	None	None	Possible Commission Meeting if Licensee Remains for 3 yrs	Commission Meeting with Senior Licensee Management Within 6 mo.	Commission Meeting with Senior Licensee Management	Commission Meetings as Requested, Restart Approval in Some Cases.
INCREASING SAFETY AND SECURITY SIGNIFICANCE ----->							34



Project Plan

Steven J. Vias
October 6, 2009

Major Project Phases

- Complete Phase 1
 - Develop/issue additional program and inspection documents for comment in October and January 2010
 - Identify and focus on difficult issues
- Begin Phase 2 in July 2010 – initial implementation
 - Determine appropriate method for initial implementation
 - Train inspectors
- Start Phase 3 in January 2011- full implementation

Phase 1 – Document Development

Group 1 (August 2009)

- IMC – Basis, Fuel Cycle Oversight Process Basis Document
 - Identified process elements and cornerstones
 - Began development of Risk-Informed Scale
- IMC 2600, Fuel Cycle Facility Inspection Program—Operations Phase
- IMC – SDP, Fuel Cycle Significance Determination Process
 - Appendix B - Emergency Preparedness
- IMC 2604, Fuel Cycle Facility Assessment Program

Phase 1 – Document Development

Group 2 (October 2009)

- Supplemental inspection procedures (IP 950X1, IP 950X2)
- Corrective Action Program inspection procedure (IP 88152) with safety culture
- IMC RFCOP-SDP Significance Determination Process for Fuel Cycle Facilities
 - Attachment 1 – Determination of Finding of Greater than Minor Significance
 - Attachment 2 - Minor Issues (examples for each cornerstone)
 - Appendix A – SDP for Criticality Safety and Chemical Process Safety (Phase 1 SDP only)
 - Appendix C – SDP for Worker Radiation Safety
 - Appendix D – SDP for Public Radiation Safety

Phase 1 – Document Development

Group 2 (October 2009) (con't)

- IMC 2600, Fuel Cycle Facility Inspection Program—Operations Phase
 - Appendices A thru E
- IMC 0616, Fuel Cycle Safety and Safeguards Inspection Reports

Phase 1 – Document Development

Group 3 (2010)

- IMC – Basis, Fuel Cycle Oversight Process Basis Document – Phase 2
- IMC 0309, Reactive Inspection Decision Basis for Fuel Facilities
- IP 950X3, Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input
- IP 88003, Reactive Inspection for Events at Fuel Cycle Facilities Program

Phase 1 - Document Development

Group 3 (2010) (con't)

- IMC – SDP, Fuel Cycle Significance Determination Process
 - Appendix E - Material Control and Accounting (MC&A)
 - Appendix F - Reserved for Information Security
 - Appendix G - Physical Security
 - Attachment 3, Significance and Enforcement Review Panel Process
 - Attachment 4, Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)
 - Attachment 5, Senior Reactor Analyst Support Expectations

Phase 1 - Document Development

Group 3 (2010) (con't)

- IMC 2681, Physical Protection and Transport of SNM and Irradiated Fuel Inspections of Fuel Facilities”
- IMC 2683, MC&A Inspection of Fuel Cycle Facilities
- Input to MD 8.3, NRC Incident Investigation Program
- Input to MD 8.14, Agency Action Review Meeting (AARM)
- Revise other baseline inspection procedures as appropriate



DAY 2

OCTOBER 7, 2009

Agenda

October 7, 2009

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- 8:40 a.m. Nuclear Energy Institute (NEI) Opening Statement - NEI
- 8:50 a.m. Meeting Protocol - NRC
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 - IMC-RFCOP-Basis Document – NRC and NEI/Industry
 - IMC-RFCOP-Inspection Program - NRC and NEI/Industry
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- 4:00 p.m. Next Steps - NRC and NEI/Industry
- 4:30 p.m. Questions and Discussion with Member of the Public
- 5:00 p.m. Adjourn

Key Objectives for Today

- Reach common understanding of industry specific comments provided by NEI
- Obtain and reach common understanding of additional comments provided today
- Discuss Next Steps

IMC-SDP for Emergency Preparedness

- Objective is to ensure that licensee or certificate holder is capable of implementing adequate measures to protect public health and safety in the event of a radiological emergency or chemical emergency from chemicals related to the processing of licensed materials

IMC-SDP for Emergency Preparedness

- Guidance uses deterministic concepts from the ROP
- SDP Appendix B is inclusive in that both SDP Phases 1 and 2 are presented
- Determination of risk-significant planning elements is essential
- Guidance addresses failures to comply and failures to implement



Discuss Industry Comments

Appendix B – EP SDP

IMC-RFCOP-Basis Document – Phase 1

- Introduction of Basis for the overall oversight program:
 - Inspection Program
 - Significance Determination Process
 - Assessment Program
- Fuel Cycle Oversight Process Chart (Exhibit 1)
- Oversight Framework w/Cornerstones (Exhibit 2)
- Introduction of Risk Informed Scale



Discuss Industry Comments IMC Basis Document

IMC-2600 Inspection Program

- Defines the baseline inspection program (formally core program)
- Defines infrastructure for inspection program (inspection types, inspection requirements, resources, frequencies, planning, etc.)
- Defines resident inspector policy



Discuss Industry Comments IMC Inspection Program

IMC-RFCOP-SDP

SDP Program Document Structure

- Guidance consists of the Program IMC, Attachments and Appendices.
- Attachments provide the guidance for all items evaluated in the SDP.
- Appendices provide cornerstone-specific guidance.
- Only the Program IMC and EP SDP were provided for review.



Discuss Industry Comments IMC SDP Program Guidance

IMC-RFCOP Assessment

- Replacement for the LPR Process
- Only uses inspection findings
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Discuss Industry Comments IMC Assessment Program

Next Steps...

- Complete Phase 1
 - Develop/issue additional program and inspection documents for comment in October and January 2010
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