

SIGNIFICANCE DETERMINATION PROCESS

Effective Date: November 15, 2016

0609-01 PURPOSE

The Significance Determination Process (SDP) uses risk insights and other relevant information, as appropriate, to assist NRC staff in determining the safety or security significance of inspection findings identified within the seven cornerstones of safety at operating reactors. The SDP is a risk-informed process and the resulting safety or security significance of findings, combined with the results of the risk-informed performance indicator program, is used to determine a licensee's level of safety performance and the level of U.S. Nuclear Regulatory Commission engagement with the licensee in accordance with Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program." Each appendix to IMC 0609 supports a cornerstone(s) associated with the strategic performance areas as defined in Management Directive (MD) 8.13, "Reactor Oversight Process" and the baseline inspection program as outlined in Inspection Manual Chapter (IMC) 2515, "Light-Water Reactor Inspection Program - Operations Phase" and IMC 2201, "Security and Safeguard Inspection Program for Commercial Power Reactors."

This document will be used in conjunction with IMC 0609 Attachment 1TP, "Significance and Enforcement Review Panel (SERP) Process" and IMC 0609 Attachment 5TP, "Inspection Finding Review Board." These procedures are intended to enhance the efficiency of the SDP with an emphasis on improved management oversight and planning of greater than Green inspection findings involving the initiating events, mitigating systems and barrier integrity cornerstones. The test activity is scheduled to end not later than December 31, 2017.

0609-02 BACKGROUND

SECY-99-007, dated January 8, 1999, described the need for a method of assigning a risk characterization to inspection findings. This risk characterization is necessary so that inspection findings can be equivalently combined with risk-informed plant performance indicators (PIs) during the plant performance assessment process.

SECY-99-007A, dated March 22, 1999, provided a set of draft cornerstone SDP appendices for the purpose of initiating a pilot program at nine reactor sites to evaluate the efficacy of the proposed revisions for risk-informing the reactor inspection program. Other safety cornerstone SDP appendices that could not be related to core damage or containment failure risk used other rationale for assigning significance, as discussed in the respective appendices to this IMC.

SECY-00-49, dated February 24, 2000, provided the results of the pilot program for risk-informing the reactor inspection program and recommended proceeding with initial implementation of the new process at all licensed power reactor sites. The guidance in this IMC and related reactor inspection program guidance in IMC 2515 and IMC 2201 were subsequently issued in support of initial implementation. Enforcement associated with violations of regulatory requirements will continue to be processed in accordance with the current revision of the NRC Enforcement Policy, Enforcement Manual, and any applicable Enforcement Guidance Memoranda (EGMs).

COMSECY-14-0030, dated September 19, 2014, provided direction to the staff to streamline the Significance Determination Process and to establish appropriate timeliness metrics for finalizing inspection findings.

0609-03 OBJECTIVES

03.01 To characterize the safety or security significance of inspection findings for the NRC Reactor Oversight Process (ROP), using best available information, as appropriate.

03.02 To provide all stakeholders an objective and common framework for communicating the potential safety or security significance of inspection findings.

03.03 To provide a basis for timely assessment and/or enforcement actions associated with an inspection finding.

03.04 To provide inspectors with plant-specific risk information for use in risk-informing the inspection program.

0609-04 APPLICABILITY

04.01 The SDP tools described in appendices to this IMC are applicable to inspection findings identified through the implementation of the NRC inspection program described in IMC 2515 and IMC 2201. Before determining safety or security significance of an inspection finding, each performance deficiency shall be screened and determined to be “more than minor” using the guidance provided in IMC 0612, Appendix B, “Issue Screening” and Appendix E, “Examples of Minor Issues”, as applicable. Violations with no associated performance deficiency are not inspection findings and therefore are not evaluated by the SDP. In addition, safety significant degraded conditions with no associated performance deficiency are not evaluated by the SDP. However, these degraded conditions may need to be addressed by other NRC processes (e.g., 10 CFR 50.109, Generic Safety Issue Program, rule-making).

04.02 A subtle yet extremely important and fundamental tenet of the SDP framework is that deficient licensee performance (as later described and documented as the inspection finding) is the proximate cause of the degraded condition(s). As such, the degraded condition in and of itself (e.g., a non-functional safety-related pump) is not the deficient licensee performance. Rather, the deficient licensee performance (e.g., inadequate maintenance procedure) is the proximate cause that led to the particular degraded condition(s). The SDP is designed to

estimate the safety or security significance of a degraded condition(s) that was caused by deficient licensee performance above the baseline risk profile (see IMC 0308, Attachment 3, "Significance Determination Process Basis Document" for more details).

04.03 Nothing in this guidance relieves any licensee from fully complying with Technical Specifications, licensing basis commitments, or other applicable regulatory requirements. Continued compliance with regulatory requirements maintains the requisite defense-in-depth and safety margins necessary to achieve adequate protection of public health and safety.

04.04 The safety significance of reactor events caused or complicated by equipment malfunction and/or operator error are initially assessed by NRC staff in accordance with IMC 0309, "Reactive Inspection Decision Basis for Reactors" and Management Directive (MD) 8.3, "NRC Incident Investigation Program." Although the outcome of this risk evaluation may provide useful risk insights to NRC staff for event response or follow-up, it was not designed to determine the safety or security significance of inspection findings. Since the SDP is used to evaluate the safety or security significance of degraded conditions caused by deficient licensee performance, including those that manifest themselves during events, inspection findings associated with a reactor event shall be processed in accordance with IMC 0609 and its associated attachments and appendices.

0609-05 DEFINITIONS

05.01 Applicable definitions are located in IMC 0612, "Power Reactor Inspection Reports" and supporting technical and program bases are located in IMC 0308, Attachment 3, "Significance Determination Process Basis Document."

05.02 Inspection findings are assigned a color representing the safety significance of the finding. The following definitions (05.02.a thru 05.02.d) include the quantitative and qualitative descriptions for each color and need to be applied appropriately to each SDP appendix listed at the end of this document. The symbol " Δ ", as used in the quantitative SDP appendices that use core damage frequency (CDF) and large early release frequency (LERF) as metrics, refers to the difference between the CDF (or LERF) resulting from the degraded condition(s) caused by deficient licensee performance and the nominal CDF (or LERF) of the facility. In other words, the quantitative SDP appendices estimate the increase in risk resulting from a degraded condition(s) caused by deficient licensee performance above a baseline risk profile. A graphical representation of the quantitative significance of findings is displayed in Exhibit 1.

- a. Red (high safety or security significance) is quantitatively greater than $10^{-4}\Delta\text{CDF}$ or $10^{-5}\Delta\text{LERF}$. Qualitatively, a Red significance indicates a decline in licensee performance that is associated with an unacceptable loss of safety margin. Sufficient safety margin still exists to prevent undue risk to public health and safety.
- b. Yellow (substantial safety or security significance) is quantitatively greater than 10^{-5} and less than or equal to $10^{-4}\Delta\text{CDF}$ or greater than 10^{-6} and less than or equal to $10^{-5}\Delta\text{LERF}$. Qualitatively, a Yellow significance indicates a decline in licensee performance that is still acceptable with cornerstone objectives met, but with significant reduction in safety margin.

- c. White (low to moderate safety or security significance) is quantitatively greater than 10^{-6} and less than or equal to 10^{-5} Δ CDF or greater than 10^{-7} and less than or equal to 10^{-6} Δ LERF. Qualitatively, a White significance indicates an acceptable level of performance by the licensee, but outside the nominal risk range. Cornerstone objectives are met with minimal reduction in safety margin.
- d. Green (very low safety or security significance) is quantitatively less than or equal to 10^{-6} Δ CDF or 10^{-7} Δ LERF. Qualitatively, a Green significance indicates that licensee performance is acceptable and cornerstone objectives are fully met with nominal risk and deviation.

05.03 Risk-Based - An approach to regulatory decision-making that is solely based on the quantitative results of a risk assessment.

05.04 Risk-Informed – An approach to regulatory decision-making that considers both quantitative and qualitative risk insights and other relevant information, as appropriate.

05.05 SDP Timeliness – The time it takes to assess the significance of an inspection finding that does not screen to Green. The goal for SDP timeliness is to complete all final significance determinations within 90 days.

To effectively monitor the SDP timeliness goal, an associated metric is included in IMC 0307, Appendix A, “Reactor Oversight Process Self-Assessment Metrics.” This metric takes into account that certain inspection findings may take additional time due to their complexity and/or potential high degree of risk significance.

05.06 Best Available Information – Information that is accessible, applicable, and ready for use at the time of the review to determine the safety significance of the inspection finding.

It is essential that the NRC make appropriate and timely decisions on inspection findings in order to promptly assure nuclear safety and to communicate the results of inspection findings to the public in a timely manner. To accomplish this, it is expected that both licensees and the NRC will use information that is most reflective of the circumstances associated with the inspection finding and is available at the time of the significance determination.

0609-06 RESPONSIBILITIES AND AUTHORITIES

All NRC inspectors are required to assess the significance of inspection findings in accordance with the guidance provided in this IMC. General and specific responsibilities are listed below.

Note: It is essential that in order to improve the efficiency and effectiveness of the SDP that the Issue Sponsor be the voice of the NRC when communicating with licensee management on the disposition of greater than Green inspection findings. Specifically, all management level communications should be directed to the chairman of the Inspection Finding Review Board, consistent with IMC 0609 Attachment 5TP.

06.01 Director, Office of Nuclear Reactor Regulation (NRR).

- a. Provide overall program direction for the ROP.
- b. Develop and direct the implementation of policies, programs, and procedures for regional application of the SDP guidance.
- c. Assess the effectiveness, uniformity, and completeness of regional implementation of the SDP.

06.02 Director, Office of Nuclear Security and Incident Response (NSIR)

- a. Provide overall program direction for the emergency preparedness and security cornerstones of the ROP.
- b. Develop and direct the implementation of policies, programs, and procedures for regional application of the emergency preparedness and security SDP guidance.
- c. Provide oversight and representatives as necessary to support the Significance and Enforcement Review Panel (SERP) in order to ensure consistent and timely application of the process.
- d. Support the development, maintenance, and periodic implementation of appropriate training to ensure both technical staff and SERP decision-makers understand the program and process guidance.

06.03 Director, Division of Inspection and Regional Support

- a. Approve all revisions to SDP procedures and direct the development of future SDP procedures and improvements through periodic revisions based on new risk insights and feedback from users.
- b. Provide oversight and representatives as necessary to support the SERP in order to ensure consistent and timely application of the process.
- c. Develop, maintain, and periodically provide appropriate training to ensure both technical staff and SERP decision-makers understand the program and process guidance, risk analysis techniques, and the treatment of uncertainty.

06.04 Director, Division of Risk Assessment

- a. Recommends improvements to all SDP tools using a probabilistic risk framework and approves changes to plant-specific risk insight information used by the SDP, based on new risk insights and feedback from users.
- b. Provide oversight and representatives as necessary to support the SERP in order to ensure consistent and timely application of the process.

- c. Support the development, maintenance, and periodic implementation of appropriate training to ensure both technical staff and SERP decision-makers understand the program and process guidance, risk analysis techniques, and the treatment of uncertainty.
- d. Provide risk analysts with a general expectation that balances the amount of time and resources allocated in determining the safety significance of an inspection finding and the goal of providing a timely response.

06.05 Director, Office of Enforcement

- a. Ensure consistent application of the enforcement process to violations of NRC regulations with the appropriate focus on the significance of the inspection finding.
- b. Provide representatives as necessary to support the SERP in order to ensure consistent application of the enforcement process.
- c. Coordinate with NRR (and NSIR when necessary) when revising agency documents used for communicating to the licensee about apparent violations and final determinations associated with the ROP.
- d. Support the development, maintenance, and periodic implementation of appropriate training to ensure both technical staff and SERP decision-makers understand the program and process guidance, risk analysis techniques, and the treatment of uncertainty.

06.06 Director, Office of Research

- a. Based on user need requests, provide support in the development and refinement of the SDP tools and research activities (e.g., SAPHIRE, SPAR Models, NUREGs, NURER/CRs) to enhance the overall implementation of the SDP.
- b. Provide representatives, when requested, to support the SERP.

06.07 Regional Administrators

- a. Provide program direction for management and implementation of the SDP to activities performed by the Regional Office.
- b. Maintain overall responsibility for, and apply regional resources as necessary, to determine the significance of specific inspection findings in a timely manner, using best available information consistent with the SDP timeliness goal and associated SDP timeliness metrics.

06.08 Director, Division of Reactor Projects and Reactor Safety.

- a. Provide oversight and representatives as necessary to support the SERP in order to ensure consistent and timely application of the process.

- b. Support the development, maintenance, and periodic implementation of appropriate training to ensure both technical staff and SERP decision-makers understand the program and process guidance, risk analysis techniques, and the treatment of uncertainty.
- c. Provide regional staff with a general expectation to balance the amount of time and resources allocated in determining the safety significance of an inspection finding and the goal of providing a timely response.
- d. Communicate effectively with licensee management on potentially greater than Green inspection findings consistent with the Inspection Finding Review Board (IFRB) process outlined in IMC 0609 Attachment 5TP.

06.09 Senior Reactor Analysts (SRAs).

- a. Support NRC objectives related to the utilization of risk insights in the reactor inspection program, the SDP, and other risk-informed applications in the ROP.
- b. Provide regional management with updates on the expected amount of resources needed to appropriately characterize the safety significance of an inspection finding.
- c. Support the specific objectives as presented in Attachment 3 to this IMC.

0609-07 SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL (SERP) PROCEDURES

The following basic process is described in detail in IMC 0609 Attachment 1TP, "Significance and Enforcement Review Panel Process."

07.01 Development of and Initial Characterization of Inspection Findings. Initial significance determination is normally performed by the inspector using IMC 0609, Attachment 4, "Initial Characterization of Findings" and the applicable appendix of IMC 0609. Once an inspection finding is determined to not screen as Green, convening the IFRB shall be considered to ensure alignment on the performance deficiency, the inspection finding, any proposed violation(s) and the actions and timeframes to determine the preliminary significance. Refer to IMC 0609.05TP, "Inspection Finding Review Board" for additional guidance.

07.02 Preliminary Significance Review and Decision. Any finding with a pending significance (see IMC 0612 for definition) of White, Yellow, Red, or GTG, shall be reviewed and decided by the SERP. The result of the SERP review and decision represents the staff's preliminary safety significance characterization. However, when a pending White, Yellow, or Red finding is determined to be Green by the SERP, this will represent a final determination and characterized as such in the inspection report.

07.03 Planning SERP. The purpose of the Planning SERP is to ensure the SERP decision-makers achieve alignment on the overall approach to characterize the significance of inspection findings that are more complex in nature and to coordinate HQ expertise and resources. Since the SERP decision-makers are involved, the Planning SERP is reserved for cases in which the Sponsor is planning to propose a GTG, White, Yellow, or Red significance characterization.

Guidelines for conducting a Planning SERP are detailed in IMC 0609 Attachment 1TP.

07.04 Obtaining Licensee Perspectives on Significance Determination. After the IFRB approves the performance deficiency for an inspection finding that did not screen to Green, the IFRB chairman will notify the licensee that the NRC will be performing additional reviews and analysis to determine significance. The chairman will also communicate the desire for timely, open and constructive dialogue using best available information emphasizing the chairman's focal point role in the process. If the preliminary significance assessment of a finding is White, Yellow, Red, or Greater than Green, the licensee will be given the opportunity to provide additional information and perspectives at a public Regulatory Conference or in a written response on the docket. This opportunity will be offered in the cover letter of the inspection report or in the preliminary significance determination letter.

07.05 Final Significance Review and Decision. If the licensee accepts the staff's preliminary significance determination and does not intend to present additional information, the staff will issue a final significance determination letter. If the licensee provides information on the docket by letter or participates in a Regulatory Conference, the staff will convene a Post-Conference Review prior to making a final significance decision. If after considering the licensee's additional information, the SERP determines that a preliminary White, Yellow, Red, or GTG finding is of Green significance, this is the final determination and will be communicated in the final significance determination letter in keeping with the SDP timeliness goal.

In the case where the staff has issued a preliminary significance determination of GTG and the licensee has not or cannot provide sufficient information to better inform the staff's significance determination in a reasonable period of time, the SERP will reconvene and make its final determination based on the readily available information. The SERP's conclusion and rationale will be documented in the final significance determination letter.

07.06 Office of Investigation (OI) and Department of Justice (DOJ). Some inspection findings may involve a formal OI or DOJ investigation. When an inspection finding involves a formal OI/DOJ investigation and it is known that the results of the investigation will not impact further evaluation of the finding's significance and/or follow-up inspection, the finding shall be resolved using the normal SDP process. If the OI/DOJ investigation does impact the timely resolution of the finding, the guidance for a Planning SERP shall be implemented.

0609-08 PROCESS FOR LICENSEE APPEAL OF A STAFF SDP DETERMINATION

If a licensee disagrees with the staff's final determination of significance, the licensee may appeal the determination to the appropriate NRC Regional Administrator as described in IMC 0609, Attachment 2, "Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)." Any such review must meet the requirements stated in the Prerequisites and Limitations sections of Attachment 2 to merit further staff consideration.

0609-09 SDP DEVELOPMENT AND FEEDBACK PROCESS

09.01 SDP Development. The development of a new SDP or significant modification of an existing SDP should follow the general process used for original SDP development. This process should include the following general steps:

- a. The draft of the new SDP (or the significant modification) should receive a thorough internal stakeholder review from both the regions and headquarters via periodic meetings, site visits, surveys, etc. Early external stakeholder input should also be solicited through public meetings (or closed meetings if discussions involve sensitive security-related information).
- b. A feasibility review should be performed, as deemed necessary, by the lead organization (e.g., NRR, NSIR) to assess the adequacy of the proposed new SDP or significant modification. This review should specifically involve regional representation and should test the SDP (preferably with real examples, however, hypothetical inspection findings and violations may be used). Based on the results of the feasibility review, a pilot should be considered to evaluate the robustness of the proposed SDP and to ensure that appropriate outcomes are achieved. The feasibility and/or pilot results should be documented in the applicable SDP technical basis document.
- c. Upon reconciliation of both internal and external feedback from the feasibility review and/or pilot, appropriate training on the SDP should be provided to NRC staff.
- d. After items 07.01a – c have been completed, the final SDP will be issued consistent with the requirements in IMC 0040, “Preparing, Revising, and Issuing Documents for the NRC Inspection Manual.”

09.02 SDP Feedback and Improvement. IMC 0801, “Reactor Oversight Process Feedback Program,” describes in detail the feedback process and feedback form used by the Office of NRR/Division of Inspection and Regional Support, to document problems, concerns, or difficulties encountered during implementation of the ROP guidance.

0609-10 REFERENCES

1. IMC 0612, “Power Reactor Inspection Reports”
2. IMC 0612, Appendix B, “Issue Screening”
3. IMC 0308, Attachment 3, “Significance Determination Process Basis Document”
4. IMC 0609, Attachment 1TP, “The Significance and Enforcement Review Panel Process”
5. IMC 0609, Attachment 2, “Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)”
6. IMC 0609, Attachment 3, “Senior Reactor Analyst Support Objectives”

7. IMC 0609, Attachment 4, "Initial Characterization of Findings"
8. IMC 0609, Attachment 5TP, "Inspection Finding Review Board"
9. IMC 0609, Appendix A, "Significance Determination Process for Findings At-Power"
10. IMC 0609, Appendix M, "Significance Determination Process Using Qualitative Criteria"
11. IMC 0040, "Preparing, Revising, and Issuing Documents for the NRC Inspection Manual"
12. SECY-99-007, "Recommendations for Reactor Oversight Process Improvements"
13. SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-up to SECY-99-007)"
14. SECY-00-0049, "Results of the Revised Reactor Oversight Process Pilot Program"
15. Staff Requirements - COMSECY-14-0030 – Proposed Suspension of the Reactor Oversight Process Self-Assessment for Calendar Year 2014

END

Exhibits:

Exhibit 1	Graphical Representation of the Quantitative Significance of Inspection Findings
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Attachments:

Attachment 1TP	Significance and Enforcement Review Panel Process
Attachment 2	Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)
Attachment 3	Senior Reactor Analyst (SRA) and Risk Analyst Support Expectations
Attachment 4	Initial Characterization of Findings
Attachment 5TP	Inspection Finding Review Board

Appendices:

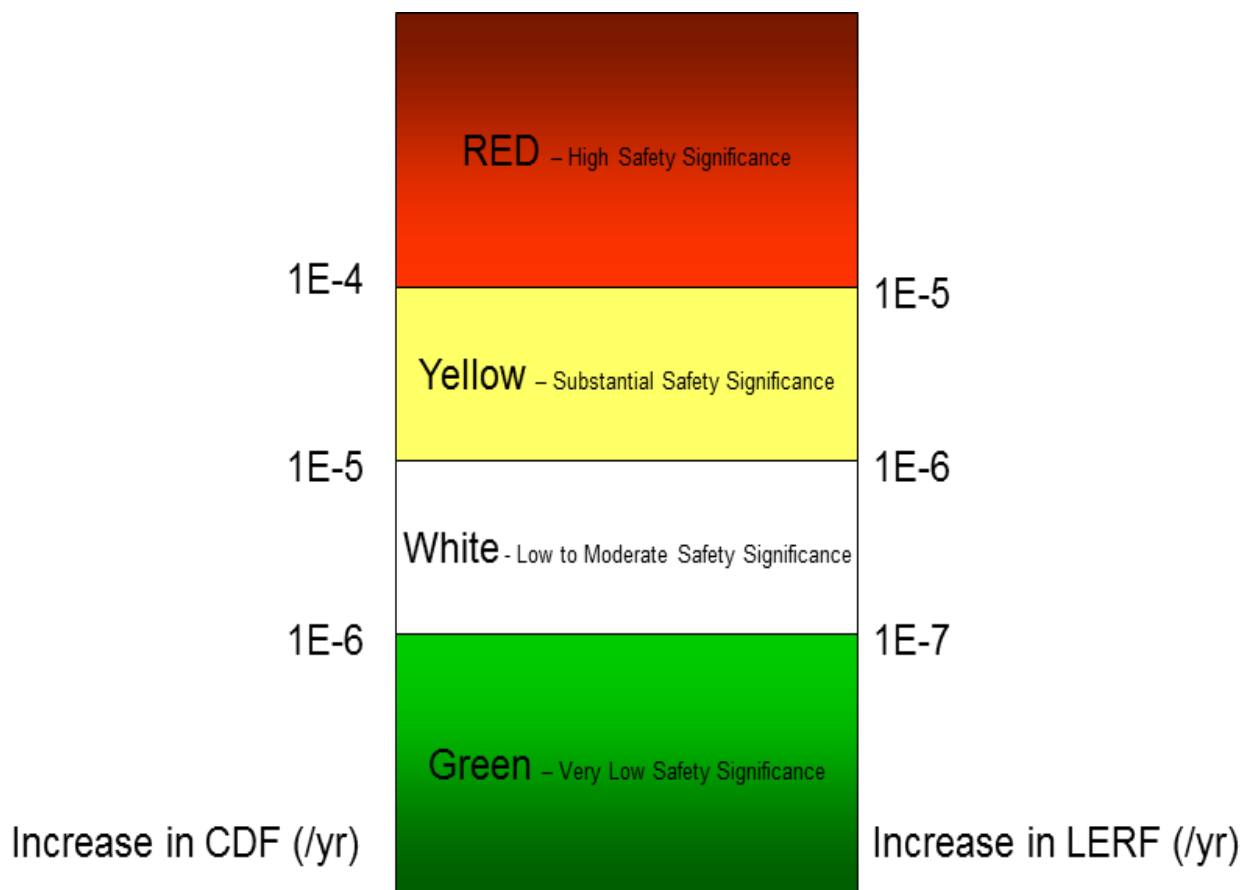
Appendix A	Significance Determination Process for Findings At-Power
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Appendix B	Emergency Preparedness SDP
Appendix C	Occupational Radiation Safety SDP
Appendix D	Public Radiation Safety SDP
Appendix E	Part I, Baseline Security SDP for Power Reactors and Part II, Force-on-Force Security SDP for Power Reactors Part III, Construction Fitness-for-Duty Significance Determination Process for New Reactors (Pilot) Part IV, Cyber Security Significance Determination Process for Power Reactors
Appendix F	Fire Protection and Post-Fire Safe Shutdown SDP
Appendix G	Shutdown Safety SDP
Appendix H	Containment Integrity SDP
Appendix I	Operator Requalification, Human Performance
Appendix J	Steam Generator Tube Integrity SDP
Appendix K	Maintenance Risk Assessment and Risk Management SDP
Appendix L	Significance Determination Process for B.5.b
Appendix M	Significance Determination Process Using Qualitative Criteria
Appendix N	Reserved
Appendix O	Significance Determination Process for Mitigating Strategies and Spent Fuel Pool Instrumentation (Orders EA-12-049 and EA-12-051)

Exhibit 1

Graphical Representation of the Quantitative Significance of Inspection Findings

NOTE: Not applicable to all safety cornerstones and IMC 0609 appendices



Attachment 1

Revision History - IMC 0609TP

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
N/A	ML16110A287 10/28/16 CN 16-028	<p>Since this is a new manual chapter, no review was done for the last four years for commitments. There are no commitments associated with this document.</p> <p>This document is intended to improve the overall efficiency of the SDP. Specifically, best available information and SDP timeliness were defined. Reference is also made to a new procedure, IMC 0609 Attachment 5TP, Inspection Finding Review Board, to improve management oversight and planning of greater than Green inspection findings. Duplication of information to IMC 0609 Attachment 1TP (SERP Process) was deleted making this document a higher tier program level document.</p> <p>This document will be used during a test phase of which is expected to end not later than December 31, 2017.</p>	Presentations were made to three of four regional offices prior to document issuance. Two Q&A sessions will be conducted shortly after the procedure is issued.	ML16110A276