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 significance of inspection findings. 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.” The SDP determinations for inspection findings and the Performance Indicator (PI) information are combined for use in assessing licensee performance in accordance with guidance provided in IMC 0305, "Operating Reactor Assessment Program.”

## 0609-02 OBJECTIVES

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

02.02 To provide all stakeholders an objective and common framework for communicating the potential safety 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. Before determining significance each inspection finding must be screened using the guidance provided in IMC 0612, Appendix B, “Threshold for Documentation.” Certain violations, as described in this Chapter, will not be subject to these SDPs (e.g., willful violations).

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.

## 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 Associate Director for Inspection and Programs

Direct the development of the SDP within NRR.

05.03 Director, Division of Inspection Program Management

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 Determination Process and Enforcement Review Panel (SERP) in order to ensure consistent application of the process.

05.04 Director, Division of Systems Safety and Analysis

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 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 process.

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 Administrator

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

b. Within the guidance of the ROP, apply inspection resources, as necessary, to determine the significance of specific inspection findings.

## 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 was subsequently issued in support of initial implementation.

Enforcement associated with violations of regulatory requirements will continue to be processed in accordance with the current revision of NUREG-1600, “General Statement

of Policy and Procedures for NRC Enforcement Actions" 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 Program Management, 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 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. Findings are inspector or licensee identified issues that meet the documentation threshold as defined in IMC 0612, Appendix B. 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 expected to be done by the inspector. If the result(s) of this determination is Green this would represent a final determination and will be characterized as Green at the exit meeting and in the inspection report. A finding characterized by the inspector as either White, Yellow, or Red will receive additional review(s) by 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. Subsequently, all findings with potential significance of White, Yellow, or Red will be reviewed by the SERP. The result of the SERP review represents the staff's preliminary safety significance assessment. However, when a potentially 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.

The staff should make reasonable and realistic assumptions in the bases for its significance determinations and should make every effort to determine a preliminary color in a timely manner. However, if the staff lacks information to make these assumptions, and the assumptions are influential to the preliminary significance result (i.e., will cause the color to vary), then SDP timeliness may be better served by characterizing the preliminary significance as "greater than Green" without identifying a specific color. 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. The "greater than Green" option is not expected to be the norm when characterizing the preliminary significance of findings.

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 an unresolved item with a note identifying that significance determination is 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.

08.03 Obtaining Licensee Perspectives on Initial Characterization of Significance. If the preliminary significance assessmentis White, Yellow, Red, or greater than Green, then the licensee will be given the choice of formally presenting any further information or perspectives, or to accept the staff's decision. This choice will be offered in the cover letter of the inspection report or other appropriate letter and will allow the licensee to request a public Regulatory Conference, or provide a written response, to present facts and their evaluation of significance.

The preliminary significance determination provided in the correspondence to the licensee should be sufficiently clear and complete to allow the licensee to understand the staff's basis such that further information could be provided, if possible, to assist the staff in making a 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.

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

information provided by the licensee during the Regulatory Conference will be made public. If the licensee declines to request a Regulatory Conference, or provide a written response, then the staff will proceed with issuing the final determination of significance.

08.04 Finalization of the Staff's Significance Determination. 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. If the staff, after consideration of the licensee's additional information, determines that a change in the initial characterization of significance is warranted or should be considered, 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, absent such information, 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 this Manual Chapter.

08.05 Suggested SDP Timeliness Goals

The Agency's goal for SDP and enforcement timeliness is that all significance determinations be completed within 90 days from the issue date of the first official inspection report that described the finding and documented the need for further review to determine significance. All attempts should be made to meet this goal, however, it is recognized that certain issues, due to their complexity, may result in exceeding the goal. The NRR Operating Plan metric for SDP timeliness is the Agency's management tool for monitoring goal performance.

The timeliness criteria below represent process milestones for meeting the 90 day goal.

$T_o$ - Inspection report issued.

$T_o$ + 30 - Choice letter issued based on the SERP.

$T_o$ + 40 - Licensee responds to choice letter

$T_o$ + 70 - Regulatory Conference

$T_o$ + 90 - Final letter issued

Further guidance on inspection report documentation is found in IMC 0612

## 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 appeals must meet the requirements stated in Attachment 2 to merit further staff review.

## 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.

## 0609-11 SENIOR REACTOR ANALYST SUPPORT OBJECTIVES

The Senior Reactor Analyst (SRA) position was established to better support NRC objectives related to improving the utilization of risk insights in the reactor inspection program. The advent of major changes in risk-informing the ROP and the use of the SDP as described in this Manual Chapter have placed even greater importance on the role of the regional SRAs and other NRC Headquarters-based risk analysts. The region-based SRAs have the most direct contact with risk-informed inspection planning and with inspectors developing emerging inspection issues, and therefore have a great influence on whether these processes benefit from the exploitation of risk insights and information. The role of the regional SRA and the specific objectives they are intended to achieve in support of the ROP are given in Attachment 3.

END

Attachments:

Attachment 1 - Significance and Enforcement Review Process

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

Attachment 3 - Senior Reactor Analyst Support Objectives

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

Appendix B Emergency Preparedness SDP

Appendix C Occupational Radiation Safety SDP

Appendix D Public Radiation Safety SDP

Appendix E Physical Protection SDP

Appendix F Fire Protection and Post-Fire Safe Shutdown SDP
Attachment 1 User Guidance
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Appendix G Shutdown Safety SDP

Appendix H Containment Integrity SDP

Appendix I Operator Requalification, Human Performance

| Appendix K Maintenance Risk Assessment and Risk Management