

ATTACHMENT 0609.01

SIGNIFICANCE AND ENFORCEMENT REVIEW PANEL PROCESS

0609.01-01 SCOPE

This Attachment describes NRC guidance for preparing and processing findings determined by the Significance Determination Process (SDP) to be potentially significant (White, Yellow, or Red). Because enforcement decisions are integrated into this process, 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. Current enforcement guidance is maintained on the Office of Enforcement's (OE's) Web site:

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>

In addition to regional offices, the guidance in this Attachment applies to other NRC offices responsible for conducting inspections and the overall management of inspection findings for operating reactors; specifically as it applies to the NRC Office of Nuclear Security and Incident Response (NSIR) for its conduct of headquarters based inspection activities.

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

The SERP provides a management review of the preliminary significance characterization and basis of findings that are potentially White, Yellow, Red, or Greater than Green. When necessary, based on the results of a Regulatory Conference or written response provided by the licensee, the SERP provides the management review of the final significance characterization and the basis of findings that are White, Yellow, or Red. No official agency preliminary significance determination of White, Yellow, Red, or greater than Green will be made without a SERP review. During the SERP, panel members will discuss the **merits of the** finding and reach consensus on:

- a. the statement of deficient licensee performance on which the inspection finding is based,
- b. the safety significance of the finding, including assignment of preliminary or final color,
- c. the apparent violation (AV) and the regulatory requirements that should be cited.

In all cases, the regions **or NRC office conducting the inspection** are responsible for the overall management 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 dispositioned in a timely manner.

02.01 Significance Determination and Preparation for the SERP.

- a. The responsible inspector shall clearly establish the licensee performance deficiency and characterize the finding as potentially greater than Green by applying the best available information and using the SDP Phase 1, “Initial Screening and Characterization” worksheet described in Attachment 0609.04 to this Manual Chapter. The inspector should use the SDP User Interface feature of SAPHIRE version 8 (when available) or the applicable SDP Appendix (A thru M) in this Manual Chapter and/or the plant-specific Pre-solved Table if further evaluation is required. The inspector may be assisted by the regional Senior Reactor Analyst (SRA), if necessary, will to determine the proposed preliminary color for the finding (White, Yellow, Red, or Greater Than Green).
- b. For the quantitative SDPs (Appendix A, F, G, K), the regional SRA will review the results of the inspector’s SAPHIRE SDP Report or the SDP Phase 2 risk evaluation. This will normally result in conducting a Phase 3 assessment using the best available information provided by the licensee and the Event Assessment or General Assessment features of SAPHIRE version 8. This assessment must take into account the SDP timeliness goal and will be documented in the “SERP Worksheet for SDP-Related Findings” (Exhibit 2 to this Attachment). The regional SRA may request support from NRR risk analysts in verifying the technical adequacy of the plant specific Phase 2 risk-informed inspection notebook (hereafter referred to as the notebook) and Pre-solved Table.
- c. The regional SRA implementing a Phase 2 or Phase 3 SDP should solicit comments on the results of the process (peer review) from at least one other regional SRA or agency risk analyst. Such comments and supporting rationale should be documented in the SERP information package (Exhibit 2). A headquarters SRA or risk analyst will peer review all Phase 3 assessments. Once the peer review is completed, the results will be presented to the SERP.
- d. Using the outline provided in Exhibit 2, the Sponsoring Region or office will assemble a package of documents that will provide the SERP members a clear understanding of the preliminary or final significance of the finding and the related enforcement recommendations.
- e. If further information and/or analysis are necessary before a finding can be evaluated and the SDP timeliness goal and associated metrics may be in jeopardy of not being met, the region may request a planning SERP. Similarly, if the region or office is considering applying Appendix M to characterize the significance of a finding, it should request a Planning SERP. A Planning SERP will reach consensus on the scope, schedule, methodology, and who is to perform the assessment (reference Section 08.06 of IMC 0609). A planning SERP is not necessary when directed to use Appendix M in the Phase 1 SDP guidance. This assessment will be documented on the “Planning SERP Worksheet” (Exhibit 3 to this Attachment). An additional SERP will be required before the preliminary significance determination is reached and a letter is issued.
- f. If the staff’s significance determination of a finding is not complete at the time of issuance of the inspection report, and not reviewed by the SERP, then the finding

will be characterized in the inspection report as “to be determined (TBD).” No inspection finding should be described by a color other than Green in official NRC correspondence unless the SERP has reviewed it.

02.02 NRR Enforcement Coordinator Preparation.

The NRR Enforcement Coordinator will arrange for support/participation by the appropriate technical and project management staff. SERPs are typically held during the scheduled weekly regional enforcement conference call. To schedule a SERP, the regional enforcement liaison, at the earliest opportunity, will notify the NRR Enforcement Coordinator and OE of a potentially White, Yellow, Red, or greater than Green finding being assessed at the region to schedule the date the finding will be ready to present at a SERP. The NRR enforcement coordinator will verify the availability of NRR SERP members and maintain the SERP calendar.

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

02.03 Participation in the SERP.

The principal objective of the SERP is to arrive at a consensus regarding the significance determinations, their bases, and the appropriate enforcement actions to be taken, if applicable. All members of the SERP, indicated in the table below, will represent their organization and participate in reaching a consensus. SERP members may request that technical specialists, risk analysts, and SRAs be available at the SERP for consultation on issues. Participation in SERPs should be in accordance with the following guidelines:

Role	Responsible Organization/Participant
<p>Sponsor</p> <p>Holds overall responsibility for issue resolution, 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>

Role	Responsible Organization/Participant
<p>Headquarters Technical Spokesperson</p> <p>Provides headquarters technical position and is the NRR authority on the SDP being used. 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 SDPs), Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Component Integrity (for steam generator and spent fuel pool SDPs), Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Policy and Rulemaking (for B.5.b SDP), Deputy Division Director (or designated Branch Chief);</p> <p>NRR Division of Inspection and Regional Support (for operator re-qualification, transportation, ALARA, public and occupational radiation, 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), deputy division director or branch chief; Division of Preparedness and Response (emergency planning SDP), Deputy Director for Response (or designated branch chief).</p>
<p>Inspection 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, Deputy Division Director (or Branch Chief)</p>

Role	Responsible Organization/Participant
<p data-bbox="203 226 602 258">Enforcement Spokesperson</p> <p data-bbox="203 300 792 548">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 data-bbox="824 300 1349 367">Headquarters Office of Enforcement, Deputy Director (or Branch Chief).</p>

Other invited participants may include the applicable NRR Project Manager, Regional Enforcement Coordinator, Office of Nuclear Regulatory Research (RES) representative for Accident Sequence Precursor (ASP) Program related issues, Office of the General Counsel, and others as applicable. SERP members can also request participation in the SERP by inspectors, SRAs, risk analysts, and technical specialists involved in the development **or peer review** of the significance of the finding.

02.04 Preliminary SERP Reviews.

Members of the SERP panel will discuss the finding and reach consensus on the statement of deficient licensee performance on which the inspection finding is based, the safety significance of the finding including assignment of preliminary color, the AV(s) and the regulatory requirements that should be cited. No official agency preliminary significance determination of White, Yellow, Red, or greater than Green will be made without a SERP review. **The following 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, Minor, or No Finding: If the SERP concludes that the **preliminary** significance determination of the finding is Green, or minor, or the SERP determines that the criteria for a finding **were** not met, 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 significance determination and will be characterized as such in the inspection report.**
- b. White, Yellow, or Red Findings:
 - 1. If the SERP reaches a consensus that the preliminary result of the significance determination associated with the finding is White, Yellow, **or** Red, the SERP’s conclusion will be documented by OE on the Strategy Form **(EATS).**
 - 2. **The final Phase 3 SERP package should include a discussion of uncertainty resulting from model completeness, parameter values, or lack of data, as well as the best case Phase 3 assumptions and analysis. Qualitative, as well**

as quantitative, information should be considered in deriving a color recommendation. Some uncertainties may include, but are not limited to, assumptions regarding exposure time, initiating event frequencies, equipment failure probabilities, and human error probabilities. It is not necessary to use Appendix M if existing SDP tools are generally sufficient to risk-inform the finding, especially if the Phase 3 assessment is clearly within one color band. However, Appendix M may be appropriate if no SDP tools exist, or inputs to an existing SDP are very influential and cannot be derived through existing SDP resources (e.g., NUREGs, industry documents, RASP guidance, etc.).

3. 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 will offer the licensee an opportunity to submit a written response or to request a Regulatory Conference described in Section 3. 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, although not required, submit materials on the docket at least seven days prior to the regulatory conference. The letter should not include the SDP worksheets or portions of the SERP package. 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 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.

c. Greater Than Green Findings.

1. The “greater than Green” option is not expected to be the norm when characterizing the preliminary significance of findings.
2. The staff should make realistic assumptions in the bases for its significance determinations and should make a reasonable effort to determine a **specific** preliminary color in a timely manner. Every effort should be made during the peer review to resolve all differences and concerns.
3. The preliminary significance of a finding should be characterized as “potentially greater than Green” if the staff:
 - (a) Is unable to determine a specific preliminary color because of the proximity to a color threshold, or
 - (b) Lacks information to make **reasonable** assumptions, and the assumptions are influential to the preliminary significance result (i.e., will cause the color to vary).

When this option is used, the SDP basis provided to the licensee must be particularly clear and complete to identify where the staff lacks information to reach a final determination.

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 results in a violation. During or subsequent to the SERP meeting, an OE Enforcement Specialist will assign an EA number to each case by completing the SDP/EA Request & Strategy Form. The Strategy Form enables tracking of individual findings and potential violations. Following the SERP, OE will send the completed Strategy Form to each SERP member to review for accuracy. Any disagreement with the contents of the Strategy Form 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 AND REGULATORY CONFERENCES**

Attending a Regulatory Conference or providing a written response are the options available to a licensee if it wants 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.

Receipt of a licensee's written response or the Regulatory Conference should normally be completed within 30 days of the licensee's receipt of the preliminary significance determination letter. The licensee will notify the NRC by phone or other means within 10 days how it intends to respond. Should the licensee decline its opportunity to participate in a Regulatory Conference, it needs to inform the NRC of this decision in writing.

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 opts to attend a Regulatory Conference, it should provide any information considered applicable to the finding(s) at least seven 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. Receiving the licensee's information several days before the conference will allow for a more informative and effective conference by providing the staff sufficient time to review the information and formulate any questions.
- 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 agreed upon between the licensee and the staff.
- 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 predecisional 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 in part or in total to public observation. For security reasons, NRC staff should not participate by telephone or video in conferences when Safeguards Information will be discussed. If such participation becomes necessary, it should be in accordance with Management Directives 12.4, "NRC Telecommunications System Security Program," and 12.6, "NRC Sensitive and Unclassified Information Security Program."
- 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 who 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 participation may be requested as deemed 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/enforcement process. Exhibit 1 of this Attachment provides standard opening remarks.
- d. The region **or responsible office** should briefly discuss the findings being considered and explain the basis of the agency's concern (i.e., safety significance and AV). The level of detail to be discussed should be commensurate with the complexity and significance of the issues. 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 risk significance.
- e. The licensee should discuss its understanding of the facts and circumstances surrounding the significance of the findings 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 the nature of any additional information under**

development that was not presented at the conference and the date the region can expect to receive it. 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 significance of the findings, 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. The discussion of corrective actions should be limited to the immediate actions taken to mitigate safety consequences of the finding. Detailed discussions of long-term corrective actions should be reserved for the Regulatory Performance meeting and for the followup inspection activities.
- g. Prior to the conclusion of the conference, the participating NRC staff should confer, independent from the licensee and other participants, to determine the need for additional information.
- 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.

03.04 Post-Conference Review. Subsequent to a Regulatory Conference, the Sponsor with the NRC staff who participated in the Regulatory Conference should review the information provided by the licensee to determine whether the finding merits further evaluation or if the staff should proceed with issuing a final significance determination. This review does not have to be a formal meeting, can be completed by teleconference or email, but should occur as close to the completion of the Regulatory conference as possible. The same guidance applies to post-conference review of a licensee's written response.

If the post-conference review concludes that the information presented by the licensee does not change the preliminary significance of the finding, a final SERP is not necessary. The region or responsible office should prepare a final significance determination letter that will affirm the significance determination of the original SERP as described in Section 02.04.

- a. The post-conference review will consider:
 - 1. the reasonableness of the risk analysis or other information provided by the licensee and whether new information or perspectives were obtained warrant reconsideration of the preliminary safety significance of the finding or of the performance deficiency
 - 2. the enforcement strategy, to determine whether it remains valid or should be changed

3. whether additional review of information provided by the licensee is necessary before a decision on a course of action can be made
4. whether additional information is necessary

03.05 Final SERP.

- a. If **participants** in the **post-conference review** conclude that the licensee presented sufficient information that changes, **or appears to change**, the significance of the finding or its basis, **a final SERP is required. If necessary**, the region **or responsible office** should coordinate completing the assessment of the new **licensee** material. 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**, following completion of **any additional final significance analysis**. The region **or responsible office** should provide a new recommendation of significance to the final SERP and discuss those issues that affected the preliminary significance determination, **whether it changed the outcome or not**.
- b. If the SERP, after considering the licensee's additional information, determines that a preliminary White, Yellow, Red, or greater than Green finding is a Green finding, this is the final determination and will be communicated as such in the cover letter of the next quarterly inspection report. Findings resulting in a final Green significance will not negatively impact the timeliness of the NRC's regulatory response. As such, these findings are not subject to the timeliness goal and associated SDP timeliness metrics, and, the next quarterly inspection report may be issued outside the 90-day timeliness period. The sponsor of the finding should verbally communicate the final results to the licensee if there is a significant delay in issuing the next inspection report.
- c. If the SERP cannot reach consensus on the final significance of the finding the SERP must either (1) direct specific actions to reconcile the different views; or (2) identify the appropriate NRC manager(s) to make a final decision; or (3) immediately escalate the issue to the manager having the overall cognizance for the organizations having differing views. If resolution is not achieved within 14 calendar days, the Inspection 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.
- d. If, as a result of the SERP discussion, a substantive change is made from the preliminary significance determination or AV(s), another exit meeting should be held with the licensee if deemed necessary by the Sponsor of the issue.

0609.01-04 **ISSUING** FINAL SIGNIFICANCE DETERMINATION (AND NOTICE OF VIOLATION (NOV) IF APPLICABLE)

04.01 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.

04.02 Final Significance Determination and NOV, Coordination and Review. All final significance determination letters for Yellow and Red **findings** shall 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 issues 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.)

04.03 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 following guidelines:

- a. The Regional Administrator or the Deputy Regional Administrator **or responsible NRC office director or deputy office director** normally signs and issues final significance determination cover letters associated with Yellow, or Red findings.
- b. The Regional Administrator or Deputy Regional Administrator **or responsible NRC office director or deputy office director** may delegate **to the division directors** the authority to sign and issue final significance determination cover letters associated with Yellow findings.
- c. Division Directors are normally expected to sign and issue final significance determination cover letters associated with White findings.

04.04 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 work 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. ENs should also be considered for any final determination without an NOV that has become a matter of public or Commission interest.

Exhibit 1 – Suggested Opening Comments for Regulatory Conference

Exhibit 2 – SERP Worksheet for SDP-Related Findings

Exhibit 3 - Planning SERP Worksheet

Attachment 1 – Revision History for IMC 0609.01

END

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 predecisional 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 for SDP-Related Findings

General Guidance.

Risk-Informed Decision Attributes Meeting Minimum Acceptable Standards for ROP

If the following guidelines are met, the SDP result may be considered meeting the minimal acceptable standard of being risk-informed, for use by the ROP.

- 1) Each assumption is considered on its own merit regardless how it influences the final result. Bounding an assumption between two reasoned limits and selecting an average value is acceptable.
- 2) The SDP result sensitivity to the assumptions is understood by the SERP members allowing them to conclude that the basis for each assumption is adequate, commensurate with its relative influence on the result.
- 3) The logic (e.g., accident sequences) and assumptions are scrutable to inspectors, risk analysts, technical staff, and licensee staff.

Specific Guidance for Final Determination SERP.

- 1) When point-estimate values of delta CDF (or delta LERF) are very close to a threshold, the SERP should re-examine the bases for all assumptions, starting with the most influential, to assure that they are reasonable and are not being biased. If these are judged reasonable, the decision should proceed based upon the resultant value of the point estimate.
- 2) When a common or programmatic weakness has affected multiple plant SSCs or functions, the SERP may base the SDP result on a probabilistic sensitivity analysis that bounds the SDP. Factual or reasoned basis must be provided for the assumptions supporting each bounding result, using a probabilistic risk model adequate to model the relevant supporting assumptions. When the span between bounding results is a single color, then this may become the SDP result. If the span between bounding results includes multiple colors, then further deliberation or fact gathering must be performed to reduce the level of uncertainty to a single color span.
- 3) If participants in the post-conference review conclude that the licensee presented sufficient information that changes the significance of the finding, or substantially changes its basis, the region will update the appropriate section(s) of the original SERP Worksheet (Exhibit 2). The region or responsible office should discuss only those issues that affected the preliminary significance determination.

Details

- A. Summary of Issue (include a brief description of the root cause and licensee's corrective action(s), if available):
- B. Statement of the Performance Deficiency:
- C. Significance Determination Basis:
1. Reactor Inspection for IE, MS, BI cornerstones
 - a. Phase 1 screening logic:

Describe the assumptions, logic, and path used that resulted in a Phase 2 or Phase 3 evaluation
 - b. Phase 2 Risk Evaluation (when applicable)
 - (1) Select Phase 2 method used
 - SDP Interface (SAPHIRE Version 8) or
 - Phase 2 SDP Appendix used: _____ (A through M)
 - (2) Preliminary Results: White Yellow Red
 - (3) Provide the Phase 2 Evaluation (SDP Interface Report or SDP Appendix worksheet).
 - (4) If the preliminary risk significance determination based on Phase 2 SDP worksheet results is "Green" (1E-7) or higher significance, screen the risk contributions from external events (e.g., fire, seismic, and floods) that may add to the preliminary risk significance determination based on Phase 2 SDP worksheet results, using guidance in IMC 0609, Appendix A, Attachment 3.
 - c. Phase 3 Analysis

Concisely address each of the analysis aspects that follow.

 - (1) The Phase 3 model revision and other PRA Tools used
 - (2) Influential Assumptions (e.g., exposure time, common cause failure, recovery and other mitigation strategies (B.5.b))
 - (3) Calculation Discussion (SAPHIRE analysis results, SPAR-H evaluation)
 - (4) Analysis of Dominant Cut-sets / sequences

- (5) Sensitivity Analysis
 - (a) Contributions of greatest uncertainty factors and impact on assumptions (The staff should describe the quantitative and qualitative uncertainties and state how they impact the influential assumptions)
 - (b) The staff should bound the uncertainties, if possible, and through sensitivity analysis (quantitative and qualitative) state why they are conservative. Bounding an assumption between two reasoned limits and selecting an average value is acceptable. The SERP will judge whether the staff's arguments are reasonable and unbiased.
- (6) Contributions from External Events (Fire, Flooding, and Seismic)
- (7) Potential Risk Contribution from LERF
- (8) Total Estimated Change in Core Damage Frequency
- (9) Licensee's Risk Evaluation
- (10) Summary of Results and Impact

d. Peer Review (name of reviewer)

Summarize any unresolved issues identified by the reviewer.

e. References

2. All Other Inspection Findings (not IE, MS, BI cornerstones)

Flowchart logic and full justification of assumptions used

Proposed preliminary or final color

D. Proposed Enforcement.

1. Regulatory requirement not met.

2. Proposed citation.

E. Determination of Follow-up Review (as needed)

For White findings propose whether headquarters (NRR and/or OE) should review final determination letter before issuance. (For greater than White findings, review and concurrence by NRR and OE is required as discussed in Section 4b.)

Exhibit 3

Planning SERP Worksheet

1. State the licensee's performance deficiency and any regulatory requirement or industry standard not met.
2. Describe the reason the regional sponsor requests the finding to be reviewed by the Planning SERP (the finding meets the criteria of Section 08.05b of IMC 0609: the technical complexity is such that existing SDP tools are not readily adaptable to the issue, the region does not have the expertise or resources to risk-inform the finding, or the finding has a potentially high safety significance [Yellow or Red]. Also, if the region determines that an existing SDP is not suitable to assess the significance of a finding and is considering applying Appendix M to characterize the significance of a finding, those considerations must be discussed in a Planning SERP if the finding is likely to be greater than green).
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. Phase 2, Appendix M, simplified Phase 3, detailed Phase 3) and justify the level of methodology recommended for the preliminary assessment.
5. Provide a recommended schedule for the completion of the assessment.
6. Provide the recommended expertise to complete the assessment.
7. Provide a discussion as to the applicability of NRC Management Review described in IMC 0612, Appendix B, should or should not be used for arriving at a preliminary determination.
8. Provide additional comments for SERP consideration such as known conservatisms, uncertainty ranges, influential assumptions, and use of what is considered best available information.

ATTACHMENT 1
Revision History - MC 0609.01

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	10/13/2006	Revision history reviewed for the last four years	NO	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.	NO	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.	NO	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	NO	N/A	N/A

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
		the sentence clarified to mean supporting information for the finding. As originally stated, "report" could be interpreted to mean inspection report.			
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.	NO	N/A	N/A
NA	11/22/05 CN 05-030 (Cont)	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.	NO	N/A	N/A

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
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.	NO	N/A	ML073460588
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.	NO	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	NO	N/A	ML103490479

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
		<p>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).</p>			