

SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL (SERP) PROCESS

Effective Date: 12/08/16

0609.01-01 SCOPE

This Attachment describes The U.S. Nuclear Regulatory Commission (NRC) guidance 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 guidance 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.

0609.01-02 THE SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL (SERP) PROCESS

The Significance and Enforcement Review Panel (SERP) provides management review and a preliminary decision regarding the proposed finding, significance characterization, and enforcement recommendations for all inspection findings in which the sponsor proposes a significance characterization of White, Yellow, Red, or GTG. 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 (see 0609.01-03 for more details), the SERP provides the management review and a final decision regarding the finding, a significance determination of Green, White, Yellow, or Red, and enforcement action as applicable. During the SERP, panel members will discuss the merits of the case and reach consensus on:

- a. the inspection finding and how the deficient licensee performance was the proximate cause of the degraded condition(s),
- b. the safety or security significance of the finding, as determined by the degraded condition, including the assignment of a preliminary or final color,
- c. the apparent violation (AV) and the regulatory requirement(s) that should be cited, as applicable.

In all cases, the regions or NRC office conducting the inspection are responsible for the overall management and processing of inspection findings. Although some findings may be referred to other technical areas of the NRC, the regions or office must maintain full awareness of the status of those findings to ensure that the findings are processed in a timely manner.

02.01 Preparation for the Preliminary 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, then the significance of the finding shall be characterized in the inspection report as "to be determined" (TBD). Only a SERP review and decision can make a preliminary significance determination of White, Yellow, Red, or GTG.
 2. If the region or office is considering the use of IMC 0609, Appendix M to characterize the significance of a finding, a Planning SERP should be held. A Planning SERP will reach consensus on the scope, schedule, methodology, and identify staff that will perform the assessment. A Planning SERP is not necessary when another SDP appendix explicitly directs the use of Appendix M (e.g., IMC 0609, Appendix A, Exhibits 2 and 3). The Planning SERP assessment will be documented on the "Planning SERP Worksheet" (Exhibit 3 to this Attachment). An additional SERP is required to arrive at a preliminary significance determination.
 3. The responsible inspector(s) should clearly articulate the licensee performance deficiency, the more-than-minor criteria that was met, describe how the deficient licensee performance (i.e., finding) 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 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 sponsor organization should periodically communicate details involving inspection, proposed enforcement, risk insights, and other pertinent information with technical staff and management in the both the region and headquarters (i.e., NRR (particularly DIRS/IPAB and DRA/APHB), OE, and NSIR, as needed.) The SERP members are responsible for ensuring that the technical staff has provided sufficient information in a timely manner to support an effective and well-informed regulatory decision.
 4. After the sponsoring region or office has developed their proposed position, it is documented using Exhibit 2, "SERP Worksheet." The SERP Worksheet, and any other supplementary documentation, provides the information needed to support a risk-informed decision by the SERP.

- 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 Senior Reactor Analyst(s) (SRAs) should coordinate efforts early in the process to achieve a common understanding of how the deficient licensee performance (i.e., finding) was the proximate cause of the degraded condition. After the SRA gains a clear understanding of the finding and its relationship to the degraded condition, they can begin formulating a risk assessment (e.g., detailed risk assessment, Phase 3) to characterize the safety significance. As mentioned in 02.01.a, the regional inspection and enforcement staff, SRA(s), and management should periodically communicate inspection details, enforcement recommendations, and risk assessment insights with technical staff and management in headquarters (i.e., NRR (particularly DIRS/IPAB and DRA/APHB), OE, and NSIR, as needed). Sharing information should balance the gained efficiencies of parallel communication with the goal of providing an independent assessment. The SERP members are responsible for ensuring that the technical staff has provided sufficient information in a timely manner to support an effective and well-informed regulatory decision.
2. The risk assessment can 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 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 risk assessment is completed, it must be independently peer reviewed by another regional SRA either from the same region or from a different region. After the regional SRA peer review a headquarters SRA or risk analyst must perform an additional peer review. The regional and headquarters peer review can be conducted in parallel to improve timeliness and each peer reviewer should typically have at least five working days to review the risk assessment. However, with proper coordination the peer review time can be shortened. Any changes to the risk assessment based on recommendations from peer reviewers should be made prior to sending documentation to NRR (see section 02.02). Both the regional SRA and headquarters SRA or risk analyst peer review should focus on:

- a. Appropriate implementation of current guidance documents (e.g., IMC 0609 attachments and appendices, RASP Handbooks, applicable NUREGs, RGs,

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 review 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.

02.02 NRR Enforcement Coordinator Preparation for the Preliminary 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.

At least five working days (earlier for more complex issues) prior to the preliminary SERP, the regions or office provide the NRR Enforcement Coordinator the SERP worksheets (Exhibit 2 or 3) and other pertinent information. The NRR Enforcement Coordinator electronically distributes the packages to all headquarter SERP participants.

As mentioned in 02.01.a, the regional inspection and enforcement staff, SRA(s), and management should periodically communicate inspection details, enforcement recommendations, and safety or security assessment insights with technical staff and management in headquarters (i.e., NRR (particularly DIRS/IPAB and DRA/APHB), OE, and NSIR, as needed). Sharing information should balance the gained efficiencies of parallel communication with the goal of providing an independent assessment. Both regional and headquarters technical staff should provide 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 all of the information.

02.03 Participation in the Preliminary SERP.

The principal objective of the SERP is to discuss, review, and arrive at a consensus decision regarding the finding, the significance determination, and the appropriate enforcement actions to be taken, as applicable. All members of the SERP, indicated in the table below, will represent their organization and participate in reaching a consensus decision. Even though each participating organization has a distinct function, as defined as a role 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, all of the members are aligned, then a preliminary determination has been reached. However, if one or more SERP members still object to the characterization of the finding, the safety or security significance, and/or the

enforcement action(s), the panel discussion should continue until all of the SERP members are aligned on the preliminary decision. 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.</p>	<p>Regional or office management representation by the responsible Division Director or Deputy Division Director</p>
<p>Headquarters Technical Spokesperson</p> <p>Provides the headquarters technical position and support with the SDP appendix implementation. Also responsible for ensuring the outcomes are consistent with program office guidelines (i.e. with respect to application of risk insights) and regulatory policy.</p>	<p>Applicable Technical Division</p> <p>NRR Division of Risk Assessment (for fire protection, reactor safety, containment, shutdown risk, transportation, ALARA, public and occupational radiation SDPs), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Component Integrity (for steam generator and spent fuel pool SDPs), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Policy and Rulemaking (for B.5.b SDP), Director or Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Inspection and Regional Support (for operator re-qualification and maintenance rule SDPs), Deputy Division Director (or designated Branch Chief);</p> <p>Office of Nuclear Security and Incident Response, Division of Security Operations (physical protection SDPs), Director or Deputy Division Director (or Branch Chief; Division of Preparedness and Response (emergency planning SDP), Deputy Director for Response (or designated Branch Chief).</p>

Role	Responsible Organization/Participant
<p>Reactor Inspection and Performance Assessment Program Spokesperson</p> <p>Provides inspection program management, ensures implementation of SERP and outcome are consistent with ROP policy, resolves ROP program issues.</p>	<p>NRR Division of Inspection and Regional Support, Director or Deputy Division Director (or Branch Chief)</p>
<p>Enforcement Spokesperson</p> <p>Responsible for determining the adequacy of NOVs related to the inspection findings either White, Yellow, or Red; and ensures the agreements reached at the SERP are documented on the Strategy Form in accordance with OE policies.</p>	<p>Headquarters Office of Enforcement, Deputy Director (or Branch Chief).</p>

Other invited participants typically include regional enforcement staff, inspectors, SRA(s), NRR OE Coordinator, and other technical and program support staff (e.g., SDP program lead, risk analysts) and sometimes include the applicable NRR Project Manager and staff from the Office of Nuclear Regulatory Research representative for Accident Sequence Precursor Program related issues and the Office of the General Counsel

02.04 Preliminary SERP Determinations.

Members of the SERP discuss, review, and decide on the finding, the safety or security significance of the degraded condition, to include the assignment of 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 preliminary SERP can be completed prior to issuing the inspection report but should not exceed 30 days after the report is issued (see IMC0609, Section 08.05 - SDP Timeliness).

- a. Green or No Finding: If the SERP concludes that the preliminary significance determination of the finding is Green or there is no finding (i.e., either a minor performance deficiency or no performance deficiency exists), the SERP's conclusion regarding enforcement (no violation or NCV) 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 (EATS). 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 the best and currently 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. In addition, for security-related findings in which the preliminary determination is White, Yellow, Red, or GTG, only the cover letter is made publically available and the security significance is characterized as GTG.
2. For quantitative analyses (e.g., IMC 0609, Appendix A, F, G), the final risk assessment (e.g., detailed risk evaluation, Phase 3 analysis) in the SERP package should clearly identify all of the significant assumptions used in the analysis and an assessment of significant uncertainties and associated sensitivity evaluations (see Exhibit 2 "General Guidance" for more details). 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 (SUNSI) 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 should 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, in that by not doing either fails to meet the appeal requirements stated in the Prerequisite and Limitation sections of Attachment 0609.02 of this Manual Chapter.

02.05 Tracking SDP/Enforcement Issues. The SERP determinations are administratively tracked and filed through the use of OE's Enforcement Action Tracking System (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 3 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 or are determined not to be findings, 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. Receiving the licensee's information at least seven days before the conference allows for a more informative and effective conference by providing the staff sufficient time to review the information and formulate any questions. 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 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 based on the best available information. Any additional information provided by the licensee will be reviewed in a timely manner consistent with the SDP timeliness goal. Providing pertinent information early on in the process will support a more timely final significance determination.
- d. The region or responsible office should promptly notify OE, the NRR Enforcement Coordinator, the appropriate Regional State Liaison Officer, and the EDO Regional Coordinator of the conference date.
- e. The region or responsible office should issue a meeting notice in accordance with regional procedures and report all conferences to the Public Meeting Announcement System as described in NRC Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings." A copy of the conference meeting notices 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 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 (S-VTC) when Safeguards Information 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:
 - 1. 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.
 - 2. OE staff should participate in all conferences.
 - 3. NRR and NSIR participation may be requested as necessary.
 - 4. Regional Counsel may be requested to attend conferences where legal issues may be raised.
- b. Licensee Personnel. The licensee should ensure that they are represented by the appropriate level of management, licensing staff, and technical staff. 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 that activity is 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 4.1.2.4 - State Government Attendance at PECs and Regulatory Conferences.

03.03 Conduct of Regulatory Conferences. The conferences should be conducted according to the following guidelines:

- a. 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, Nuclear Security and Incident Response (NSIR) if needed, and OE before scheduling the conference.

- b. 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.
- c. The presiding NRC official should (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.
- d. The region or responsible office should 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.
- e. 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 issues of disagreement 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 region or the responsible NRC office can expect to receive it. As noted in 03.01.c, the NRC staff will make a risk-informed decision based on the best available information. 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 and keep the conference productive.
- f. 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.
- g. Prior to the conclusion of the conference, the participating NRC staff should have a separate discussion (often referred to as a caucus), independent from the licensee and other participants, to determine if there are any additional questions.

- h. The region or responsible office should provide closing remarks and the presiding NRC official 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 region should 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-CONFERENCE REVIEW AND FINAL SERP

04.01 Post-Conference Review.

In some cases the licensee provides the NRC staff with both technical and risk information early on in the inspection process. This information provided by the licensee, along with the information that the staff has gathered, supports the staff's independent assessment of the safety or security significance of the finding. However the licensee's formal response to the preliminary determination letter is provided via written response or participation in a Regulatory Conference. The NRC staff that participated in the Regulatory Conference or reviewed a written response should hold a Post-Conference Review to go over the technical and risk information provided by the licensee to determine whether any of the information is considered new and if any new information has a significant effect on the preliminary determination. New information should be considered to have a significant effect on the preliminary determination, if it could reasonably change the significance determination (i.e. color). If it is determined that no new information was provided at the Regulatory Conference or in a written letter, or new information was provided but it did not have a significant effect on the preliminary determination, and the enforcement strategy remains valid, the Post-Conference Review can arrive at a final significance determination. The Post-Conference Review does not have to be a formal meeting and can be completed by teleconference or email; however, it should occur as close to the completion of the Regulatory Conference or receipt of the written response as possible. The participants in the Post-Conference review are the same participants in the SERP.

If the staff determines that new technical or risk information was provided that warrants reconsideration of the finding, the preliminary significance determination, or enforcement, the staff should convene a final SERP (see section 04.02).

04.02 Final SERP.

- a. The new information provided at the Regulatory Conference or written letter should be reviewed, taking into account the scope and breadth of the information and the goal of making a timely risk-informed decision. The region or responsible office will update the appropriate section(s) of the original SERP Worksheet (Exhibit 2) affected by the new information and conduct the final SERP. The region or responsible office should provide a new recommendation of significance to the final SERP and discuss those issues that had a significant effect on the preliminary determination.

- b. If the SERP, 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 and is considered as an input to the SDP timeliness goal metric.
- c. If the SERP cannot reach consensus on the final significance of the finding the SERP should direct specific actions to reconcile the different views. If a resolution is not achieved within 14 calendar days, the Inspection and Assessment Program Spokesperson, through the appropriate management, will notify the applicable office director, Regional Administrator, and the Director of NRR of the issues and the actions being taken to resolve them.

0609.01-05 ISSUING FINAL SIGNIFICANCE DETERMINATION (AND NOTICE OF VIOLATION (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. The licensee decision to not submit a written response or to arrange a Regulatory Conference will affect their ability to appeal the final SDP determination, in that not doing either fails to meet the appeal requirements stated in the Prerequisite and Limitation sections of Attachment 0609.02 of this Manual Chapter.
- 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 apparent root 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 its 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 headquarters' 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. EN's 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

Exhibit 3 - Planning 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 new information 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.

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

General Guidance:

If the following guidelines are met, the SDP outcome, either a preliminary or a final determination, is considered in keeping with the risk-informed framework of the ROP.

- 1) All of the influential assumptions are understood by both the NRC technical staff and management (i.e., SERP decision-makers).
- 2) If an influential assumption has more than one equally valid input (e.g., a significant model uncertainty), sensitivity evaluations should be performed to appropriately account for all of the potentially valid outcomes (i.e., account for uncertainties). If each influential assumption only has one valid input then a technical basis should be provided to substantiate that value.
- 3) The NRC technical staff and management understand the licensee's perspectives and insights, if provided, and have a reasoned basis for either incorporating (or not incorporating) each perspective or insight in the staff's evaluation.
- 4) Taking into account guidelines 1-3, the preliminary or final significance determination should be based on the need to make a timely regulatory decision given the best available information during that timeframe.

SERP Worksheet

SERP INFORMATION:

Sponsor	Organization that has the lead for the inspection activity and overall ownership of the inspection finding
Type (Prelim/Fin)	Preliminary SERP or Final SERP
Date	Date the SERP is held
EA Number	Enforcement Action Number for the finding

LICENSEE INFORMATION:

Name	Name of the utility or licensee
Facility	Name of the plant and number of the unit as applicable
Docket Number(s)	Docket number(s) for the applicable unit(s)

INSPECTION INFORMATION:

IR Number	Number of the Inspection Report
Type and sample	Type of inspection (e.g., quarterly, team, reactive) and inspection procedure sample (e.g., 71111.15)
Inspection Start Date	Date the inspection officially began (i.e., entrance meeting)
Exit Meeting Date	Date of the exit meeting (i.e., date the inspection is officially completed)

STAFF SUPPORT:

Director/Deputy	Name(s)
Branch Chief	Name(s)
Inspectors	Name(s)
SRA (as applicable)	Name(s)
Peer reviewers (as applicable)	Name(s)

Executive Summary

OVERVIEW:

Cornerstone	Applicable safety cornerstone. If multiple cornerstones are applicable, provide a justification for the cornerstone selected.
Proposed Significance	Color (i.e., White, Yellow, Red, or Greater-than-Green)
Finding and Degraded Condition	Clearly articulate the inspection finding. Describe how the deficient licensee performance (i.e., finding) was the proximate cause of the degraded condition. Describe the degraded condition.

SIGNIFICANCE DETERMINATION:

SDP Appendix	List the SDP Appendix that was used to determine the significance.
Influential Assumptions	List all of the influential assumption(s) that have a significant effect on the overall determination. Provide a technical basis for each influential assumption.

FOR QUANTITATIVE APPENDICES (i.e., use CDF and LERF metrics)

Uncertainty and/or Sensitivity Analyses	Describe any uncertainties involved in the detailed risk evaluation. Based on the influential assumption(s), if there are additional valid values or inputs for an assumption, perform sensitivity analyses to demonstrate how the outcomes vary given changes in assumptions.
Qualitative Risk Insights	After identifying areas in which the quantitative model does not capture the overall safety significance, provide qualitative risk insights to compliment the detailed risk evaluation. Uncertainty and/or sensitivity analyses may or may not be considered gaps in the quantitative model
Licensee's Perspectives/Analyses	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.

FOR QUALITATIVE APPENDICES (i.e., do not use CDF and LERF as metrics)

Applied SDP logic (e.g., flowchart)	Describe the progression through the SDP logic from start to finish.
Licensee's Perspectives/Analyses	Provide any licensee technical 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.

ENFORCEMENT:

Associated Apparent Violation(s)	List the proposed apparent violation(s)
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Details

INSPECTION:

Inspection Activity Background	Describe the details of the inspection activity in a chronological format.
Description of the Performance Deficiency and More-than Minor Criteria	Clearly articulate the performance deficiency (as defined in IMC 0612). Provide the basis for the more-than-minor determination (as defined by 0612, Appendix B).
Causal Link Between Finding and Degraded Condition	Describe how the deficient licensee performance (i.e., finding) was the proximate cause of the degraded condition. The cause and effect relationship between the finding and degraded condition is based on reasonable technical judgment of the staff. An in-depth root cause should not be required to substantiate the causal link between the finding and degraded condition.

SIGNIFICANCE DETERMINATION (QUANTITATIVE):

Screening Questions/Logic	Describe the screening question(s) and/or logic process that led to the finding and associated degraded condition not screening to Green.
Influential Assumptions	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.
Uncertainty Analysis	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.
Sensitivity Evaluations	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).
Contributions from External Events	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.
Potential Risk Contribution from LERF	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.

Licensee's Risk Evaluation and Technical Analysis	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.
Peer Reviewer(s) Recommendations	List any peer reviewer recommendations that were not incorporated into the evaluation and provide a basis for the exclusion.
Significance Determination (i.e., Color)	State the recommended significance determination (i.e., color). Provide a critical argument that integrates all of the pertinent information (i.e., Δ CDF (or Δ LERF), sensitivity evaluations, qualitative risk insights) into a risk-informed decision.
References	List any references that were used to support the inspection and/or risk evaluation (e.g., NUREGs, Industry Reports, Engineering evaluations, SPAR Model).

SIGNIFICANCE DETERMINATION (QUALITATIVE):

Description of the Applied SDP Logic	Describe the progression through the SDP logic (e.g., flowchart, decision diagram, matrix) from start to finish.
Influential Assumptions	Describe all of the influential assumption(s) that have a significant effect on the overall determination. Provide a technical basis for each influential assumption.
Licensee's Perspectives and Insights	Provide any licensee technical perspectives that either 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.
Proposed Color	State the recommended significance determination (i.e., color). Provide a critical argument that integrates all of the pertinent information (e.g., influential assumptions, licensee perspectives, SDP logic).

ENFORCEMENT:

Regulatory requirement(s) not met	Describe how the licensee failed to meet a regulatory requirement(s) (i.e., the "contrary to" statement(s)).
Proposed citation(s)	List the proposed apparent violation(s)

Exhibit 3

PLANNING SERP WORKSHEET

1. State the inspection finding and associated degraded condition.
2. Describe the reason(s) the sponsor requests the finding to be reviewed by the Planning SERP.
3. State why more assessment time is needed beyond the 90 day timeliness goal, if applicable.
4. Describe the proposed scope of the assessment, identify the proposed methodology (e.g. Appendix M, engineering evaluation) and justify the level of effort recommended for the preliminary assessment.
5. Provide a recommended schedule for the completion of the assessment.
6. Provide the recommended expertise needed to complete the assessment.
7. Provide additional comments for SERP consideration (e.g., known conservatisms, significant uncertainties, influential assumptions.).

ATTACHMENT 1
Revision History for MC 0609.01

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	10/13/2006	Revision history reviewed for the last four years	N/A	N/A
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	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 and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
C1	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	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 and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
N/A	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

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	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
	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

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)
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