

### SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL (SERP) PROCESS

Effective Date: 01/01/2019

#### 0609.01- 01 PURPOSE

This attachment describes the U.S. Nuclear Regulatory Commission (NRC) procedure for preparing, processing, and finalizing inspection findings determined by the Significance Determination Process (SDP) to have White, Yellow, Red, or greater than Green (GTG) safety or security significance. Since enforcement decisions are integrated into the SDP, this procedure includes enforcement-related information for clarity and convenience. The Commission's Enforcement Policy, Enforcement Manual, and Enforcement Guidance Memoranda remain the governing documents for enforcement-related activities. This attachment applies to both regional and headquarters offices responsible for conducting inspections in support of the Reactor Oversight Process (ROP) and the overall management of inspection findings for operating reactors.

This document will be used in conjunction with Inspection Manual Chapter (IMC) 0609, "Significance Determination Process," and IMC 0609, Attachment 5, "Inspection Finding Review Board." These procedures are intended to ensure the SDP is efficient through appropriate management oversight and planning of the disposition of potentially GTG inspection findings.

#### 0609.01-02 THE SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL PROCESS

The Significance and Enforcement Review Panel (SERP) provides a management review of the inspection finding, a preliminary decision regarding the significance characterization, and enforcement recommendations for all inspection findings in which the Sponsor (defined in Section 02.03) proposes a significance characterization of White, Yellow, Red, or GTG. The documentation of Inspection Finding Review Board (IFRB) results provides information to support efficient SERP decision making. An official agency preliminary significance determination of White, Yellow, Red, or GTG can only be made by a SERP. When necessary, based on the results of a Regulatory Conference or written response provided by the licensee, the SERP provides the management review and a final decision regarding the finding's significance determination and enforcement action, as applicable. During the SERP, panel members will review the inspection finding and reach consensus on:

- a. The safety or security significance of the finding, including the assignment of a preliminary or final color, and
- b. The apparent violation (AV) and the regulatory requirement(s) that should be cited, and associated enforcement action(s), as applicable.

Unanimous agreement of the SERP voting members is not needed to establish consensus; rather, a consensus decision is one in which all SERP voting members at least generally accept the position, agreement, or decision reached, such that the outcome is representative of the entire group rather than attributed to an individual. In all cases, the region or responsible NRC office conducting the inspection is responsible for the overall management and processing of inspection findings. Although some findings may be referred to other technical branches of the NRC, the regions or responsible office must maintain full awareness of the status of those findings to ensure that the findings are processed in an effective and efficient manner.

Each designated SERP member is required to complete SERP training prior to participating in SERP meetings. The training is an online iLearn training module (iLearn course ID 339150) that focuses on basic probabilistic risk assessment techniques and the importance of understanding the most influential assumptions presented by risk analysts, risk-informed decision-making, and the role and responsibilities of SERP members. This training is required only once, but can be accessed at any time as a refresher course. To take advantage of lessons learned on decision-making for inspection findings that go through the SERP process, regional and headquarters SERP members are expected to share these lessons learned in routine meetings, such as during periodic counterpart meetings.

#### 02.01 Preparation for the SERP.

a. For all SDP appendices, the following specific guidance is applicable:

1. If the staff's significance determination of a finding is not complete or the significance determination is complete but a SERP was not able to review and make a preliminary decision prior to the deadline to issue the inspection report, the significance of the finding shall be characterized in the inspection report as "to be determined" (TBD).
2. A Planning SERP will be held in each of the following situations:
  - (a) The region or responsible office is considering the use of IMC 0609, Appendix M to characterize the significance of a finding unless governing SDP documents explicitly direct the use of Appendix M,
  - (b) The inspection finding involves a licensee performance deficiency that was the proximate cause of an actual initiating event and requires a detailed risk evaluation,
  - (c) The inspection finding involves complex technical issues (e.g., natural hazards) that would require a significant amount of resources (e.g., headquarters analysts of specialized expertise) and coordination as determined by the IFRB. Refer to IMC 0609 Attachment 5.
  - (d) The inspection finding involves a formal Office of Investigations (OI) and Department of Justice (DOJ) investigation, and the timely resolution of the finding is impacted by the ongoing OI/DOJ investigation.
  - (e) The IFRB determined that a Planning SERP is needed.

The Planning SERP will reach consensus on the scope, schedule, methodology, and identify staff that will perform the assessment. The recommendation to conduct a Planning SERP is brought to an IFRB by the lead inspection branch and the recommendation is then approved or disapproved by the IFRB. The recommendation and IFRB decision are documented on the IFRB Worksheet (Exhibit 1 of IMC 0609, Attachment 5). The Planning SERP should be conducted using the SERP worksheet. An additional SERP is then required to arrive at a preliminary significance determination.

3. Consistent with the IFRB process, the responsible inspector(s) should clearly articulate the performance deficiency, the more-than-minor criteria that was met, describe how the deficient licensee performance was the proximate cause of the degraded condition, the basis for not screening the finding to Green (only applicable to the SDP appendices that use screening questions), the proposed safety or security significance (only applicable to SDP appendices that do not require Senior Reactor Analyst (SRA) support), and any enforcement recommendations. Additional staff in the region and headquarters should provide technical and programmatic support to the inspector(s), as appropriate. The region or responsible office should periodically communicate details involving inspection, proposed enforcement, risk insights, and other pertinent information with technical staff and management in both the region and headquarters (i.e., the Office of Nuclear Reactor Regulation (NRR) (particularly the Reactor Assessment and Human Factors Branch (IRAB) in the Division of Inspection and Regional Support (DIRS) and the PRA Oversight Branch (APOB) in the Division of Risk Assessment (DRA)), the Office of Enforcement (OE), and the Office of Nuclear Security and Incident Response (NSIR), as needed). The SERP members are responsible for ensuring that the technical staff in their respective organizations have provided sufficient information in a timely manner to support an effective and well-informed regulatory decision.
  4. After the region or responsible office has developed their proposed position, it is documented using the IFRB process outlined in IMC 0609, Attachment 05. The documentation of IFRB results provides information to support efficient SERP decision making.
- b. For the quantitative SDP appendices that use core damage frequency (CDF) and large early release frequency (LERF) as metrics, the following specific guidance is also applicable:
1. The regional inspection staff and SRAs should coordinate efforts early in the process to achieve a common understanding of how the deficient licensee performance was the proximate cause of the degraded condition. Sharing information should balance the gained efficiencies of parallel communication with the goal of providing a timely assessment. After the SRA gains a clear understanding of the finding and its relationship to the degraded condition, the risk assessment (i.e., detailed risk evaluation) may begin.
  2. The detailed risk evaluation may be developed by a single SRA or a collaboration of more than one SRA. *[C2 - In developing the risk assessment, a degree of flexibility is needed in terms of how the assessment should be performed. Although there are conventional and acceptable methods for performing risk*

*assessments, typically using the guidance provided in the Risk Assessment Standardization Project (RASP) Handbook, a certain degree of skill of the craft is oftentimes necessary because of the high variability among inspection findings. The various methods used in performing the risk assessment should be consistent with current program guidance and the more detailed guidance provided in the RASP Handbook, recognizing that new and different approaches may be needed for specific situations. In particular, some unique situations may require an enhancement of an existing method or development of new guidance. As such, deviations from methods and guidance in the RASP Handbook may be necessary for the analysis of atypical events or conditions. However, such deviations should be adequately documented in the analysis to allow for the ease of peer review].*

Once the evaluation is completed, it shall be peer reviewed by a headquarters SRA or other qualified risk analyst with specialized expertise, as appropriate. Only one peer review is required. The peer reviewer should have at least five working days to review the evaluation. Any changes to the evaluation based on recommendations from the peer reviewer should be appropriately considered prior to sending documentation to NRR (see Section 02.02). The peer review should focus on:

- (a) Appropriate implementation of current guidance documents (e.g., IMC 0609 attachments and appendices; RASP Handbooks; applicable NUREGs, Regulatory Guides, and generic communications; and other consensus risk assessment publications or standards). Any alternative approaches to the current guidance documents should have a clear and reasonable technical basis.
- (b) Reasonableness of significant assumptions made. If there are additional equally valid assumptions, the peer reviewer should make recommendations for consideration in the risk assessment.
- (c) Appropriate treatment of uncertainty and/or sensitivity evaluations to support risk-informed decision-making.
- (d) Consistency with similar past SDP risk assessments, as appropriate.
- (e) Use of best available information.

## 02.02 NRR Enforcement Coordinator Preparation for the SERP.

The NRR Enforcement Coordinator arranges support and participation by the appropriate management, technical, and project management staff. SERPs are typically held during the scheduled weekly regional enforcement conference call. In scheduling a SERP, the regional enforcement liaison (or staff from NSIR for some security findings) notifies the NRR Enforcement Coordinator and OE of a pending White, Yellow, Red, or GTG finding being processed. All parties should coordinate in scheduling an appropriate date to present the case to the SERP. The NRR Enforcement Coordinator verifies the availability of NRR SERP members and maintains the SERP calendar.

Normally, the OE SERP member would attend the SERP meeting. However, OE has the option to decline participation if there is full agreement by OE staff on the proposed violation. If the OE SERP member exercises this option, the decision will be deferred to the other SERP members. In these cases, OE retains the responsibility for documentation of the SERP's decision in the

OE strategy form, remains on distribution for all related documents, and will be on concurrence for the final significance letter.

At least five working days (earlier for more complex issues) prior to the SERP, the region or responsible office will provide the NRR Enforcement Coordinator the information developed by the IFRB, if one was held. The NRR Enforcement Coordinator electronically distributes the information to all headquarters SERP participants.

Both regional and headquarters technical staff should conduct pre-briefings to SERP decision-makers as needed to ensure that the panel members have been afforded an appropriate amount of time to review and understand the information.

#### 02.03 Participation in the SERP.

The principal objective of the SERP is to discuss, review, and arrive at a consensus decision regarding the significance determination of the inspection finding and the appropriate enforcement actions to be taken, as applicable. All members of the SERP, indicated in the table below, will represent their respective organization and participate as voting members in reaching a consensus decision. The Director of DIRS, or designee, is responsible for determining whether there is sufficient consensus to move forward. Even though each participating organization has a distinct function, as defined in the table below, the panel members have the opportunity to question or challenge any of the information and analyses presented.

If, after the SERP discussion and review, the DIRS Director or designee has determined that the members have reached consensus, then a preliminary determination has been reached. However, if consensus has not been reached on the characterization of the finding, the safety or security significance, and/or the enforcement action(s), the panel members should hold a follow-up SERP within a reasonably prompt timeframe (typically within 2 weeks) focusing on the areas of disagreement. Prior to the follow-up SERP, each voting member should provide the other voting members with a one page document summarizing their position on the areas of disagreement. If the DIRS Director, or designee, determines that consensus is still not reached after the follow-up SERP, then the SERP members should raise the areas of disagreement to the applicable office directors and regional administrator and a SERP will be held with the office directors and regional administrator as decision-makers. Once again, before the final SERP, the voting members should document the areas of disagreement and various views and provide this to the other voting members and to the office directors and regional administrators involved in the final SERP. Should the office directors and regional administrator fail to reach consensus at the third SERP, the issue should be raised to the appropriate Deputy Executive Director for resolution.

A modified SERP may be used as an efficiency enhancement when all the criteria below are satisfied. This process is expected to be conducted via an email being sent to all SERP members by the Sponsor.

- a. The SERP members agree with the preliminary significance determination and violation documented in the SERP worksheet.
- b. The preliminary significance determination is White. This process is not allowed for Yellow or Red findings.
- c. All SERP members agree to the use of the modified SERP process.

SERP members may request that technical specialists, risk analysts, SRAs, and program experts be available at the SERP for consultation. Participation in SERPs should be in accordance with the following guidelines:

Role	Responsible Organization/Participant
<p>Sponsor</p> <p>Holds overall responsibility for resolution of the finding, including assuring appropriate SDP results and achieving SDP timeliness milestones. Leads the meeting in accordance with the guidelines of this Manual Chapter and the Enforcement Manual. Also leads the presentation of the finding. If an IFRB was held, this individual should be the same individual as the IFRB Chair.</p>	<p>Regional or office management representation by the responsible Division Director or Deputy Division Director</p>
<p>ROP Inspection and Assessment Program Spokesperson</p> <p>Provides inspection program management, ensures implementation of SERP and outcome are consistent with ROP policy, resolves ROP program issues, and determines whether consensus has been achieved at a SERP.</p>	<p>NRR DIRS, Director or Deputy Division Director (or Branch Chief)</p>

<p>Headquarters Technical Spokesperson</p> <p>Provides the headquarters technical position and support with SDP appendix implementation. Also responsible for ensuring the outcomes are consistent with program office guidelines (i.e., with respect to application of risk information) and regulatory policy.</p>	<p>Applicable Technical Division</p> <p>NRR DRA (for fire protection, reactor safety, containment, shutdown risk, transportation, ALARA, public and occupational radiation, mitigating strategies, and spent fuel pool SDPs), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Materials and License Renewal (DMLR) (for steam generator SDP), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Licensing Projects (DLP) (for B.5.b SDP), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR DIRS (for operator re-qualification and maintenance rule SDPs), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NSIR, Division of Security Operations (DSO) (physical protection SDPs), Director or Deputy Division Director (or Branch Chief; Division of Preparedness and Response (DRP) (emergency planning SDP), Deputy Director for Response (or designated Branch Chief).</p>
<p>Enforcement Spokesperson</p> <p>Responsible for determining the adequacy of NOV's related to White, Yellow, or Red inspection findings; and ensures the agreements reached at the SERP are documented on the Strategy Form in accordance with OE policies.</p> <p>Ensures the guidelines within the Enforcement Policy are met.</p>	<p>Headquarters OE, Director or Deputy Director (or Branch Chief).</p>

#### 02.04 SERP Determinations.

Members of the SERP discuss, review, and decide on the finding, the safety or security significance of the degraded condition including the assignment of a preliminary color, and the AV(s) and regulatory requirements that should be cited, as applicable. No official agency

preliminary significance determination of White, Yellow, Red, or GTG can be made without a SERP review and decision. The SERP should be completed within 30 days after the inspection report is issued, though it can also be completed prior to issuing the inspection report.

- a. Green: If the SERP concludes that the preliminary significance determination of the finding is Green, the SERP's conclusion regarding enforcement (no violation or non-cited violation) will be documented by OE on the Enforcement Action Tracking System (EATS) Strategy Form. The decision of the SERP will represent a final determination and will be characterized as such in the inspection report.
- b. White, Yellow, Red, or GTG Findings:
  1. If the SERP reaches a consensus that the preliminary significance determination of a finding is White, Yellow, Red, or GTG, the SERP's conclusion will be documented by OE on the Strategy Form. If the staff does not have sufficient information to make reasonable assumptions and the assumptions have a significant impact to the preliminary significance result (i.e., can cause the color to vary across multiple thresholds), the preliminary significance should be characterized as GTG. A GTG preliminary determination allows the NRC staff to document the preliminary significance, based on best available information, in a timely manner and officially begins the opportunity to gather additional information through a Regulatory Conference or letter. The preliminary determination letter must clearly identify the information that is needed to improve the fidelity of the significance characterization.
  2. For quantitative analyses (e.g., IMC 0609, Appendix A, F, G), the final risk assessment should clearly identify all of the significant assumptions used in the analysis and an assessment of significant uncertainties and associated sensitivity evaluations. It is not necessary to use Appendix M if existing SDP tools are generally sufficient to risk-inform the finding and associated degraded condition. However, Appendix M may be appropriate if there is not a SDP tool or inputs to an existing SDP tool cannot be adequately determined through existing SDP resources (e.g., NUREGs, industry documents, RASP Handbook guidance, etc.).
  3. *After the SERP has reached a preliminary decision on the significance determination, the region or responsible office will issue a preliminary significance determination letter to the licensee in the inspection report cover letter or by a separate letter using Enforcement Manual, Appendix B – Standard Formats for Enforcement Packages -Form 3-II, or 3-II(S) for security-related matters. For security-related findings, the preliminary determination letter will be controlled as per the guidance in Commission Policy SECY-04-0191 for Safeguards Information or Sensitive Unclassified Non-Safeguards Information and will not be publicly available. [C1]*
  4. The inspection report cover letter or the preliminary significance determination letter offers the licensee an opportunity to submit a written response or to request a Regulatory Conference (see Section 3 for more details). The preliminary significance determination letter must provide sufficient detail for the licensee to understand the basis of the staff's preliminary significance determination. This will enable the licensee to determine if (and what) additional information is needed to



better inform the final significance determination. If appropriate, the letter should contain specific questions or request specific information the staff needs to make its final significance determination. In all cases, the correspondence to the licensee should include a date for the licensee to provide the information requested to support SDP timeliness. The licensee should submit materials on the docket at least seven calendar days prior to the Regulatory Conference. The preliminary determination letter shall not include any SDP worksheets or portions of the SERP package. All security-related details shall be provided in a non-public attachment to the letter.

5. If the SERP's preliminary significance is determined to be White, Yellow, or Red and the licensee declines to submit a written response or to arrange a Regulatory Conference, then the preliminary assessment of significance becomes final, and the region will issue the final significance determination letter (as described in Section 4). The cover letter should include the appropriate paragraph referencing the licensee's letter declining to provide a written response or attend a Regulatory Conference. By declining the opportunity to submit a written response or to request a Regulatory Conference, the licensee relinquishes its right to appeal the final significance determination consistent with the appeal process outlined in IMC 0609, Attachment 2.

#### 02.05 Tracking SDP/Enforcement Issues.

The SERP determinations are administratively tracked and filed through the use of EATS. Enforcement Action (EA) numbers are assigned to findings that have been discussed during a SERP, regardless of whether the finding is associated with a violation. Prior to the SERP, an Enforcement Specialist or an Enforcement Coordinator will assign an EA number in EATS. Following the SERP, an Enforcement Coordinator in OE will complete and send a Strategy Form to each SERP member to review for accuracy. The Strategy Form enables tracking of individual findings and potential violations. If there are any disagreements with the content in the Strategy Form, all comments should be provided to OE within three working days.

If additional related findings are identified subsequent to a SERP, additional SERP meeting(s) would be conducted and separate EA tracking number(s) may be assigned. If the findings are determined to be Green, the related EA number(s) should be closed to reflect final disposition and the Strategy Form(s) should be updated to provide the basis for the final determination. Once an EA number has been assigned to a finding (and any related violations), all subsequent documents involving the finding should include the complete EA number (EA-YY-XXX).

#### 0609.01-03 LICENSEE'S RESPONSE – REGULATORY CONFERENCES AND LETTERS

Attending a Regulatory Conference or providing a written response are the options available to a licensee if they want to provide the staff with additional information related to a finding. Both options provide an opportunity for the staff to receive information that was not considered in the preliminary assessment and that may affect the outcome of the final significance determination. The licensee should notify the NRC by phone or other means within 10 calendar days how they

intend to respond. Should the licensee decline the opportunity to participate in a Regulatory Conference or provide a written response, the licensee should inform the NRC of this decision in writing (e.g., formal letter, email). The licensee's response, either written or via participation in a Regulatory Conference, should be completed within 40 calendar days of the licensee's receipt of the preliminary significance determination letter.

#### 03.01 Scheduling and Announcing Regulatory Conferences.

- a. The region or responsible office should inform the licensee whether the Regulatory Conference will be open or closed to public observation and that any handouts at the conference will subsequently be made available to the public, unless the conference meets the provisions of 10 CFR 2.390 (a)(4) or (6).
- b. If the licensee decides to attend a Regulatory Conference, they should provide any technical and risk information considered applicable to the finding at least seven calendar days prior to the conference. This information must be provided on the docket. All electronic correspondence received from the licensee communicating its official response will be docketed. Any non-sensitive information provided by the licensee during the Regulatory Conference will also be made public.
- c. The licensee should also inform the NRC of any additional information that is under development and not included in the written response or to be presented at the Regulatory Conference. To allow the staff adequate time to review information provided by the licensee, the NRC must receive all additional information that is to be considered when determining the final significance of the finding within a reasonable period of time. The NRC staff will make a risk-informed decision using best available information. Any additional information provided by the licensee will be reviewed in a timely manner consistent with the SDP timeliness goal.
- d. The region or responsible office should promptly notify OE, the NRR Enforcement Coordinator, the appropriate Regional State Liaison Officer, and the Executive Director for Operations Regional Coordinator of the conference date.
- e. The region or responsible office should issue a meeting notice in accordance with office procedures and report all conferences to the Public Meeting Notification System as described in NRC Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings." A copy of the conference meeting notice should be sent to the NRR Enforcement Coordinator. If the finding involves an AV, the meeting notice should also be posted on the OE web site. The region or responsible office should include OEMAIL and OEWEB as addressees. The meeting notice and meeting information should clearly indicate the pre-decisional nature of issues and state that the purpose of the conference is to discuss the preliminary safety significance of a particular finding. The discussion of the finding should be brief, but detailed enough to inform the public of what will be discussed at the conference. If appropriate, the notice should then include a statement that the conference will also address any AV(s) associated with the finding. For security-related findings, the notice should not include any description of the findings.
- f. Conferences in which security findings will be discussed are closed to the public. For security reasons, NRC staff shall participate via secure video teleconference when safeguards information, force on force-based security findings, and security SDP

information specific to an inspection finding will be discussed.

- g. The region or responsible office should consult with the Office of Public Affairs to determine whether to issue a press release announcing the conference.

### 03.02 Attendance at Regulatory Conferences.

This section provides specific guidance concerning attendance at conferences, including NRC personnel, licensee personnel, media representatives and members of the public, and State government personnel.

- a. NRC Personnel. NRC personnel should attend conferences according to the following guidelines:

The responsible Division Director will designate the appropriate staff that should be in attendance. At the Division Director's discretion and in accordance with security guidelines, NRC staff may participate in conferences by telephone or video.

1. OE staff should participate in all conferences.
2. NRR and NSIR participation may be requested as necessary.
3. Regional Counsel may be requested to attend conferences where legal issues may be raised.
4. All SERP members necessary to make the final decision shall participate either in person or by telephone or video teleconference.

- b. Licensee Personnel. The licensee should ensure that they are represented by the appropriate level of management, licensing staff, and technical staff. The licensee's legal counsel may attend the conferences where legal issues may be raised.

- c. Media and Members of the Public. The public attending an open conference may observe but not participate in the conference. Members of the public may record (including videotape) a conference if not disruptive. The purpose of conducting open conferences is to provide the public with opportunities to be informed of NRC activities while balancing the need for the NRC staff to exercise its regulatory and safety responsibilities without undue administrative burden. Following the conference, the staff will be available to respond to questions and comments from the media and members of the public concerning matters discussed at the conference.

- d. State and Local Officials. When conferences are open to the public, interested State and local officials should also be invited to attend. When other circumstances warrant, the Director, OE, may authorize the Regional Administrator to permit State personnel to attend a closed Regulatory Conference in accordance with the guidance in the Enforcement Manual, Section 1.2.15.2.D, "State Government Attendance at PECs and Regulatory Conferences."

### 03.03 Conduct of Regulatory Conferences.

The conferences should be conducted according to the following guidelines:

Conferences are normally conducted in the regional offices or in the office that conducted the inspection activity. There may be special circumstances where the agency determines that it would be beneficial to the process to conduct the conference elsewhere. In these cases, the region should consult with NRR, NSIR (for emergency preparedness or security findings), and OE before scheduling the conference.

- a. The Regional Administrator or office director responsible for the inspection activity should determine the appropriate member of management to serve as the presiding official at the conference.
- b. The presiding NRC official should communicate the following:
  1. Announce the conference as an open or closed meeting,
  2. Discuss the purpose of the conference,
  3. Inform the licensee and public attendees that the decision to hold the conference does not mean that the agency has determined the significance of the issues, that violations have occurred, or that enforcement action will be taken,
  4. Inform the public attendees that the conference is a meeting between the NRC and the licensee and that the meeting is open for public observation, but not participation, and
  5. Briefly explain the SDP and enforcement process. Exhibit 1 of this Attachment provides standard opening remarks.
- c. The region or responsible office shall briefly discuss the finding being considered and explain the basis of the agency's preliminary determination (i.e., safety or security significance and AV(s)). The level of detail to be discussed should be commensurate with the complexity and significance of the finding. Most of the detailed information should be included in the inspection report. The discussion should include the assumptions and methods used by the NRC to arrive at the preliminary determination of safety or security significance.
- d. The licensee should discuss its understanding of the facts and circumstances surrounding the significance of the finding and where it agrees and disagrees with the NRC's assumptions and analysis. Any disagreements should be discussed in enough detail for the NRC to fully understand the licensee's basis and any new information introduced. The licensee will notify the region or the responsible NRC office of any additional information under development that was not presented at the conference and the date the information will be received. Any additional information provided by the licensee will be reviewed in a timely manner consistent with the SDP timeliness goal. Once the pertinent facts have been established and understood by all parties, the presiding official must recognize and briefly summarize differences of opinion.

- e. After completing discussions related to the safety or security significance of the finding, addressing any AV(s) and/or discussing applicable corrective actions is appropriate. The licensee should indicate its agreement or explain why it does not agree with the AV(s). The discussion of corrective actions should be limited to the immediate actions taken to mitigate safety or security consequences of the finding. Detailed discussions of long-term corrective actions should be reserved for the Regulatory Performance meeting and for potential follow-up inspection activities.
- f. Prior to the conclusion of the conference, the participating NRC staff shall conduct a caucus, independent from the licensee and other participants, to determine if there is any additional information required from the licensee.
- g. The presiding NRC official shall provide closing remarks and should remind the licensee and public attendees that the preliminary significance determination and the AV(s) discussed are subject to further review and are subject to change prior to any resulting action. The presiding NRC official shall also make it clear that the statements of views or expressions of opinion made by NRC employees at the conference, or the lack thereof, are not final conclusions.

#### 0609.01-04 POST-REGULATORY CONFERENCE REVIEW

##### 04.01 Post-Conference Review.

The NRC staff that participated in the Regulatory Conference or reviewed a written response shall hold a Post-Regulatory Conference Review (PRCR) to review the technical and risk information provided by the licensee to determine whether any of the information presented changed the significance determination. The PRCR should be a formal meeting, but can be completed by teleconference or email for simple issues. The participants should be the same participants as in the SERP and the meeting should be conducted in the manner that a SERP is conducted using the SERP worksheet. The PRCR will enable the same members that were at the SERP to make a final significance determination.

If the licensee presented new information during the Regulatory Conference or in their written response that affected the final outcome, the region or responsible office will update the SERP documentation affected by the licensee's submittal prior to the PRCR. The region or responsible office will provide a new recommendation of significance to the PRCR and discuss those issues that had a significant effect on the preliminary determination.

If the PRCR, after considering the licensee's additional information, determines that a preliminary White, Yellow, Red, or GTG finding is characterized as Green safety or security significance, the determination is final.

If the PRCR cannot reach consensus on the final significance of the finding, the same process used when SERP members cannot reach consensus, documented in Section 02.03, should be used.

## 0609.01-05 ISSUING FINAL SIGNIFICANCE DETERMINATION (AND NOTICE OF VIOLATIONS (NOV) IF APPLICABLE)

### 05.01 Final Significance Determination Letter and NOV.

The region or responsible office prepares the cover letter transmitting the final assessment results using the standard format in Form 3-III or 3-III(S) for security-related matters, located in the Enforcement Manual, Appendix B, "Standard Formats for Enforcement Packages." The letter includes additional language if an NOV is included. The staff is responsible for ensuring that the NOV and letter is consistent with the guidance in the Enforcement Manual. The letter should effectively and succinctly communicate the NRC safety significance assessment of the findings and any related violations and should include the elements listed below. For security-related findings, the region or responsible office addresses the elements in a non-public enclosure to the cover letter.

- a. A summary of (1) the purpose of the inspection; (2) if and how the finding was reported (e.g., 50.72, LER); (3) when the inspection report related to this action was issued; and (4) if and when (and where) a conference was held, if a conference was declined, or if there was a response to a preliminary determination letter.
- b. A conclusion that the finding represented an issue of safety significance and that a violation occurred (if applicable). A very brief summary of the event or circumstances that resulted in the finding and/or violation, including such issues as the length of time the issue lasted, the proximate cause, and the operational mode of the plant at the time.
- c. Justification for not incorporating into the significance determination licensee perspectives presented at the conference, if applicable.
- d. A statement that the licensee may appeal the staff's determination of the significance of the finding in accordance with Attachment 2 of this Manual Chapter, if applicable. This statement should not be included if the licensee accepted the preliminary determination without contest or declined the opportunity to respond in writing on the docket or request a Regulatory Conference.
- e. A discussion of the related violation(s).
- f. If an NOV is included, a description of whether a response from the licensee is necessary, including any area that deserves special emphasis, such as a provision that the licensee respond if the understanding of the required corrective action is different than that stated.
- g. A statement that the letter and the licensee's response will be made available to the public or that the letter and the licensee's response will not be made public if it contains security-related, safeguards, or classified information.

### 05.02 Final Significance Determination and NOV, Coordination and Review.

All final significance determination letters for Yellow and Red findings should be sent to headquarters for concurrence. The Office of Enforcement will coordinate the collection of

comments and concurrence from all headquarters reviewers. The SERP will determine if letters transmitting White issues need headquarter's review on a case-by-case basis.

- a. NRR Enforcement Coordinator will ensure appropriate review of the proposed action by appropriate risk program, and technical branches with a focus on the proper characterization of the safety significance of the finding and on the technical accuracy of the violations.
- b. OE will review all final significance determinations that include an NOV and will forward comments to the region indicating where the action was revised and explain any significant changes. (Refer to the Enforcement Manual for specific guidance on coordination and review of escalated NOV's without civil penalties.)

#### 05.03 Final Significance Determination and NOV Signature Authority.

Final significance determination cover letters associated with White, Yellow, or Red issues should be signed and issued according to the memorandum dated January 17, 2008, "Delegation of Authority for Certain Enforcement Actions to the Regional Administrators" (ML080100183).

#### 05.04 Licensee Notification, Mailing, and Distribution of Final Significance Determination Letters.

Final significance determination letters are normally mailed to licensees and States by regular mail. Distribution is made according to the NOV distribution guidance in the Enforcement Manual and regional procedures. The Commission must be provided with an Enforcement Notification (EN) three working days before a final letter containing an NOV is sent to a licensee. ENs are prepared by OE and issuance must be coordinated through the Region or NRR (NSIR) Enforcement Coordinator, as applicable. ENs should also be considered for any final determination without an NOV that has become a matter of public or Commission interest.

END

#### Exhibits:

- |           |  |
|-----------|--|
| Exhibit 1 | Suggested Opening Comments for Regulatory Conference |
| Exhibit 2 | SERP Worksheet                                       |

#### Attachments:

Attachment 1 Revision History for IMC 0609.01

## Exhibit 1

### SUGGESTED OPENING COMMENTS FOR REGULATORY CONFERENCE

After a potentially safety-significant finding is identified and characterized by the Significance Determination Process (SDP) as either White, Yellow, Red, or greater than Green, an opportunity for a Regulatory Conference is offered to a licensee. In this case, [the licensee's name] requested that a conference be held to discuss the issues and their significance.

This conference is OPEN to public observation. Members of the public who are in attendance at this meeting, you should be aware that this is a meeting between the Nuclear Regulatory Commission and [the licensee's name]. Following the conference, NRC staff will be available to answer questions and receive comments from members of the public concerning matters discussed at this conference.

A Regulatory Conference is the last step of the inspection process before the NRC makes its final decision on the significance of the inspection findings. [Using the subject finding provide a brief summary of the SDP and how the process led to the conference].

The purpose of this conference is to allow you to identify your disagreements, in part or all, with facts and assumptions used by the NRC to make the preliminary significance determination, and to allow you to present any clarifications that may assist the NRC in arriving at the most appropriate final significance determination.

We would also appreciate your views as to whether there is any other information that may be relevant to the application of significance determination in this case, including your position on the content and accuracy of the inspection report findings which were provided to you in advance of this conference. If you have any additional information that is under development and is not available to be presented at this Regulatory Conference, please inform us of the nature of the information and the date the NRC can expect to receive it. The NRC must receive all additional information, which is to be considered for the finding, within a reasonable period of time to allow the staff adequate time to review the information. This timeframe must take into account the NRC's goal to complete SDP decisions in a timely manner.

In addition to discussing your views on the safety significance of the finding(s), you may want to present your views on the identified apparent violation(s). Please note that the primary purpose of this meeting is to discuss issues related to the safety significance of the finding(s), which informs the outcome of the apparent violation. But, because a pre-decisional enforcement conference is normally not convened to discuss the apparent violation, any discussion concerning apparent violations and the applicable corrective actions is permitted. It is important to note that the decision to conduct this conference does not mean that the NRC has determined that a violation has occurred. Violations related to the findings being discussed today will be assessed in accordance with the Commission's Enforcement Policy.

I should also note at this time that any statements of view or expressions of opinion made by NRC employees at this conference do not represent final agency determinations or beliefs relative to the matter before us today.

Following this conference, the Regional and NRC Headquarters staff, will reach a significance determination and enforcement decision. The NRC's goal is to issue the final significance determination letter within 90-days of the first official notification describing the finding.



If you have any questions now or at any time during this conference, we would be pleased to answer them.

Exhibit 2

SERP WORKSHEET

<u>SERP WORKSHEET</u>	
Section 1 – SERP OVERVIEW Lead branch to complete at SERP	
Purpose of SERP: Choose an item.	Date of SERP: Click here to enter a date.
Facility: Click here to enter text.	Licensee: Click here to enter text.
EA Number: EA-Click here to enter text.	IR Number: Click here to enter text.
Type of Inspection: Choose an item.	Inspection Procedure: Click to enter text
Sponsoring Organization: Click here to enter text.	
SERP Voting Members: Sponsor (same as IFRB Chair): Click here to enter text. ROP Inspection and Assessment Program Spokesperson: Click here to enter text. HQ Technical Spokesperson: Click here to enter text. Enforcement Spokesperson: Click here to enter text.  Non-Voting Attendees: Click here to enter text.	

Section 2 - ISSUE OVERVIEW Lead branch to complete prior to SERP in coordination with SRA			
Issue Start Date	120 Days	165 Days	255 Days
Click to add date	Click to add date	Click to add date	Click to add date
Is the assessment expected to exceed any timeliness metrics? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>If yes, please explain.</i>			
IFRB Conducted: <input type="checkbox"/> Yes <input type="checkbox"/> No  If yes, attach IFRB worksheet. Do not complete this section, proceed to Section 3. If no, document basis for not holding an IFRB and complete remainder of this section: Click here to enter text.			
Performance Deficiency: <i>State the exact performance deficiency to be assessed</i>			
Issue Summary: <i>Provide a short summary of the degraded condition or issue of concern and how it was identified. Describe how the performance deficiency is the proximate cause of the degraded plant condition.</i>			
Proposed Associated Violation: Click here to enter text.			

<b>Affected SSCs, Operator Actions, and Risk-Relevant Functions:</b> <a href="#">Click here to enter text.</a>
<b>Exposure Time:</b> <a href="#">Click here to enter text.</a>
<b>Initial SDP Screening:</b> <a href="#">Click here to enter text.</a>
<b>Initial Licensee Perspectives/Analyses:</b> Provide any significant licensee technical, engineering, and/or risk perspectives that diverge from the staff's assumptions. Provide a justification for either incorporating or not incorporating the perspective(s) into the staff's determination. <u>Note:</u> Do not use CDF or LERF as metrics if Qualitative Appendix was used.

<b>Section 3 - RISK ANALYSIS DETAILS (SRA USE ONLY)</b> <b>To be completed by SRA in consultation with lead branch prior to SERP</b>	
<b>Cornerstone:</b> Choose an item. Provide justification for selected cornerstone, if multiple cornerstones are applicable: <a href="#">Click here to enter text.</a>	
<b>Proposed Significance:</b> Choose an item.	<b>SDP Appendix:</b> Choose an item.
<b>QUANTITATIVE APPENDICES</b>	
<b>Influential Assumptions:</b> Describe in detail any assumptions that cannot be substantiated to have a single value (i.e., a model uncertainty) and has a significant effect on the overall outcome. Some examples include exposure time, common cause failure, recovery credit, human error probabilities, failure phenomenology, and initiating event frequencies.	
<b>Uncertainty Analysis:</b> Identify any significant parametric, model, and completeness uncertainties. Any influential assumption that could reasonably have multiple valid values should be considered a model uncertainty and addressed via sensitivity evaluations. A model that is determined to be incomplete for the purposes of the analysis should be considered a completeness uncertainty and addressed via qualitative risk insights.	
<b>Sensitivity Evaluations:</b> All influential assumptions considered to be a model uncertainty should be analyzed with a sensitivity evaluation. Based on the number of significant model uncertainties, a sufficient number of sensitivity evaluations should be performed to account for all of the permutations. The results of the sensitivity evaluations could result in a variety of outcomes (i.e., different colors).	
<b>Contributions from External Events:</b> Describe any contributions from external events or hazards (e.g., seismic, external flooding, fire, high winds). If the contribution from an external event or hazard is significant ensure that an appropriate nominal risk profile is established.	
<b>Potential Risk Contribution from LERF:</b> Determine whether LERF is an appropriate metric to characterize the safety significance of the degraded condition. If so, describe how the degraded condition impacted the LERF metric.	
<b>Qualitative Risk Considerations</b> <i>List any additional qualitative insights to be considered</i>	

QUALITATIVE APPENDICES
<b>Qualitative SDP Logic:</b> <i>Describe the progression through the qualitative SDP logic and the bases for the chosen progression.</i>
RISK ANALYSIS OUTCOME
<b>Peer Reviewer(s) Recommendations:</b> <i>List any peer reviewer recommendations that were not incorporated into the evaluation and provide a basis for the exclusion.</i>
<b>Licensee's Risk Evaluation and Technical Analysis:</b> Describe any significant licensee technical, engineering, and/or risk perspectives that align or diverge from the staff's assumptions. Provide a justification for either incorporating or not incorporating the perspective(s) into the staff's determination.
<b>Significance Determination (i.e., Color):</b> Choose an item. State the recommended significance determination (i.e., color). Provide a critical argument that integrates all of the pertinent information (i.e., $\Delta$ CDF (or $\Delta$ LERF), sensitivity evaluations, qualitative risk insights) into a risk-informed decision.
<b>References:</b> List any references that were used to support the inspection and/or risk evaluation (e.g., NUREGs, Industry Reports, Engineering evaluations, SPAR Model).

# ATTACHMENT 1

## Revision History for IMC 0609.01

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	04/21/2000 CN 00-007	This manual chapter supports the New Reactor Oversight Program for significant determination of findings. The significance determination process detailed in the manual chapter is designed to characterize the significance of inspection findings for the NRC licensee performance assessment process using risk insights, as appropriate.	N/A	N/A
N/A	04/30/2002 CN 02-022	0609.01 has been revised to include comments and recommendations provided by the Regions, OIG, and OE. Guidelines for SERP membership and assignments of SERP member responsibilities are provided in Section 2. Guidelines for conducting post Regulatory Conference Caucus appear in Section 3.	N/A	N/A
N/A	ML031810463 06/24/2003 CN 03-021	This revision added a requirement that WEB site references be verified and updated. Also, the word "report" in the choice letter was deleted, and the sentence clarified to mean supporting information for the finding. As originally stated, "report" could be interpreted to mean inspection report.	N/A	N/A

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
C1	ML052790178 11/22/05 CN 05-030	0609.01 has been revised to reflect a concerted effort to provide guidance which will help meet the Commission's guidance on the timeliness for finalizing the significant determination of inspection findings. The revision considers the regional comments on the proposed guidance on how to meet the timeliness goal. The document reflects the introduction of the Planning SERP as described in IMC 0609 where new guidance on the Planning SERP is detailed. It also allows per Section 2 of the document, that a SERP be re-designated as a Planning SERP and to follow guidance in Section 08.05 of IMC 0609 if the SERP determines that further information and/or analysis is necessary before a finding can be evaluated. A Planning SERP worksheet was added as Exhibit 5.	N/A	N/A
N/A	10/13/2006	Revision history reviewed for the last four years	N/A	N/A
N/A	ML063060356 01/10/08 CN 08-002	This revision added reference to the Phase 2 Pre-solved Tables, corrected hyperlinks to WEB site references, and added a caveat the licensee's ability to appeal the final SDP determination if they decline to request a Regulatory Conference or submit a response in writing.	N/A	ML073460588

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML080730041 08/05/08 CN 08-023	This revision reformats several sections, deletes the IMC0612 definition of AV, replaces the term “choice” letter with Preliminary Determination letter, and replaces Exhibit 2, 3, and 6, and Enclosure 1 with Enforcement Manual Form 3-II, or 3-II(S) for security-related matters as derived from SECY-06-0036 and Enforcement Manual Form 3-III, or Form 3-III(S) for security-related matters. The SERP Worksheet was revised and the exhibits are reordered.	N/A	ML081720377
N/A	ML101400488 06/08/11 CN 11-010	This revision updates the hyperlink to the OE Web page. It adds use of SAPHIRE version 8 and updates the participants and members of the SERP. The IMC has been better aligned with IMC0609 – SDP to remove redundancy. Clarification was added for the deadline that licensees have to submit additional information. The term ‘caucus’ was changed to ‘post-conference review’. Clarification was added for findings in which the post-conference review determines the significance of a finding should be changed as a result of new data provided by the licensee, then the finding will be reviewed at a final SERP. The material covered at the final SERP should focus on those areas affected by the Regulatory Conference and that changed the original SERP outcome. A review of related documents will be completed to ensure conforming changes to other related areas in IMC0609, including those governing the scope and content of the final SERP package, are reflected as well (ROPFF 0609.01-1481).	N/A	ML103490479

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
	ML14153A568 04/29/15 CN 15-008	Several significant changes to the guidance were made based on recommendations from the SDP Business Process Improvement (BPI) Report (ML14318A512) and the ROP Independent Assessment Report (ML14035A571). Incorporated recommendations from ROPFF 0609.01-1759, 1908, 1910.	N/A	ML15072A302 ML14099A265 ML14099A277 ML14099A285
C2	ML16288A119 12/08/16 CN 16-032	Revised to clarify the expected need for flexibility in performing SDP evaluations. This item is a commitment related to a recommendation made in response to DPO-2015-01.	No training is needed.	ML16291A560
N/A	ML18187A177 10/23/18 CN 18-036	Revised to incorporate applicable recommendations from the Inspection Finding Resolution Management Effectiveness review Report (ML18123A319) and clarifications to the SERP decision-making process, reflecting the EDO's consensus decision-making model. Changes include: (1) the role of the SERP was modified to focus on the significance of the inspection finding and any related enforcement action(s), (2) Planning SERP details were moved to this procedure from IMC 0609 and the Planning SERP Worksheet was eliminated, (3) incorporation of best available information, (4) Added references to the Inspection Finding Review Board process and associated documentation, (5), reduction to one SDP peer review performed by HQ, (6) assignment of NRR/DIRS as SERP facilitator, (7) numerous editorial changes to eliminate redundancy and provide succinctness, (8) incorporation of the final SERP into the Post-Conference review, and (9) development of a Table of Contents.	N/A	ML18191A002