NRC INSPECTION MANUAL

IRIB

MANUAL CHAPTER 0609

SIGNIFICANCE DETERMINATION PROCESS

0609-01 PURPOSE

The Significance Determination Process (SDP) uses risk insights, where appropriate, to help NRC inspectors and staff determine the safety or security significance of inspection findings. The safety significance of findings, combined with the results of the performance indicator (PI) program, are used to define a licensee's level of safety performance, and to define the level of NRC engagement with the licensee. Each SDP supports a cornerstone associated with the strategic performance areas as defined in Inspection Manual Chapter (IMC) 2515, "Light-Water Reactor Inspection Program- Operations Phase" and IMC 2201, "Security and Safeguard Inspection Program for Commercial Power Reactors." The SDP determinations for inspection findings and the PI information are combined for use in assessing licensee performance in accordance with guidance provided in IMC 0305, "Operating Reactor Assessment Program" and IMC 0320, "Operating Reactor Security Assessment Program."

The staff should recognize the importance of completing SDP evaluations in a timely manner in order to promptly direct NRC resources to those licensees with relatively weaker performance. However, for some findings where circumstance may require delay in the issuance of final significance determination, the guidance of this inspection manual chapter should be implemented.

0609-02 OBJECTIVES

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

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

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

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

0609-03 APPLICABILITY

03.01 The SDPs described in the Appendices of this Manual Chapter are applicable to inspection findings identified through the implementation of the NRC inspection program described in IMC 2515 and IMC 2201. Before determining significance, each inspection finding must be screened to determine if it meets the documentation threshold using the guidance provided in IMC 0612, Appendix B, "Issue Screening" and/or Appendix E, "Examples of Minor Issues." Violations with no associated performance deficiency will not be subject to these SDPs. Conditions that do not represent deficient licensee performance are not subject to this guidance but may need to be addressed by other NRC processes (e.g., Backfit Rule, Generic Safety Issues, Rule-making).

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

03.03 The risk significance of actual reactor events caused or complicated by equipment malfunction or operator error must be assessed by NRC risk analysts in accordance with IMC 0309, "Reactive Inspection Decision Basis for Reactors." This manual chapter provides guidance to the staff for determining the appropriate event response that was originally prescribed in MD 8.3, "NRC Incident Investigation Program." Although the product of this risk evaluation may provide useful risk insights to inspectors for event response or follow-up, it was not designed to determine the risk significance of a licensee performance deficiency.

Because the SDP is used to estimate the risk significance of licensee performance deficiencies, including those that manifest themselves during events, the performance deficiencies associated with an actual reactor event should be dispositioned using the SDP in the same fashion as all other performance deficiencies.

0609-04 DEFINITIONS

Applicable definitions are located in IMC 0612-03, "Power Reactor Inspection Reports."

0609-05 RESPONSIBILITIES AND AUTHORITIES

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

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

a. Provide overall program direction for the ROP.

b. Develop and direct the implementation of policies, programs, and procedures for regional application of the SDP in the evaluation of findings and issues associated with the ROP.

c. Assess the effectiveness, uniformity, and completeness of regional implementation of the SDP.

05.02 Director, Nuclear Security Incident Response.

a. Provide overall program direction for the security ROP.

b. Develop and direct the implementation of policies, programs, and procedures for regional application of the security SDP in the evaluation of findings and issues associated with the security ROP.

05.03 Director, Division of Inspection and Regional Support.

a. Approve all SDPs and direct the development of future SDPs and improvements through periodic revisions based on new risk insights and feedback from users.

b. Provide oversight and representatives as necessary to support the Significance and Enforcement Review Panel (SERP) in order to ensure consistent and timely application of the process.

05.04 Director, Division of Risk Assessment.

a. Recommends improvements to all SDPs using a probabilistic risk framework and authorizes changes to plant-specific risk insight information used by the SDP, based on new risk insights and feedback from users.

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

05.05 Director, Office of Enforcement.

a. Ensure consistent application of the enforcement process to violations of NRC regulations with the appropriate focus on the significance of the finding.

b. Provide representatives as necessary to support the SERP in order to ensure consistent application of the enforcement process.

c. Coordinate with NRR (and NSIR when necessary) when revising agency documents used for communicating to the licensee about apparent violations and final determinations associated with the ROP.

05.06 Director, Office of Research.

a. Provide support in the development and refinement of the SDPs, which use risk insights from research activities, based on user need requests.

b. Provide representatives, when requested, to support the SERP.

05.07 Regional Administrators.

a. Provide program direction for management and implementation of the SDP to activities performed by the Regional Office.

b. Maintain overall responsibility for, and apply regional resources as necessary, to determine the significance of specific inspection findings in a timely manner, using best available information consistent with the SDP timeliness goal and associated SDP timeliness metrics.

05.08 Senior Reactor Analysts.

a. Support NRC objectives related to the utilization of risk insights in the reactor inspection program in the form of a risk-informed ROP, and in the use of the SDP.

b. Support the ROP and its specific objectives as presented in Attachment 3 to this Manual Chapter.

0609-06 BACKGROUND

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

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

SECY-00-49, dated February 24, 2000, provided the results of the pilot program for risk-informing the reactor inspection program and recommended proceeding with initial implementation of the new process at all licensed power reactor sites. The guidance in this Manual Chapter and related reactor inspection program guidance in IMC 2515 and IMC 2201 was subsequently issued in support of initial implementation. SRM-SECY 04-0020, “Treatment of Physical Protection Under the Reactor Oversight Program”, dated March 29, 2004, directs the staff to establish a separate but parallel oversight program for the security cornerstone.

Enforcement associated with violations of regulatory requirements will continue to be processed in accordance with the current revision of the NRC Enforcement Policy and any applicable Enforcement Guidance Memoranda (EGMs). Minor violations, as defined by the enforcement policy, do not need to be reviewed using the SDP process.

0609-07 SDP DEVELOPMENT AND FEEDBACK PROCESS

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

a. The draft of the SDP or the modification is subjected to internal NRC stakeholder review, including NRC regional input. Early external stakeholder input may also be solicited through public meetings, if appropriate.

b. A feasibility review is performed by the NRC staff to assess the adequacy of the proposed SDP or changes. This review should specifically involve regional representation and should test the SDP with real (preferred) or hypothetical inspection finding examples. This review should determine if the proposed SDP or change is ready to be issued for public comment and/or for initial evaluation through field use by regional inspectors.

c. Upon reconciliation of public comments and initial user feedback, the SDP or change is issued as a revision to this Manual Chapter.

d. Appropriate training will be provided to the NRC inspection staff.

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

0609-08 SDP AND ENFORCEMENT REVIEW PANEL PROCEDURES

The following basic process is described in detail in Attachment 1 to this Manual Chapter.

08.01 Development of Inspection Findings. All operating reactor inspection findings are developed as a result of the implementation of the NRC reactor inspection program described in IMC 2515 or IMC 2201. Findings are inspector or licensee-identified issues that meet the documentation threshold as defined in IMC 0612, Appendices B and E. Findings must represent a deficiency in a licensee's performance. Findings are generally discussed with licensee representatives during the inspection process and are formally presented at an exit meeting with licensee management at the conclusion of the inspection period. The significance determination for each finding will generally take place in parallel with the development of the facts surrounding the finding but may not be complete at the

time of the exit meeting. Documentation of findings, including details required to support the results of the SDP, will be done in accordance with guidance provided in IMC 0612.

08.02 Initial Characterization of Significance. Initial significance determination is normally performed by the inspector using the Phase 1, "Initial Screening and Characterization" worksheet described in Attachment 4 to this Manual Chapter.

a. If the determination result is Green, then this would represent a final determination and will be characterized as Green at the exit meeting and in the inspection report.

b. If the determination result is potentially White, Yellow, or Red, then it will receive additional review(s) by the regional staff. The inspectors and regional staff should obtain from the licensee any readily available information in a timely manner to best inform the staff's preliminary significance determination, taking into account SDP timeliness goals as described in Section 08.05 of this Manual Chapter.

All findings documented in an inspection report with a potential significance of White, Yellow, Red, or greater than Green will be reviewed by the SERP as described in Attachment 1 to this Manual Chapter. The result of the SERP review represents the staff's preliminary safety or security significance assessment. However, when a potential White, Yellow, or Red finding is determined to be Green by the SERP, this will represent a final determination and will be characterized as such in the inspection report.

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 or security-related greater than Green in official NRC correspondence unless the SERP has reviewed it.

08.03 Obtaining Licensee Perspectives on Initial Characterization of Significance. If the preliminary significance assessment is White, Yellow, Red, or greater than Green, then the licensee will be given the opportunity to formally present any further information or perspective, or to accept the staff's decision. This opportunity will be offered in the cover letter of the inspection report or the Preliminary Determination letter and will allow the licensee to request a public Regulatory Conference, or provide a written response on the docket, to present facts and their evaluation of significance. Security related matters will normally not be public, either at a conference or in correspondence.

The preliminary significance determination letter must clearly state, with sufficient detail, the staff's basis for their decision to enable the licensee to understand and provide further information to assist the staff in making the best informed final significance determination. In the case of a greater than Green finding, the staff should request from the licensee additional information needed to assist the staff in making its final 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.

It is expected but not required that the licensee provide on the docket, prior to the Regulatory Conference, any information considered applicable to the finding(s). Any non-

sensitive information provided by the licensee during the Regulatory Conference will be made public.

08.04 Finalization of the Staff's Significance Determination. If the licensee accepts the staff's preliminary determination in a written response, then the staff will issue it as the final determination of significance. If the licensee provides further information on the docket by mail or during a Regulatory Conference, then the regional staff with NRC headquarters staff participation will make its final significance determination after evaluating this information. If the staff, after consideration of the licensee's additional information, determines that the initial characterization of significance should not change, the final determination of significance will be issued. The final significance determination will be a color (White, Yellow, or Red) which corresponds to the safety significance of the finding as determined by the appropriate analyses. After considering the licensee's additional information, if the staff determines that a change in the initial characterization of significance is warranted or should be considered, then the SERP will schedule a review in accordance with the guidelines in this Manual Chapter.

In the case where the staff has issued a preliminary significance determination of greater than Green and the licensee has not or cannot provide sufficient information to better inform the staff's significance determination in a reasonable period of time, then the staff should determine final significance using its best objective rationale, and document this rationale fully in a letter to the licensee. This is expected to be rare and should conform to all SDP procedural requirements.

When the SERP agrees on the final determination of significance, the licensee will be informed of the final color of the finding in a letter. Enforcement actions stemming from the finding, if applicable, will generally be forwarded at that time, and the licensee will be informed of the SDP appeal process described in Attachment 2 of this Manual Chapter.

08.05 SDP Timeliness. The Agency's goal for SDP timeliness is that all final significance determinations be completed within 90 days from the issue date of the first official correspondence that described the finding or documented the need for further review to determine significance (TBD). All attempts should be made to meet this goal, however, it is recognized that certain issues, due to their complexity, may result in occasions where the goal is exceeded. The NRR Operating Plan and Regional Operating Plans are Agency management tools for monitoring staff performance in achieving the goal.

The timeliness criteria below represent the maximum time approximated for each process milestone in order for the Agency to meet the 90 day goal.

T_0 - The issue date of the first official correspondence describing the finding, either in an inspection report and/or Preliminary Determination letter

T_{30} - Latest date to issue the Preliminary Determination letter

T_{70} - Latest date for completing the Regulatory Conference with licensee

T_{90} - Final Determination letter issued

The Agency successfully completing the SDP process within 90 days is dependent upon timely completion of a public Regulatory Conference or receipt of a written response. The timeliness criterion below represents the maximum time approximated for each process milestone for the licensee to establish the Regulatory Conference within the 90 day goal. This timeliness goal is developed in detail in Attachment 1 to this Manual Chapter.

T_{L0} - Issue date of the Preliminary Determination letter issued in an inspection report cover letter or separate correspondence

T_{L10} - Licensee responds no later than 10 days from the issue date of the notification of the Preliminary Determination

T_{L40} - Regulatory Conference completed or licensee's written response received by NRC no later than 40 days from the issue date of the notification of the Preliminary Determination

a. Exceptions to the Timeliness Goal.

1. Experience has shown that inspection findings that may take longer than the 90 day goal to assess for significance meet one or more of the following criteria:

   - Findings are of such technical complexity that existing SDP evaluation tools are not readily adaptable to the issue; and/or the region does not have the expertise or resources to risk inform the finding.

   - Findings have potentially high safety significance (i.e., Yellow or Red) that should be carefully examined for potential impact on plant safety and subsequent NRC action.

   In these cases, additional time may be necessary to complete a preliminary and/or a final determination of safety significance. However, findings for which the 90 day goal is not met, including findings where the limit was extended, will continue to negatively impact the timeliness goal and associated SDP timeliness metrics.

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

08.06 Planning SERP. For findings considered by the Region to meet the criteria of Section 08.05a, a Planning SERP, convened early in the process, will reach consensus on the scope of evaluation to be performed, the schedule on which the evaluation will be

completed, and who will perform the evaluation. This Planning SERP is convened at the discretion of the applicable regional sponsor of the finding with cooperation of the HQ staff.

Before presenting to the Planning SERP, the regional sponsor should coordinate with HQ staff on determining the scope for the evaluation (e.g., Phase 2 SDP, simplified Phase 3, or detailed Phase 3 SDP), the need for additional information and expertise, and the estimated time necessary to obtain an acceptable risk informed preliminary finding.

It is expected that no assessments will be delayed beyond 90 days. However, if the SERP agrees that specific circumstances will delay the final characterization beyond 90 days, the Regional Administrator and the NRR Office Director must be notified.

If the Planning SERP reaches consensus that additional time is warranted beyond 90 days, a schedule must be developed for the key milestones above. Findings requiring greater than the 90 day goal will continue to have a negative impact on the SDP timeliness metrics.

0609-09 PROCESS FOR LICENSEE APPEAL OF A STAFF SDP DETERMINATION

If a licensee disagrees with the staff's final determination of significance, the licensee may appeal the determination to the appropriate NRC Regional Administrator as described in Attachment 2 of this Manual Chapter. Any such review must meet the requirements stated in the Prerequisites and Limitations sections of Attachment 2 to merit further staff consideration. Specifically, the licensee must have opted for an opportunity to present additional information to the staff either by meeting with regional management at a Regulatory Conference or by submitting additional information in writing on the docket.

0609-10 USING THE SDP TO DETERMINE THE SIGNIFICANCE OF INSPECTION FINDINGS THAT ARE NOT VIOLATIONS OF THE LICENSING OR DESIGN BASIS

The staff's use of the SDP to determine the significance of the result or consequence of a licensee performance deficiency will be made regardless of whether the result or consequence constitutes a violation of a licensee's licensing or design basis or any other regulatory requirement or commitment. Agency follow-up of such findings, if determined to be significant, will be handled in accordance with the backfit rules of 10 CFR 50.109 as appropriate.

END

Attachments:

Attachment 1 - Significance and Enforcement Review Panel Process

Attachment 2 - Process For Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)

Attachment 3 - Senior Reactor Analyst Support Objectives

Attachment 4 - SDP Phase 1 - Initial Screening and Characterization of Findings

Appendices:

Appendix A Significance Determination of Reactor Inspection Findings for At-Power Situations
- Attachment 1 User Guidance
- Attachment 2 Site Specific Risk-Informed Inspection Notebooks Usage Rules
- Attachment 3 User Guidance for Screening of External Events Risk Contributions

Appendix B Emergency Preparedness SDP

Appendix C Occupational Radiation Safety SDP

Appendix D Public Radiation Safety SDP

Appendix E Part 1, Baseline Security SDP for Power Reactors and Part II, Force-on-Force Security SDP for Power Reactors

Appendix F Fire Protection and Post-Fire Safe Shutdown SDP

Appendix G Shutdown Safety SDP

Appendix H Containment Integrity SDP

Appendix I Operator Requalification, Human Performance

Appendix J Steam Generator Tube Integrity SDP

Appendix K Maintenance Risk Assessment and Risk Management SDP

Appendix M Significance Determination Process Using Qualitative Attributes

Revision History - IMC 0609

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	02/27/2001 CN 01-005	0609 has been revised to correct minor errors and inconsistencies, and to clarify the overall SDP description.	NO	N/A	N/A
N/A	08/16/2001 CN 01-015	0609 has been revised to correct the title of Attachment 2 (0609.02) as listed in the attachments to this manual chapter.	NO	N/A	N/A
N/A	04/30/2002 CN 02-022	0609 has been revised to reflect revisions to Attachments 1 and 2, and changes to the recently issued Appendix A to IMC 0609.	NO	N/A	N/A

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
N/A	05/19/2005 CN 05-014	0609 is revised to add Appendix K, ”Maintenance Rule Risk Assessment and Risk Management” as an attachment.	NO	N/A	N/A
NA	11/22/05 CN 02-030	0609 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 includes the regional comments on the proposed guidance on how to meet the timeliness goal. The document continues to emphasize the importance of timely issuance of the final SDP result. However, complexity of issues, lack of evaluation tools, lack of expertise, and findings of high safety significance can contribute to delays in finalizing findings. To that affect, new guidance is provided in Section 08.05 of the document on how to approach such findings using the Planning SERP process.	NO	N/A	ML061590493

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 provides the staff clarification to use IMC 0309, “Reactive Inspection Decision Basis for Reactors” in place of MD-8.3, to use Attachment 4 to perform SDP Phase 1 screenings, to incorporate feedback responses to add NSIR requirements, clarify guidance for SDP timeliness in regard to OI/DOJ investigations, and to add references to SDP Appendix M and the Attachment 4 for Phase 1 Initial Screening and Characterization attachment.	NO	N/A	ML073460588
N/A	08/05/08 CN 08-023	This revision changes the term “choice” letter to “Preliminary Determination” letter and adds a third responsibility to OE in Section 05.05. The section on SDP Timeliness was clarified to eliminate literal interpretation of timeliness goals by the licensee. Replaced term AV(TBD) with (TBD) due to changes in IMC0612. Repetitive guidance that appears in both this IMC and Attachment 1 was removed and is in Attachment 1 only.	NO	N/A	ML081720377