TECHNICAL BASIS FOR ENFORCEMENT

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1 INTRODUCTION

As described in NUREG-1600 (Ref. 23), the purpose of the NRC enforcement program is to support the NRC's overall safety mission in protecting the public health and safety and the environment. NRC requirements were developed to ensure adequate protection or no undue risk to public health and safety through design, construction operation, maintenance, modification, and quality assurance measures. Consistent with that purpose, enforcement actions have been used as a deterrent to emphasize the importance of compliance with these requirements and to encourage prompt identification and prompt, comprehensive correction of violations.

Historically, the Enforcement Policy provided vigorous enforcement sanctions when dealing with licensees, contractors, and their employees who did not achieve the high standard of compliance with NRC requirements. The enforcement program: (1) assesses the significance of individual inspection findings and events, (2) formulates the appropriate agency response to these findings and events, (3) emphasizes good performance and compliance, (4) provides incentives for performance improvement, and (5) provides public notification of the NRC's views on licensees' performance and actions. It is noteworthy that while there have been substantial changes to the enforcement program since 1980, the basic theory of enforcement using sanctions, including the use of civil penalties to deter noncompliance, has been used by the Commission for almost thirty years. In sum, escalated enforcement actions have been used to provide regulatory messages in the context of sanctions to encourage licensees to improve their performance.

However, the enforcement program was not designed to be integrated with the performance assessment process. This may have resulted in mixed regulatory messages regarding the NRC's assessment of licensee performance and improvement initiatives. The development of the Reactor Oversight Process (ROP) with a more structured performance assessment process, including a process to evaluate the significance of individual violations with more predictable regulatory responses through its Action Matrix, provided an opportunity to integrate assessment and enforcement. In adopting this approach to enforcement, the staff's goal was to provide a more predictable and scrutable ROP, a greater agency focus on risk and performance, and to address the improved overall performance exhibited as a result of the maturing of the industry. This was identified as an opportunity to implement an approach to enforcement that would better integrate with the overall ROP. The ROP was intended to provide functions similar to the traditional enforcement program. For example both:

- evaluate individual compliance findings for significance.
- result in formulating agency responses to violations and performance issues, the traditional enforcement program through sanctions such as citations and penalties and the ROP through citations and the Action Matrix. Both use meetings to discuss deteriorating performance, 50.54(f) letters, Demands for Information, Confirmatory Action Letters, and Orders.
- provide incentives to improve performance and compliance as they provide measures of deterrence since licensees normally strive to avoid regulatory actions and enforcement sanctions.
- provide the public with the NRC views on the status of licensees' performance and compliance.

Given the similarities in the purposes of the two processes, it was determined that the assessment process should complement the enforcement program by focusing on individual violations. The agency response to declining performance, whether caused by violations or other concerns, is dictated by the Action Matrix. The result was to be a unified approach within the agency for determining and responding to performance issues of a licensee that: (a) maintained a focus on safety and compliance, (b) was more consistent with predictable results, (c) was more effective and efficient, (d) was easily understandable, and (e) decreased unnecessary regulatory burden. It should, therefore, promote public confidence in the regulatory process.

2 ENFORCEMENT AND THE SIGNIFICANCE DETERMINATION PROCESS

The Significance Determination Process (SDP) was developed as the predominant agency method for characterizing the significance of power reactor inspection findings or performance deficiencies on the basis of their risk significance to ensure a consistent approach between the enforcement program and the assessment process. In order to achieve optimum levels of integration between assessment and enforcement, the enforcement program was modified to utilize the final significance determination from the SDP as a means of characterizing the significance of the associated violation.

The significance of a finding under the new assessment process may differ from that under the traditional enforcement program because of program focus shifts and the new methodologies developed for the SDP. The traditional enforcement program focuses on the cause of violations, as well as the consequence resulting from the violations. In some cases, the root cause was perceived to be more significant than the consequence. The SDP for three of the seven safety cornerstones uses risk analysis to calculate the effect of equipment degradation on the ability of the licensee to mitigate an accident and the resulting change in core damage frequency ( ) CDF). Each performance deficiency is evaluated to determine its risk significance and formulate an input to the assessment process. Performance deficiencies in a risk range of greater than 10^{-6}) CDF are evaluated as "significant" and are assigned the color White, Yellow, or Red for assessment purposes. Performance deficiencies evaluated at less than 10^{-6}) CDF are not be considered significant and are assigned the color Green. Within the remaining four cornerstones (occupational radiation safety, public radiation safety, physical protection, and emergency preparedness), performance deficiencies are analyzed to categorize the significance of findings using a set process.

To make the ROP significance determination results consistent with the enforcement policy, the significance categories were determined to relate approximately as follows:

- Green - Severity Level IV
- White - Severity Level III
- Yellow - Severity Level II
- Red - Severity Level I

An assessment process that was based on severity levels with sanctions similar to the traditional enforcement program could have been used. Although this option would preserve a more traditional approach to enforcement, there were a number of questions as to whether it was a viable approach. The SDP often requires a case specific risk analysis that relies on a unique set of inputs and assumptions. The lack of standards for the development of inputs, assumptions, and methodologies for these types of risk assessments, and the lack

of fidelity in Probabilistic Risk Assessments (PRAs), made decisions to cite a deficiency at a particular severity level difficult to defend when confronted with a licensee's differing inputs, assumptions, and risk assessment methodology. Further, mixed messages could occur as enforcement action resulting from the traditional enforcement approach could be inconsistent with the actions called for in the Action Matrix, which has the ability to assign actions based on the significance of multiple inspection findings in both related and unrelated areas.

3 THE ENFORCEMENT APPROACH

The assessment process provides many of the functions and objectives inherent in the traditional enforcement program. In light of the maturing of the industry and overall improved performance of licensees, a new enforcement approach was developed to complement the assessment process. In developing this new approach, the staff identified the following objectives:

- Enforcement needs to be consistent with the safety philosophy of the assessment process.
- Enforcement needs to maintain an emphasis on compliance.
- Enforcement needs to be simplified and predictable to create an efficient and effective process.
- Enforcement needs to support public confidence in the NRC regulatory process.
- Enforcement should neither create nor perpetuate unnecessary regulatory burdens.

The current enforcement program divides violations into two groups, violation whose significance can be evaluated under the SDP and those violations outside the capability of the SDP. The second group would consist of willful violations, violations that may impact the NRC's ability for oversight of the regulatory process, and violations which result in actual safety consequences, such as overexposure, loss of radioactive material, core damage, or loss of significant safety barriers.

3.1 Violations Assessed using the SDP

Initially, violations are evaluated to determine the appropriate significance, which will determine whether formal or informal enforcement action should be taken. Normally, this evaluation would result in a preliminary severity level. For performance deficiencies evaluated using the SDP, however, a color would be identified rather than a severity level. Performance deficiencies determined not to be significant from a risk perspective (assigned the color Green) are inputs into the assessment process in the licensee response band in the Action Matrix. Such violations are considered for informal enforcement and treated as Non-Cited Violations (NCVs) consistent with the criteria in the Enforcement Policy for reactor Severity Level IV violations. For reactor cases, a Notice of Violation (NOV) would normally not be issued for a Severity Level IV violation or Green finding unless: (1) the licensee fails to restore compliance within a reasonable time after the violation was identified, (2) the licensee fails to place the violation into the corrective action program to address recurrence, (3) the violation was willful, or (4) the violation was repetitive as a result of inadequate corrective action and unidentified by the NRC. Note: This exception does not apply to violations associated with Green SDP findings. The last criterion applies to traditional enforcement only. In other words, under the ROP, if a finding associated with a violation is determined to be of very low safety significance, the violation will be treated as an NCV, regardless of the number of times the violation is repeated.

Performance deficiencies that are evaluated using the SDP as risk significant are assigned a preliminary color related to their significance (White, Yellow, or Red) and are considered for escalated enforcement action. As a result of being risk-significant, a formal NOV will normally be issued requiring a formal written response unless sufficient information is already on the docket. Although this approach may have some of the same concerns as noted above by using non-standardized assumptions and methodologies for assessing risk, it is expected to be easier to determine whether a violation is risk-significant (i.e., at least White) than to determine and defend a severity level based on the specific color assigned (i.e., White, Yellow, or Red). The enforcement approach is based on the significance of the violation independent of the overall Action Matrix response band that the licensee is in at the time.

The Action Matrix is used to formulate the agency response and to emphasize the need to improve performance for safety-significant performance deficiencies. Regulatory performance meetings and other actions as determined by the Action Matrix are held, if called for in the Action Matrix based on the specific performance deficiency or the overall performance of the licensee. Use of the Action Matrix with its escalating responses, (e.g., increased inspection, regulatory attention, and regulatory actions) should provide appropriate incentives and should deter licensee's from being in the increased regulatory response band. This approach is expected to result in enforcement complementing assessment, maintaining consistency, and promoting a predictable and unified regulatory message. If consistently applied, it should build public confidence.

3.2 Violations Subject to Traditional Enforcement Actions

The traditional enforcement program is used with the second group of violations, those involving: (1) willfulness, including discrimination, (2) actions that may impact the NRC's ability for oversight of licensee activities[1], and (3) situations which result in actual safety consequences, such as overexposure, loss of radioactive material, core damage, or loss of significant safety barriers. A more traditional enforcement approach is warranted for deterrence. This approach would retain the four severity levels and civil penalties under the current Enforcement Policy.

3.3 The Role of Enforcement Discretion Under the ROP

The Enforcement Policy has been modified to clarify that the mitigation discretion addressed in Sections VII.B.2 - VII.B.6 (e.g., violations identified during shutdowns, involving past enforcement actions, old design issues, certain discrimination issues, or special circumstances) does not normally apply to violations associated with issues evaluated by the SDP. The ROP will use the Action Matrix to determine the agency response to performance issues. The Action Matrix has provisions to consider extenuating circumstances that were previously addressed through enforcement mitigation. However, the Commission has reserved the right to use enforcement discretion for particularly significant violations (e.g. an accidental criticality) to assess civil penalties in accordance with Section 234 of the Atomic Energy Act of 1954.

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[1] Violations that involve actions that may impact the regulatory oversight process include those associated with reporting issues, failure to obtain NRC approvals such as for changes to the facility as required by 10 CFR 50.59, 10 CFR 50.54(a), 10 CFR 50.54 (p), 10 CFR 50.54 (q), and failure to provide the NRC with complete and accurate information or to maintain accurate records.

3.4 Accuracy and Completeness of Performance Indicator Data

The staff proposed a unique approach for addressing the accuracy and completeness of performance indicator (PI) data. In order to fulfill its regulatory obligations, the NRC is dependent upon its licensees for complete and accurate information. The Commission uses the requirements of 10 CFR 50.9 as the primary means of enforcing its expectations for complete and accurate information from reactor licensees. The staff's proposed approach maintains this focus. Unlike previous practice with respect to 10 CFR 50.9 violations, the proposed approach does this through both the Action Matrix and enforcement sanctions. The proposed severity level categorizations of 10 CFR 50.9 violations for inaccurate or incomplete PI data recognizes that an enforcement sanction is one part of the overall regulatory response to the change in PI data. The Action Matrix will cause the staff to consider specific regulatory responses based upon the corrected PI data. An enforcement sanction is appropriate because the inaccurate PI data prevented or delayed the appropriate NRC actions which would have taken place had accurate information been provided. The staff recognized that the use of thresholds in the ROP result in a situation where errors of the same magnitude may not receive identical enforcement treatment. However, under the ROP, the magnitude of the error in and of itself is not critical, but rather it is the impact on the regulatory process that is important. Inaccurate or incomplete PI data that prevented the proper entry into the Yellow or Red performance band (i.e., required regulatory response, unacceptable performance, respectively) is more significant than an error that prevented entry into the White band (increased regulatory response). Thus, there is an appropriate distinction between Severity Level III and IV. The staff believes that a Severity Level III enforcement action is a significant action and in combination with the Action Matrix provisions places a strong emphasis on accuracy and completeness of information. The ROP actions might include increased PI verification inspections, Demands for Information, or Orders. Enforcement sanctions greater than Severity Level III are not necessary for non-willful violations because once the PI data error is corrected, the agency will initiate actions in accordance with the Action Matrix. If a licensee is not capable of reporting accurate and complete data, the NRC will consider other ROP actions. In addition, there is no need to distinguish between the errors that prevented the proper entry into either the Yellow or Red performance bands in terms of enforcement severity levels because the agency response (Action Matrix and enforcement action) will now address the differences in significance through an approach that integrates various escalating regulatory tools of which enforcement is but one. The ROP and the Enforcement Policy provide a strong incentive for licensees to submit complete and accurate PI data.

4 SUMMARY OF CHANGES

The following are some of the more significant changes made to the Enforcement Policy in response to implementation of the ROP. The last complete revision that was issued as a NUREG series publication (NUREG-1600) was dated May 1, 2000. Changes to this policy are published in the Federal Register. (Ref. 24).

4.1 Section III, Responsibilities

The term "escalated enforcement action" has been expanded to include an NOV associated with an inspection finding that the SDP evaluates as low to moderate (White), or greater safety significance. These actions warrant consideration as escalated actions given the risk significance associated with the violations.

4.2 Section IV, Assessing Significance

This section has been modified to address violations associated with inspection findings evaluated through the SDP. The NRC will continue to assess significance by considering: (1) actual safety consequences; (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the NRC's ability to perform its regulatory function; and (4) any willful aspects of the violation. Paragraph (5) has been added to recognize that with implementation of the ROP, the NRC will rely on inputs from the SDP to address violations associated with inspection findings evaluated through the SDP. Consistent with the guidance previously included in the Interim Policy, violations associated with findings that the SDP evaluates as having very low safety significance (i.e., Green) will normally be described in inspection reports as NCVs. The finding will be categorized by the assessment process within the licensee response band. However, a NOV will be issued if the issue meets one of the three applicable exceptions in Section VI.A.1. Violations associated with findings that the SDP evaluates as having low to moderate safety significance (i.e., White), substantial safety significance (Yellow), or high safety significance (Red) will normally be cited in an NOV requiring a written response unless sufficient information is already on the docket. The finding will be assigned a color related to its significance for use by the assessment process. Violations associated with issues that do not lend themselves to a risk analysis (i.e., potential for impacting the NRC's function and willfulness), will be evaluated in accordance with the guidance in paragraphs (1) through (4) of this section. The guidance also notes that the Commission reserves the use of discretion for particularly significant violations (e.g. an accidental criticality) to assess civil penalties in accordance with Section 234 of the Atomic Energy Act of 1954, as amended.

4.3 Section V, Predecisional Enforcement Conferences

This section has been modified to address the relationship between Regulatory Conferences and the enforcement program. The ROP uses Regulatory Conferences as opportunities for the NRC and licensees to discuss the significance of findings evaluated through the SDP whether or not violations are involved. The Enforcement Policy has been revised to state that Regulatory Conferences may be conducted in lieu of predecisional enforcement conferences if violations are associated with potentially significant findings under the ROP. While the primary function of a Regulatory Conference is on the significance of findings, the significance assessment from the SDP provides an input into the enforcement program in terms of whether escalated enforcement action (i.e., an NOV associated with a White, Yellow, or Red finding) should be issued. Given this process, a subsequent predecisional enforcement conference is not normally necessary.

4.4 Section VI, Disposition of Violations

This section has been renamed and modified by consolidating all of the guidance on the normal approach for dispositioning violations. Depending on the significance and circumstances, violations may be considered minor and not subject to enforcement action, dispositioned as NCVs, cited in NOVs, or issued in conjunction with civil penalties or orders. The NCV guidance has been moved out of Section VII.B.1 of the Policy that discusses special types of mitigation discretion and into this section because issuance of an NCV is a routine method for dispositioning Severity Level IV violations and violations associated with Green SDP findings. For consistency, the guidance in Section VI.A.8 for dispositioning Severity Level IV violations for all licensees other than power reactor licensees has been

reworded to express the guidance in terms of conditions when an NOV should be issued rather than criteria for dispositioning a violation as an NCV.

4.5 Section VI.B, Notice of Violation

This section has been modified to state that the NRC may require that a response to an NOV be under oath if the violation is associated with a low to moderate, or greater safety significant finding as evaluated by the SDP. This is consistent with the agency's existing practice of requiring that an NOV response be under oath for Severity Level I, II, or III violations.

4.6 Section VI.C, Civil Penalty

This section has been modified to state that civil penalties are also considered for violations associated with inspection findings evaluated through the ROP's SDP that involved actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, failure to make the required notifications that impact the ability of Federal, State and local agencies to respond to an actual emergency preparedness event (site area or general emergency), transportation event, or a substantial release of radioactive material. This is consistent with the Interim Policy, in that civil penalties will not be proposed for violations associated with low to moderate, or greater safety significant findings absent actual consequences.

4.7 Section VII.A, Escalation of Enforcement Sanctions

Consistent with the Interim Policy, this section has been modified to recognize that the NRC may also exercise discretion and assess civil penalties for violations associated with significant findings evaluated by the ROP's SDP that the NRC believes warrant penalties. Exercise of this discretion is expected to be rare.

4.8 Section VII.B, Mitigation of Enforcement Sanctions

This section has been modified by adding footnote 10 to clarify that the mitigation discretion addressed in Sections VII.B.2 - VII.B.6 does not normally apply to violations associated with issues evaluated by the SDP. The revised ROP will use the Action Matrix to determine the agency response to performance issues. The Action Matrix has provisions to consider extenuating circumstances that were previously addressed through enforcement mitigation.

4.9 Supplement I--Reactor Operations

Examples C.9, C.10, D.5, and E involving changes, tests, and experiments (i.e., 10 CFR 50.59) have been modified. The previous examples were developed in conjunction with the final rule for 10 CFR 50.59 and were based on the "change acceptability" criterion, i.e., whether the changes would be found acceptable by the Commission. Before publication of the final rule, the NRC determined that the change acceptability criterion was not conducive to efficient or effective enforcement or regulation. The inefficiency stemmed from the fact that, in many instances, the acceptability of a change could not be determined without having the type of information that would be provided with the formal submission of a license amendment. Taking enforcement action after the often lengthy evaluation of a license amendment was not considered effective. The examples have been modified by basing the significance of the 10 CFR 50.59 or related violation on the resulting physical, procedural, or analytical change to the facility as evaluated through the SDP. This will

ensure a consistent approach for significance determinations. Violations will be categorized at Severity Level III if the resulting change were evaluated by the SDP as having low to moderate, or greater safety significance (i.e., White, Yellow, or Red finding). Violations will be categorized at Severity Level IV if the resulting change were evaluated by the SDP as having very low safety significance (i.e., Green finding). Violations will be considered minor if there was not a reasonable likelihood that the change requiring 10 CFR 50.59 evaluation would ever require Commission review and approval prior to implementation. Violations of 10 CFR 50.71(e) will be considered minor if the failure to update the Final Safety Analysis Report would not have a material impact on safety or licensed activities.

4.10 Supplement VII--Miscellaneous Matters

New examples (C.3, D.3, and E) have been added to address inaccurate or incomplete PI data from the ROP. Inaccurate or incomplete PI data that would have caused a PI to change from Green to White are categorized at Severity Level IV. Inaccurate or incomplete PI data that would have caused a PI to change from Green to either Yellow or Red; White to either Yellow or Red; or Yellow to Red are categorized at Severity Level III. Inaccurate PI data that would not have caused a PI to change color are considered minor. Consistent with existing policy, enforcement action is not taken for minor violations.