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NRC INSPECTION MANUAL

Manual Chapter 0609

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SIGNIFICANCE DETERMINATION PROCESS

0609-01 PURPOSE

The Significance Determination Process (SDP), as described in this Chapter for each cornerstone of reactor safety defined in Chapter 2515, aid NRC inspectors and staff in determining the safety significance of inspection findings, using risk insights where appropriate. The SDP determinations for inspection findings and the PI information are combined for use in assessing the performance of licensees through the NRC Reactor Oversight Process described in Chapter 2515.

0609-02 OBJECTIVES

- 02.01 To characterize the significance of an inspection finding for the NRC licensee performance assessment process, 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 assessment and/or enforcement actions associated with an inspection finding.

0609-03 APPLICABILITY

- 03.01 The SDPs described in this Chapter are applicable to inspection findings identified through the implementation of the NRC inspection program described in Chapter 2515 of this Manual. Before entering the SDPs each issue must screen through MC 0610*, Appendix B, Threshold for Documentation. Licensee-identified issues, when reviewed by NRC inspectors, are also candidates for this process. 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 the public health and safety.

0609-04 DEFINITIONS

The following definitions apply to all SDPs defined in this Chapter.

Observation. A fact; any detail noted during an inspection.

Finding. An issue with some significance that has been placed in context, and determined to be of sufficient significance to warrant more detailed analysis using the SDP or that has extenuating circumstances. To be a finding, it must pass through the threshold screening process described in Manual Chapter MC 0610* Appendix B, "Threshold for Documentation",

Green Finding. A finding of very low safety significance.

White Finding. A finding of low to moderate safety significance.

Yellow Finding. A finding of substantial safety significance.

Red Finding. A finding of high safety significance.

Significance Determination. The characterization of the significance of an inspection finding using the SDP outcome color scheme to identify the level of significance (i.e., Green, White, Yellow, or Red).

Apparent Significant Finding. Inspection findings that have been processed through the SDP and whose preliminary significance determination is greater than "Green", although a final determination of significance may be pending.

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 Inspection Manual Chapter. General and specific responsibilities are listed below.

05.01 Director, Office of Nuclear Reactor Regulation.

- a. Provide overall program direction for the reactor inspection program.
- b. Develop and direct the implementation of policies, programs, and procedures for regional application of the Significance Determination Process in the evaluation of findings and issues associated with the Reactor Oversight Program.

- 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 in order to ensure consistent application of the process.

05.04 Director, Division of Systems Safety and Analysis.

- a. Recommends improvements to all SDPs utilizing 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 Significance Determination Process and Enforcement Review Panel 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-issue.
- b. Provide representatives as necessary to support the Significance Determination Process and Enforcement Review Panel 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 Significance Determination Process and Enforcement Review Panel in order to ensure consistent application of the process.

05.07 Regional Administrator

- a. Provide program direction for management and implementation of the SDP to activities performed by the Regional Office.
- b. Provide representatives as necessary to support the Significance Determination Process and Enforcement Review Panel in order to ensure consistent application of the process.
- c. Within the guidance of the Reactor Oversight Program, 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 performance indicators (PIs) during the plant performance assessment process. The SDP is organized by cornerstone and Figure 1 describes the SDP process flow for inspection findings. The output of each cornerstone SDP process is shown as an input to the assessment and/or the enforcement 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 oversight process. 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 Chapter.

SECY-00-49, dated February 24, 2000, provided the results of the pilot program for risk-informing the reactor oversight process 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 oversight process 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 Memorandums (EMGs). 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 Chapter.
- d. Appropriate training will be provided to the NRC inspection staff.

07.02 SDP Feedback and Improvement

All recommendations for improvements to this Chapter and its Attachments and Appendices should be forwarded to the Chief, Inspection Programs Branch, NRR, with a copy to the Chief, Probabilistic Safety Assessment Branch, NRR. In addition, for recommendations associated with Appendices A, F, G, and H a copy should be forwarded to the Chief, Operator Licensing, Human Performance, and Plant Support Branch, NRR; for recommendations associated with Attachment 1 a copy should be forwarded to the Director, Office of Enforcement. All submittals must include a complete description of the problem, recommended solutions, and point-of-contact information.

0609-08 SDP AND ENFORCEMENT REVIEW PANEL PROCEDURES

The following basic process is described in detail in Attachment One Supplement 4 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 inspection program described in Inspection Manual Chapter 2515. Findings are inspector or licensee identified issues that meet the threshold as defined in IMC 0610*, Appendix B, for assessment using the SDP. Findings are discussed with licensee representatives throughout 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.

08.02 Initial Characterization of Significance

Initial significance determination is 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. All findings with potential assessment other than Green will be reviewed by the SDP and Enforcement Review Panel (SERP). Generally the result of the SERP represents the staff's preliminary safety significance assessment. However, when a potentially greater than Green 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. Findings which are determined by the SERP to be of significance greater than Green are considered apparent significant findings and are given preliminary significance characterization (W/Y/R). If the staff's significance determination of a finding that is potentially other than Green is not complete at the time of issuance of the inspection report, not reviewed by the SERP, then the finding will be characterized in the inspection report 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 safety significance assessment, other 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 with regional inspection staff to present facts and their evaluation of significance. It is expected but not required that the licensee provide on the docket, prior to the regulatory conference, any information they consider applicable to the finding(s). If the licensee declines to request an regulatory conference, 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. 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 strongly considered, the SDP and Enforcement Review Panel (SERP) will schedule a review in accordance with the guidelines in this Chapter. 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. Appropriate enforcement action stemming from the finding will be forwarded at that time, and the licensee will be informed of the SDP appeal process described in this Chapter. The staff should make the final determination of significance not later than 90 days following the NRC exit meeting during which the licensee was officially notified of the apparent significant finding.

Further guidance on inspection report documentation is found in IMC 0610.

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

If a licensee disagrees with the staff's final determination of significance, they may appeal the determination to the appropriate NRC Regional Administrator as described in Attachment 2 to this 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 position was established in 1995 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 NRC Reactor Oversight Process and the use of the SDP as described in this 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 Reactor Oversight Process are given in Attachment 3.

0609-12 ATTACHMENTS AND APPENDICES AND SUPPLEMENTS

Attachment 1 - Significance Determination Process and Enforcement Review Panel

Attachment 2 - Significance Determination Process Licensee Appeal Procedures

Attachment 3 - Senior Reactor Analyst Support Objectives

Appendix A Significance Determination of Reactor Inspection Findings for At-Power Situations

Attachment 1 User Guidance
Attachment 2 Basis Information

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
Attachment 2 Basis Information

Appendix G Shutdown Safety SDP

Appendix H Containment Integrity SDP

Appendix I Operator Requalification, Human Performance

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