

CHAPTER 7

REACTOR OPERATIONS

Chapter 7 provides specific guidance regarding various reactor operations issues, including:

- ▶ enforcement activities involving reactor operations and facility construction
- ▶ safeguards
- ▶ emergency preparedness
- ▶ enforcement actions involving fitness-for-duty (ffd)

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7.1 Actions Involving Inoperable Equipment

a. Whether to take enforcement action for equipment inoperability:

1. Equipment operability is an important factor in establishing the safety significance of a violation.
 - (a) Judgement should be exercised in expending resources to determine operability.

- (b) Analyses may be required to frame the safety significance of the deficiency and discover all relevant aspects of the discrepant condition.

2. For cases where it is obvious that the system, subsystem, train, or component is inoperable, e.g., where the valves are closed or circuit breakers are open such that no flow or power is available and the complete function is lost:

- (a) It is appropriate to cite directly against the Technical Specification (TS) requirement for operability.
- (b) In accordance with example B.1 of Supplement I of the Enforcement Policy:

☞ The significance of findings associated with operating power reactors is normally determined by the Significance Determination Process (SDP) of the Reactor Oversight Process (ROP). To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the guidance in this section of this manual.

- (1) Consideration should be given to issuing a Severity Level II violation when a system designed to prevent or mitigate a serious safety event could not perform its intended function.

- (2) Consideration should be given to issuing a Severity Level III violation, when a redundant safety train or subsystem (or for BWRs, a diverse system), is available.

☞ From an enforcement perspective, the NRC has the burden of proof to demonstrate inoperability in an enforcement hearing.

3. For cases where it is not obvious that a degraded system is inoperable, extensive resources may be needed to determine operability:

- (a) In some cases, the message inherent in a Severity Level II enforcement action may be worth the resources to develop and prove an operability issue.
- (b) The escalated enforcement package should not be delayed beyond established timeliness goals pending the results of operability evaluations without prior consultation with OE.

✓ If the region believes that there is a significant operability issue, but does not believe that they can justify an operability citation, OE should be consulted:

(1) Before escalated action is ruled out; and,

(2) If, in order to make an operability judgment, excessive resources must be expended.

4. If the region believes that there is a significant operability issue, but does not believe that they can justify an operability citation without expending significant resources, a more appropriate and timely enforcement action (and more effective in achieving lasting corrective action) may be available by citing against the root cause of the violation (e.g., inadequate corrective action, procedures, reviews, design, or tests) rather than against the operability requirement for the system.

b. **How to cite for equipment inoperability:**

1. Technical Specifications include a section specifying **Limiting Conditions for Operation** (LCOs). LCOs are the lowest functional capability or performance levels of equipment required for safe operation of the facility. Each individual LCO includes both an applicability and action statement.
 - (a) The **applicability statement** specifies when the LCO is applicable (e.g., Modes 1, 2, and 3).
 - (1) Many action statements first identify the time necessary to restore the piece of inoperable equipment (commonly referred to as the allowed outage time (AOT)), and then identify the time necessary to take other action, such as compensatory measures or shutdown, in the event that compliance with the LCO is not restored.
 - (A) A violation does not necessarily exist based solely on the failure to restore equipment to operable status within the AOT.
 - (B) A violation would exist when an LCO is not met and all necessary actions have not been completed within all applicable completion times.
 - (2) An action statement remains in effect until the condition no longer exists or the unit is not in a MODE within the LCO APPLICABILITY. While the term "AOT" is not used in improved Standard Technical Specifications (STS), the term and concept of "AOT" is being used for the purposes of this guidance.
 - (3) For improved STS (i.e., [NUREG-1430](#) through NUREG-1434), action statements are written in a matrix format and are separated into three discreet parts, i.e., Conditions, Required Action(s), and Completion Time(s).
 - (b) The **action statement** prescribes remedial measures required under designated conditions in a narrative paragraph format.
 - (1) Many action statements first identify the time necessary to restore the piece of inoperable equipment (commonly referred to as the allowed outage time (AOT)), and then identify the time necessary to take other action, such as compensatory measures or shutdown, in the event that compliance with the LCO is not restored.
 - (A) A violation does not necessarily exist based solely on the failure to restore equipment to operable status within the AOT.
 - (B) A violation would exist when an LCO is not met and all necessary actions have not been completed within all applicable completion times.
 - (2) An action statement remains in effect until the condition no longer exists or the unit is not in a MODE within the LCO APPLICABILITY. While the term "AOT" is not used in improved Standard Technical Specifications (STS), the term and concept of "AOT" is being used for the purposes of this guidance.
 - (3) For improved STS (i.e., [NUREG-1430](#) through NUREG-1434), action statements are written in a matrix format and are separated into three discreet parts, i.e., Conditions, Required Action(s), and Completion Time(s).
2. **AOT Examples:** The following examples illustrate the use of completion times with different types of conditions and changing conditions.

Example 1:

When a pump is declared inoperable, Condition A is entered. If the pump is not restored to operable status within seven days (the AOT), a violation does not exist. Instead, Condition B is entered and the Completion Time clocks for Required Actions B.1 and B.2 start. A total of 12 hours is allowed for reaching Mode 3 and a total of 36 (not 48 hours) is allowed for reaching Mode 4 from the time that Condition B was entered. If Mode 3 is reached within six hours, the time allowed for reaching Mode 4 is the next 30 hours because the total time allowed for reaching Mode 4 is 36 hours. A violation exists if the pump cannot be restored to operable status after seven days and the unit is not placed in Mode 3 within the next 12 hours or a violation exists if the pump cannot be restored to operable status after seven days and the unit is not placed in Mode 4 within the next 36 hours.

Example 2:

A pump in a two train system is declared inoperable and Condition A is entered. Before Condition A expires, a second pump is declared inoperable. In this case, Condition A is not re-entered for the second pump. Instead, LCO 3.0.3 is entered, since the actions do not include a Condition for more than one inoperable pump. The Completion Time clock for Condition A does not stop after LCO 3.0.3 is entered, but continues to be tracked from the time Condition A was initially entered. While in LCO 3.0.3, if either one of the inoperable pumps is restored to OPERABLE status and the Completion Time for Condition A has not expired, LCO 3.0.3 may be exited and operation continued in accordance with Condition A with the original completion time applicable.

3. Potential enforcement should be considered based on the total duration that a condition may have existed. i.e., when the time of occurrence and the extent to which the licensee should have identified the condition earlier, is readily determined.

(a) In order to address the issue of potential enforcement for a pre-existing condition, it is necessary to clearly distinguish between:

- (1) Compliance with the TS ACTION statements; and
- (2) Compliance with the TS LCOs.

 This guidance emphasizes the importance of licensees taking appropriate actions upon discovery of inoperable equipment, rather than focusing resources to attempt to determine when the condition occurred, e.g., choosing to shutdown the plant in a less than orderly fashion solely to comply with the TS.

- (b) The distinction between the TS ACTION statement and the TS LCOs is evident in the general TS usage rules in the improved STS, i.e.:
- LCO 3.0.1 - LCOs shall be met during the modes or other specified conditions in the applicability, except as provided in LCO 3.0.2.
 - LCO 3.0.2 - Upon discovery of a failure to meet an LCO, the Required Actions of the associated conditions shall be met, except as provided in LCO 3.0.5 and LCO 3.0.6. If the LCO is met or is no longer applicable prior to expiration of the specified completion time(s), completion of the Required Action(s) is not required unless otherwise stated.
- (c) The determination of whether an action statement (LCO 3.0.2) is met is based on when the condition is discovered.
- (1) Once discovered, the question is whether the actions to be completed are completed on time.
 - (2) While a licensee may be in compliance with the action statement of a TS based upon the discovery of the violation, a licensee may not be in compliance with the TS LCO (3.0.1) based on when the violation occurred.
- (d) The following guidelines should be used for cases where the time of occurrence can be established and the licensee should have discovered the condition sooner:
- (1) If the time between the occurrence of the condition and the discovery of the condition is greater than the AOT for that condition, then the licensee should be cited for a failure to satisfy the TS LCO. If the licensee otherwise satisfied the TS Required Action(s) from the time of discovery of the condition, the citation and enforcement correspondence should acknowledge this.
 - (2) If the time between the occurrence of the condition and the discovery of the condition is less than the AOT for that condition, and upon discovery the Required Actions are completed within the AOT or the shutdown track is satisfied, there is not an LCO violation. This would be true even if the time between the occurrence of the condition and the completion of Required Actions is greater than the AOT. However, there may be a root cause issue outside of the TS issue warranting appropriate enforcement action.
 - (3) If the time between the occurrence of the condition and the completion of Required Actions is less than the AOT, then there is no violation.
- (e) In determining whether to cite a violation against the LCO, consideration should also be given to other violations, such as root causes that may focus the corrective action. If there is a clear root cause violation, the LCO violation and the root cause violation should normally be combined into one escalated issue or problem.

- (f) Depending on the regulatory and technical significance (i.e., actual and potential consequences, including risk considerations), there may also be cases where the significance dictates more than one escalated action, one for the LCO violation and one (or more) for the root causes, e.g.:
- (1) Depending on the total time the equipment was inoperable and other factors determined by the root cause evaluation, enforcement discretion may be warranted to increase the amount of the civil penalty based on a substantial increase in risk due to the excessive duration of the inoperability and/or increase the severity level above Severity Level III.
- (2) LCO Examples: The following examples illustrate these guidelines. (Use TABLE 1 for TS examples.)

TABLE 1

CONDITION	REQUIRED ACTION	COMPLETION TIME
A. One pump inoperable.	A.1 Restore pump to OPERABLE status.	7 days
B. Required Action and associated Completion Time not met.	B.1 Be in MODE 3.	12 hours
	<u>AND</u> B.2 Be in MODE 4.	36 hours

Example 1:

Upon discovery of an inoperable pump, Condition A is entered. The licensee is able to restore the pump in seven days and three hours. Therefore, the licensee was able to comply with the TS action statement. During the root cause analysis, the licensee was able to determine that the violation occurred seven days and nine hours prior to discovery because of not following a procedure required by 10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings." It is further determined that the licensee should have identified this condition at that time. In this case, the time between the occurrence of the violation and the time of discovery of the violation was seven days and nine hours... a time greater than the AOT of seven days. Therefore, a violation of the TS LCO would be warranted. Citations against 10 CFR Part 50, Appendix B, Criterion V and Criterion XVI, "Corrective Action" should also be considered.

Example 2:

Upon discovery of an inoperable pump, Condition A is entered. The licensee is able to restore the pump in seven days and three hours. Therefore, the licensee was

- able to comply with the TS ACTION statement. During the root cause analysis, the licensee was able to determine that the violation occurred six days prior to discovery because a procedure was not properly followed. It is further determined that the licensee should have identified this condition. In this case, the time between the occurrence of the violation and the time of discovery of the violation was six days...a time less than the AOT of seven days. Therefore, a violation of the TS LCO for the pre-existing condition would not be warranted. However, enforcement action for the root cause (i.e., Criterion V) and the failure to identify (i.e., Criterion XVI) should be considered.
- (g) When an inoperable condition is discovered, the TSs should be reviewed to determine if a violation of the TS action statement has occurred based on the time of discovery.
- (1) The next step would be to determine if the time of occurrence can be established and to determine if the licensee should have discovered the condition sooner.
 - (2) The time between discovery and occurrence should be compared to the AOT to determine if a violation of the TS LCO has occurred.
7. Proper citations against equipment operability should include a paragraph describing the requirement and a paragraph describing how the requirement was not met.
- (a) The requirement paragraph should identify and establish:
- (1) What the applicable TS is;
 - (2) When the LCO is applicable;
 - (3) What the LCO requires; and
 - (4) What the action statement requires.
- (b) The citation should establish how the requirement was not met. The "contrary to" paragraph should establish:
- (5) When the equipment was inoperable;
 - (6) That the LCO was applicable;
 - (7) How the specified equipment was rendered inoperable, and
 - (8) That action was not taken within the specified time to restore operability.

(c) Refer to the following example:

Technical Specification (TS) 3.6.6.1 requires (1)
 that while the plant is in Modes 1, 2, 3, or 4, (2)
two independent Supplemental Leak Collection Release Systems shall be
operable. The TS ACTION statement requires that, "with one Supplemental Leak (3)
Collection and Release System inoperable,
restore the inoperable system to operable status within seven days or be in at least(4)
hot standby within the next six hours and in cold shutdown within the following 36
hours."

Contrary to the above, between June 9, 2006 and (5)
June 27, 2006, while the plant was in Mode 1, (6)
the "A" train of the SLCRS was inoperable, in that the fire damper in the train was (7)
closed, thereby stopping the flow of air in the system,
and action was not taken to either restore the system to operable status within
seven days or place the unit in cold shutdown within the following 36 hours. (8)

8. When a **situation exists that exceeds the designated conditions of a specific TS ACTION statement**, then it may be necessary to include the generic LCO, traditionally TS 3.0.3, as part of the citation. The following example illustrates this point, i.e., the TS ACTION statement prescribes remedial measures to be taken when one of the subsystems is inoperable, but does not address when both subsystems are inoperable:

Technical Specification (TS) 3.5.2 requires, in part, that in MODES 1,2, and 3, two independent Emergency Core Cooling System (ECCS) subsystems shall be operable with each subsystem comprised of, in part, an operable flow path capable of taking suction from the refueling water storage tank on a Safety Injection signal and automatically transferring suction to the containment sump during the recirculation phase of operation.

TS 3.0.3 requires, in part, that when a Limiting Condition for Operation is not met, except as provided in the associated ACTION requirements, within one hour action shall be initiated to place the unit in a MODE in which the specification does not apply by placing it, as applicable, in at least HOT STANDBY within the next six hours, at least in HOT SHUTDOWN within the following six hours, and at least COLD SHUTDOWN within the subsequent 24 hours.

Contrary to the above, between July 15, 2006 and August 13, 2006, while in MODE 1, both independent ECCS subsystems were inoperable in that both flow paths were incapable of supplying water from the refueling storage tank to the reactor core on a Safety Injection signal because normally open valves in each flow path were closed.

With both flow paths inoperable, the licensee failed to take action within one hour to place the unit in a MODE in which TS 3.5.2 does not apply.

9. There may be cases when it is **not clear exactly when a piece of equipment became inoperable**. In such cases, the burden is on the agency to establish realistic time-frames for when it is most likely that the piece of equipment was rendered inoperable.

☞ In cases where it is not clear exactly when a piece of equipment became inoperable, the burden is on the agency to establish realistic time-frames for when the piece of equipment likely became inoperable.

- (a) In establishing realistic time-frames, consideration should be given to issues such as:

- (1) When the equipment was last tested as operable;
- (2) Whether other activities were conducted that could have impacted equipment operability;
- (3) Whether prior indication of inoperability existed; and
- (4) When the inoperable piece of equipment was discovered.

- (b) As long as time-frames can be established to substantiate a TS violation, the cited time-frames should be as conservative as possible. The following example illustrates this scenario.

TS 3.5.2 requires that two independent emergency core cooling system (ECCS) subsystems be operable in Modes 1, 2, and 3 with each subsystem comprised, in part, of one operable safety injection (SI) pump.

TS 3.0.3 requires that when a Limiting Condition for Operation is not met, that action be initiated within one hour to place the unit in at least HOT STANDBY within six hours, at least HOT SHUTDOWN within the following six hours, and at least COLD SHUTDOWN within the subsequent 24 hours.

Contrary to the above, on December 23, 2005 between at least 12:07 a.m. and 12:30 p.m., the reactor was operated in Mode 1 with both SI pumps inoperable, in that they could not have performed their intended function for a limited range of loss of coolant accidents, due to a freeze protection system failure that caused ice to block the common recirculation line between the SI pumps and the refueling water storage tank. With both SI pumps inoperable during this period, the licensee failed to place the unit in at least hot standby within six hours.

- (1) In this example, 12:07 a.m. represents the time at which there was an indication that the equipment was inoperable. Specifically, at this time, the licensee attempted to add water to the Refueling Water Storage Tank (RWST)

unsuccessfully via the recirculation line. Therefore, from at least this time, one can conclude that the recirculation line was frozen, rendering the SI pumps inoperable. 12:30 p.m. represents the time at which the licensee declared both SI pumps inoperable.

- (2) Although it is highly likely that the recirculation line was frozen before 12:07 a.m., proving that this was the case is not necessary to support the TS violation.

7.2 Actions Involving Degraded Equipment

- a. Additional guidance on inoperable and degraded equipment is included in [Generic Letter 91-18, "Degraded Conditions and Operability."](#)
- b. It may be better to focus the enforcement action on the root cause of the problem rather than on the issue of operability for those cases where:
1. Inoperability is difficult to establish, such as cases that involve significant differences in system performance capabilities as compared to Final Safety Analysis Report (FSAR) assumptions (e.g., where margins explicitly stated or implied in the FSAR are under dispute, or the original design basis is no longer available); or
 2. Complicated or complex analyses are required to determine the safety significance.
- c. In cases involving degraded (but not clearly inoperable) equipment:
1. The enforcement action should not cite the TS for the piece of equipment (since being degraded is not of itself a violation).
 2. The enforcement action should cite the requirement that addresses the root cause of the problem that ultimately caused the piece of equipment to be significantly degraded, e.g.:
 - The licensee's failure to take corrective action (i.e., 10 CFR Part 50 Appendix B, Criterion XVI)
 - The failure to follow procedures (administrative TS requirement Appendix B, Criterion V)
 - The failure to control design (Appendix B, Criterion III)
 - The failure to control tests (Appendix B, Criterion XI)
 - The failure to perform a safety analysis (10 CFR 50.59)

☛ In many cases, resources would be better spent in focusing on identifying and correcting root cause issues that, corrected, will prevent future failures, than in determining whether or not a piece of equipment or a system was, in hindsight, operable.

- d. The cover letter for enforcement actions involving degraded equipment should focus on the licensee's root cause failure as the basis for the action, emphasizing that it represents a regulatory concern (rather than focusing on whether the equipment was or was not inoperable).

7.3 Enforcement of 10 CFR 50.59 and Related FSAR

- a. One of the requirements of 10 CFR 50.34 is that each application for a license to operate a facility shall include a FSAR.

- b. A licensee who fails to meet an FSAR commitment that describes how it intends to meet a regulatory requirement may have, depending on the circumstances, violated that requirement.

☞ The **FSAR** contains design bases, operational limits and analyses of facility structures, systems and components. In essence, it is a statement by the applicant of how it intends to comply with many of the NRC's requirements.

1. Enforcement action may be taken directly against the underlying requirement (e.g., the TS or the regulation).

2. A departure from an FSAR commitment that directly involves a specific legally binding NRC requirement can cite that specific requirement.

- c. If the departure from the FSAR does not directly involve a specific requirement, the failure to implement the FSAR commitment involving safety-related matters may constitute a violation of the licensee's quality assurance requirements.

☞ When the departure from the FSAR does not directly involve a specific requirement, the NOV may cite the particular criterion of 10 CFR Part 50, Appendix B (e.g., Criterion III, Design Control) as the basis for the violation.

- d. The failure to update the FSAR that does not have a material impact on safety or licensed activities is considered a minor violation of 10 CFR 50.71(e).

- e. Changes to the facility or procedures as described in the safety analysis report, or performance of tests or experiments not described in the FSAR may also be a violation of 10 CFR 50.59. This regulation was changed on October 4, 1999 (64 FR 53582), as amended on December 21, 2001 (66FR 64738).

1. Under either the revised or current 10 CFR 50.59, the Commission can take enforcement action concerning departures from FSAR provisions if a licensee:

- (a) Incorrectly concludes that a change from the FSAR does not involve a change in the technical specifications incorporated in the license or does not require prior NRC review and approval prior to implementation;
- (b) Fails to conduct a safety evaluation for a change; or
- (c) Fails to report the change to the NRC or to keep a record of the change as required by the regulations.
2. Citations against 10 CFR 50.59 are appropriate when the licensee makes changes not allowed by 10 CFR 50.59 and/or when a 10 CFR 50.59 evaluation is not performed when required.
3. Citations against 10 CFR 50.59 are not generally appropriate when the facility never matched its description in the FSAR.
- (a) This type of citation, known as a “defacto 50.59 violation” had been used in the past to avoid statute of limitation concerns.
- (b) Latent design defects should be treated as degraded, nonconforming conditions consistent with Generic Letter 91-18, Revision 1.
- (1) Sections 4.7 and 4.8 of the Attachment to Generic Letter (GL) 91-18 correctly describe how 10 CFR 50.59 is to be applied to degraded, nonconforming conditions.
- (2) Latent nonconformances with FSAR specifications should be dispositioned as Appendix B violations (normally Criterion III or Criterion V), when applicable.
4. A citation against 10 CFR 50.59 should:
- (a) Set out the specific FSAR language at issue and describe how it was not met;
- (b) Establish that an evaluation was not performed; and/or
- (c) Establish that the change constituted an unreviewed safety question (old rule) or otherwise required prior NRC review and approval prior to implementation (new rule) or a change to a TS.

Note that the fundamental difference in the revised rule is the criteria under which prior NRC review and approval is required. The old rule uses the concept of an unreviewed safety question exists when changes make any increase in probabilities of accidents or malfunctions, or consequences, or any decreases in margin of safety. The revised rule deletes the concept of the unreviewed safety question and allows for minimal increases or decreases in related parameters.

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5. There may be issues concerning compliance with 10 CFR 50.59 that will be complicated by whether the new rule or old rule is applicable. The following guidance is provided:
 - (a) For situations that violate the “old” requirements, but that would not be violations had the evaluation been performed under the revised rule:
 - (1) The NRC will exercise discretion pursuant to VII.B. 6 of the Enforcement Policy and not issue citations or document non-cited violations against the “old” rule.
 - (2) The staff will document in inspection reports that the issue was identified, but that no enforcement action is being taken because the revised rule requirements are met. Approval by the Director, OE, is required for use of Section VII.B.6 discretion.
 - (b) For situations identified prior to the effective date of the revised rule that involve a violation of the existing rule requirements but that would not be violations under the revised rule:
 - (1) By definition, if it is not a violation under the revised rule, then the significance of the violation is low; and
 - (2) Corrective actions are required to be taken in a time frame commensurate with the significance of the violation.
 6. Because violations of 10 CFR 50.59 are violations that potentially impede or impact the regulatory process, they are:
 - (a) Not processed through the ROP’s SDP; and
 - (b) Are processed through the examples of Supplement I of the Enforcement Policy.
 - (1) Although the SDP is not designed to assess significance of violations that potentially impact or impede the regulatory process, the staff has determined that the significance of a 10 CFR 50.59 violation can be assessed through the SDP.
 - (2) To ensure a consistent approach for significance determinations, The Supplement I 10 CFR 50.59 violation severity level examples have been established to base the significance of 10 CFR 50.59 violations on the resulting physical, procedural, or analytical change to the facility as evaluated through the SDP.
 - (A) Violations will be categorized at Severity Level III if the resulting changes were evaluated by the SDP as having low to moderate, or greater safety significance (i.e., white, yellow, or red finding).
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- (B) Violations will be categorized at Severity Level IV if the resulting changes were evaluated by the SDP as having very low safety significance (i.e., green finding).
 - (C) 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.
7. In addition to the guidance provided regarding citations against 10 CFR 50.59, in cases where a licensee has never implemented a commitment made under oath in the FSAR or amended FSAR, a material failure to have the facility conform to the FSAR may also constitute a violation of 10 CFR 50.9 if it occurred after 10 CFR 50.9 became effective (December 31, 1987), or may constitute a material false statement.
- e. In determining which enforcement action to recommend for a failure to implement an FSAR commitment (i.e., NOV against a specific requirement, Appendix B, 10 CFR 50.59, 10 CFR 50.9; or Notice of Deviation against the FSAR), the region should consider which enforcement action will convey the appropriate message to the licensee and which enforcement action will constitute the most defensible citation.

7.3.1 Application of the Corrective Action Civil Penalty Assessment Factor for 10 CFR 50.59 Violations

- a. In the event a violation of 10 CFR 50.59 results in an SDP finding of red, yellow or white, it may be necessary to assess corrective actions under the traditional enforcement approach.
- b. Corrective actions should normally be considered prompt and comprehensive only if the licensee makes a prompt decision on operability, and either:
 - 1. Makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the “as found” condition; or
 - 2. Promptly initiates corrective action consistent with criterion XVI of 10 CFR 50, Appendix B if it intends to restore the facility or procedure to the FSAR description.

☛ It is important for licensees to recognize the need for prompt and comprehensive corrective actions because until such actions are taken the violation continues unabated.

7.3.2 Exercise of Enforcement Discretion for FSAR Issues

- a. To encourage licensees to promptly undertake voluntary initiatives to identify and correct FSAR noncompliances, the staff may exercise enforcement discretion to either mitigate or escalate the enforcement sanction.

1. **Mitigation: Old Design Issues.** The staff may refrain from issuing civil penalties and in some instances, citations, for a two year period where a licensee undertakes voluntary initiative to identify and correct FSAR noncompliances that will be completed within that two year period.
2. This discretion would not normally be applied if:
 - (a) The NRC identifies the violation unless it was likely in the staff's view that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of the licensee's initiative;
 - (b) The licensee identifies the violation as a result of an event or surveillance or other required testing where required corrective action identifies the FSAR issue;
 - (c) The licensee identifies the violation but had prior opportunities to do so (was aware of the departure from the FSAR) and failed to correct it earlier;
 - (d) There is willfulness associated with the violation;
 - (e) The licensee fails to make a report required by the identification of the departure from the FSAR; or
 - (f) The licensee either fails to take comprehensive corrective action or fails to appropriately expand the corrective action program. The corrective action should be broad with a defined scope and schedule.
2. **Escalation: Civil Penalties.** The staff may escalate the amount of the civil penalties for FSAR/50.59 noncompliances identified by the NRC subsequent to the two year voluntary initiative period.
 - (a) The staff should use this discretion to increase the fine and consider assessing civil penalties for each violation or problem of \$130,000 which may be further escalated after considering the number and nature of the violations, the severity of the violations, whether the violations were continuing, and who identified the violations (and if the licensee identified the violation, whether to exercise discretion in accordance with the Enforcement Policy), rather than the normal assessment factors.
 - (b) This approach is intended to increase the incentive for licensees to take timely action to ensure that their facilities match the FSAR, e.g.:
 - (1) If a single Severity Level III violation is identified by the NRC and it lasted for more than 1 day, a civil penalty of \$260,000 could be assessed.

- (2) If the licensee identified the same violation and application of enforcement discretion under Section VII.B.3 was not warranted, a civil penalty of \$130,000 (\$65,000 x 2 days) could be assessed for the example cited above, providing some recognition of the licensee's efforts.

7.4 Citations Against 10 CFR Part 50, Appendix A, General Design Criteria (GDC)

- a. When the Commission developed and adopted Appendix A, the GDC were intended to provide a basis for judging the adequacy of:
1. The preliminary design of the facility at the construction permit stage; and
 2. The detailed design and construction at the operating license stage.
- b. The **GDC** function as criteria for assessing the design criteria for the plant; therefore:
1. The GDC carry over into the requirements for the FSAR (50.34(b)) for analyses of safety-significant structures, systems, and components (SSCs) with emphasis upon performance requirements, the bases upon which such performance requirements have been established; and
 2. Technical specifications (TSs) are required to be derived from the analyses in the FSAR (50.36(b)).
- ✓ Citations against the GDC are expected to be rare and require OE approval prior to issuance.
- c. The GDC are not directly applicable to operating requirements.
1. The GDC were not intended, in and of themselves, to constitute the controlling parameters for operation of nuclear power plants.
 2. TSs provide the controlling parameters on operation of a nuclear power plant, as is contemplated by Section 182.a of the AEA.

7.5 Citations Against 10 CFR Part 50, Appendix B

- a. Citations for Quality Assurance (QA) issues that are violations of 10 CFR Part 50, Appendix B, should be constructed with a clear statement of the applicable Appendix B criterion, followed by a statement of how that requirement was not met.
- b. Normally, for citations for QA issues, it is not necessary to:

1. Include a reference to 10 CFR 50.54(a) or 50.55(f) as the underlying regulation when citing Appendix B; or

☞ 10 CFR Part 50, Appendix B applies to safety-related structures, systems, and components (SSCs).

2. Reference that portion of the licensee's approved QA program which implements Appendix B, unless the licensee's approved QA program significantly differs from that of Appendix B.

(a) In most circumstances, the licensee's QA program is consistent with and amplifies the provisions of Appendix B; therefore a reference to the licensee's QA program is not normally necessary.

(b) If there is a conflict between an approved QA plan and Appendix B, the matter should be discussed with OE and NRR before issuing a violation.

- c. In the case of operating reactors where the TS administrative requirements may encompass certain Appendix B requirements such as procedures, the TS, if more specific, should be cited.

1. It may be appropriate in a particular case to utilize Appendix B for the citation if broader corrective action is appropriate.
2. It is essential for Appendix B, Criterion XVI citations, that the "contrary to" paragraph indicates that the licensee failed to take corrective action for a condition adverse to quality.
3. The following is an example of a citation against 10 CFR Part 50 Appendix B for failure to take corrective action.

10 CFR Part 50 Appendix B, Criterion XVI, "Corrective Action," requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, deficiencies, and deviations, are promptly identified and corrected.

Contrary to the above, from June 10, 2006 to August 3, 2006, the licensee failed to take prompt and adequate corrective action for a condition adverse to quality. Specifically, on June 10, 2006, a quality assurance auditor identified that a longitudinal pipe weld on the low head safety injection system was not included in the licensee's In-Service Inspection program and the licensee failed to conduct sufficient additional reviews to identify and resolve similar problems with longitudinal pipe welds that were present in other safety-related piping.

- d. The provisions of Appendix B do not generally apply to the radiation protection and safeguards areas.
 1. Appendix B applies to safety-related SSCs.
 2. There may be cases where procedures relating to security and radiation protection might be subject to Appendix B quality assurance criteria under certain circumstances, e.g., where "quality assurance" as defined in Appendix B comprises all those **planned and systematic actions** necessary to provide adequate confidence that an SSC will perform satisfactorily in service.

7.6 Enforcement Actions in Conjunction With Plant Shutdowns

- a. Enforcement actions based on findings at plants with major shutdowns:
 1. Should be processed substantially before restart is contemplated; and
 2. Should normally be submitted to OE at least two months before scheduled startup, if possible, to permit:
 - (a) The case to be issued; and
 - (b) The licensee's corrective action to be assessed prior to startup in order to avoid issuing sanctions at the same time or after startup is authorized.
- b. The logic in the preceding paragraph should be followed for plants that are to be licensed.

7.7 Actions Involving Fire Protection

- a. Fire protection requirements are established by:
 - 10 CFR Part 50, Appendix A
 - GDC 3
 - 10 CFR 50.48
 - 10 CFR Part 50, Appendix R
 - Facility license conditions
 - Facility TSs
 - Other legally binding requirements, as applicable
- b. Fire protection violations may involve:
 - Inoperable or inadequate fire barriers
 - Separation, suppression, or detection systems
 - Repair parts
 - Procedures

- Other conditions or items required to prevent fires, protect shutdown equipment during a fire, or restore safe shutdown equipment to service following an actual fire
 - c. Failures to meet regulatory requirements for protecting trains of equipment required for achieving and maintaining safe shutdown constitute serious violations.
 - d. The significance of fire protection violations is normally determined by the SDP.
 - e. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be:
 1. Assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy; and
 2. Assigned a severity level commensurate with the significance.
 - f. The following guidance provides examples of violations at various severity levels and should be used as a guide to determine the appropriate enforcement action. (For purposes of this guidance, required SSCs are those that are necessary to achieve and maintain safe shutdown and that require the application of fire protection features as described in the licensee's fire hazards analysis report and NRC's safety evaluation report.)
 1. **Severity Level I:** Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which an actual fire damages that equipment to such a degree that safe shutdown could not be achieved or maintained.
 2. **Severity Level II:** Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which a postulated fire in the area would so damage that equipment that safe shutdown would not be achieved and maintained.
 3. **Severity Level III:** Violations of fire protection requirements established to protect or enable operation of safe-shutdown equipment, for cases in which a postulated fire in the area, in the absence of additional evaluation, could so damage that equipment that shutdown could not be achieved and maintained using the applicable equipment identified in the fire hazards analysis in accordance with applicable requirements.
 - (a) Failure to have an adequate written evaluation available for an area in which Appendix R compliance is not apparent will be taken as an indication that the area does not comply with NRC requirements, and may result in enforcement action at this severity level.
 - (b) Licensees may exercise engineering judgement as to the threshold for documenting detailed analysis for spurious equipment actuations following a fire. Thus, potential
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spurious actuations judged by the licensee to not involve substantial risk to safe shutdown capability may not be covered by documented evaluations.

(c) The NRC may judge differently the potential impact on safe shutdown capability, and may request the licensee to provide additional analysis. A Severity Level III violation is probably not warranted unless this additional analysis confirms a significant problem.

4. **Severity Level IV:** Failures to meet one or more fire protection requirements that do not result in a Severity Level I, II, or III violation and which have more than minor safety or environmental significance.

7.8 Actions Involving Loss of Decay Heat Removal (DHR)

- a. The significance of decay heat removal violations is normally determined by the SDP.
- b. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and in this section.
- c. Because of the NRC staff's reassessment of the potential consequences of DHR events, actions in this area must be critically assessed to apply the appropriate severity level.
 1. In some scenarios, the precursors to core damage (such as boiling in the core) may occur much sooner after a loss of DHR than previously thought, and the implications of such a loss may be more serious.
 2. To ensure that these cases are handled uniformly and to better determine whether escalated action is appropriate, all actions (cited or non-cited) that result in a loss of DHR or shutdown cooling, require prior OE notification.
- d. A citation against a TS Limiting Condition for Operation may not always be available since TSs may not be specific about the amount of time allowed to restore DHR after an interruption.
 1. An exception is where the licensee took little or no action to immediately correct the problem. Such rare cases would clearly warrant consideration of escalated enforcement no matter what caused the DHR loss.
 2. The majority of DHR problems do not involve prolonged losses or losses for which the licensee does not take at least some corrective action.
- e. Under current NRC requirements, enforcement actions related to DHR events will generally consist of 10 CFR Part 50 Appendix B violations for lack of adequate procedures or not following procedures.

1. The NRC has reassessed the significance of this issue and has provided extensive prior notice to the industry on this subject (particularly events occurring during reduced reactor coolant system inventory operations) in the form of Generic Letters (GL 87-12 and GL 88-17), Information Notices, meetings with various industry groups, and letters to licensed operators.
 - (a) Much of the NRC guidance focuses on losses of DHR during reduced reactor coolant system (RCS) inventory operation; however,
 - (b) Other types of losses of DHR, such as one caused by an improper design change, can also be evaluated using some or all of the guidelines as appropriate.
2. Given the potential for core damage and the guidance provided by the NRC, failure of licensees to take aggressive action to assure appropriate procedures, procedure implementation, and training may be appropriately categorized at Severity Level III.

☞ There is no exact formula for arriving at a severity level and the factors discussed below may be weighted differently or may not be applicable in any given case.
- f. The following guidelines, which have been coordinated with NRR, should be used to evaluate whether a particular loss of DHR should be considered a Severity Level III matter. The factors to consider are:
 1. How similar was the root cause of the loss of DHR to the deficiencies addressed in NRC generic guidance such as GL 87-12 and GL 88-17?
 2. Given that a deficiency similar to that in NRC guidance occurred, how sensitive were the operators to the problem?
 3. How quickly did the operators respond? (Core decay heat level may not call for instantaneous response; however, the failure to correct such a situation quickly simply because the operator does not view it as particularly pressing may indicate a lack of sensitivity to this type of problem.)
 4. Did they respond using detailed procedural guidance, and if they did not, was their training sufficient in and of itself?
 5. Given that the operators procedurally treated the "symptoms," did they recognize the problem as a loss of DHR?
 6. Did the operators have other available indications not specified in the procedures that could have been consulted, and did they use them?

7. Does the plant have a history of interruptions of DHR? (This may indicate a continuing lack of sensitivity to this issue.)
8. Were procedures in place to provide operator guidance for alternative DHR options not normally employed? (In a number of instances licensees have made after-the-fact arguments about alternative sources of circulation and cooling. Because such sources were not defined by procedures, it was unclear if the operator in such cases could have aligned such sources quickly enough and whether the availability of such sources was only fortuitous.)
- g. The scenarios provided in the two examples that follow illustrate certain key actions or inactions that, when considered under the guidance provided earlier, would result in the recommended severity level classifications. It should be noted that in neither instance was DHR flow lost for an extended period, if it was ever fully lost.

Example 1: For maintenance work on a reactor coolant pump seal, reactor vessel water level needs to be lowered to mid-loop. In preparation for the draindown, an auxiliary operator performs a full inspection of the tygon tube level-indication system and then reports to the control room that he is standing by to monitor level during the draindown. Shortly before level reaches the mid-loop area, the control room secures the draindown to allow the level indicators to stabilize before draining the last few inches of water. Simultaneously, maintenance personnel arrive in the containment in preparation for the seal work and inadvertently place a large box on the tygon hose. Upon resuming the draindown, the control room operator notes a growing discrepancy between the level being reported from the containment and the control room indication. Just as the control room operator terminates the draindown to investigate the discrepancy, the operating DHR pump begins to cavitate. The operator quickly secures the pump, restores RCS inventory, and starts the standby pump. The auxiliary operator again performs a walk-on of the tygon hose, discovers the blockage, and removes it before resuming draindown.

Recommendation: The licensee should be assessed either an NCV or NOV for a Severity Level IV violation for inadequate work control. Although pump cavitation occurred after a loss of adequate level, due to erroneous level indication, proper preparation for the draindown was accomplished and the operators responded quickly and correctly to the event.

Example 2: Before the draindown to mid-loop, an auxiliary operator is stationed to monitor level without first having anyone walk down the tygon hose. Earlier, maintenance personnel had entered the containment and inadvertently placed a large box on the tygon hose. After the draindown begins, the control room operator notes a growing difference between control

✓ The more a case appears similar to the circumstances of the generic guidance and the less responsive the operators are, the more likely the case should be considered at Severity Level III.

room level indication and that being reported from the containment. He secures the draindown and then asks the auxiliary operator about the condition of his indicating hose. The auxiliary operator replies that the level seems to be decreasing more slowly than he anticipated but the decrease has been smooth and he doesn't see any air bubbles. With that information, the control room operator decides to continue the draindown relying solely on the tygon hose rather than on the relatively new control room indicator with which there have been problems. The control room operator makes this decision despite the fact that, at the time, the control room indicator is providing a level reading significantly lower than that of the tygon hose. After recommencing the draindown, the operating DHR pump begins to cavitate. The control room operator gets a report from the containment that the level is still indicated to be well above mid-loop and, therefore, he starts the standby pump and secures the cavitating pump. Almost immediately, the standby pump also begins to cavitate. The operator, realizing that level must be too low, finally takes action to restore level and directs the auxiliary operator to walk down the tygon hose.

Recommendation: The licensee should be assessed a Severity Level III violation. Proper preparations were not made, the operator made a nonconservative judgment in choosing which level indicator to use, and when given an opportunity to recognize the mistake, chose to start a second pump rather than to learn why the first pump was cavitating.

7.9 Actions Involving Service Water Systems

- a. The significance of service water system violations is normally determined by the SDP.
- b. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the guidance in this section.
- c. Although the specific title of the system(s) may vary, as used in the context of this guidance, the term "service water system" (SWS) refers to the cooling water system that provides the ultimate heat sink for the plant's safety-related systems.
- d. Determining the appropriate enforcement action for cases involving the SWS may be challenging because of the potential difficulty in determining whether or not the SWS can adequately perform its design function. Deficiencies that can effect the operability of the SWS include problems such as:
 - Inadequate heat removal capability as a result of bio-fouling
 - Silting
 - Erosion and corrosion
 - Single failure concerns
 - Inadequate original design margin

- e. The first decision in SWS cases is whether the agency should cite against SWS operability.
1. Licensee expenditures of time and resources to perform after-the-fact analyses supporting SWS operability do not obligate similar NRC expenditures to review the analysis to support enforcement action.
 2. It may be preferable to cite against the root cause of the deficiency rather than to expend resources to perform complex operability analyses.
- f. In some cases, it may not be prudent to cite against the SWS being unable to perform its intended function (e.g., one train of the SWS is not available).
1. In such cases, an enforcement action citing the requirement that best reflects the root cause failure may be used to establish a Severity Level III violation, e.g., the licensee has a degraded system.
 2. The following example illustrates this point:

10 CFR Part 50, Appendix B, Criterion XVI (Corrective Action), requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, deficiencies and deviations, are promptly identified and corrected.

Contrary to the above, between June 15, 2006 and August 31, 2006, a condition adverse to quality at the ABC Nuclear Station was not promptly identified or corrected. Specifically, mussel clusters of enough volume to cause significant reductions in service water flow to vital components had accumulated along an 80 foot section of service water system piping. On at least nine occasions during that time period, actions taken by licensee personnel in reaction to indications of degraded service water flow were ineffective in identifying and correcting the full extent of the problem. These ineffective corrective actions resulted in significantly reduced service water flow to the "B" Diesel Generator heat exchanger which in turn resulted in a reduction in the diesel generator's electrical load carrying capability.
- g. Additional examples of requirements that could be cited for the root cause failure include:
- Failure to perform a design change safety analysis (10 CFR 50.59)
 - Failure to follow procedures (administrative TS requirement)
 - Failure to control design (Appendix B, Criterion III)
 - failure to control tests (Appendix B, Criterion XI)
- h. For those enforcement actions that do not cite against operability, the cover letter should focus on the licensee's root cause failure as the basis for the action, rather than focusing on whether the SWS was or was not operable.

- i. Additional information on SWSs is addressed in [Generic Letter \(GL\) 89-13, "Service Water System Problems Affecting Safety Related Equipment."](#)
 1. Failure to comply with a Generic Letter is not a violation unless the commitment is addressed by a legal requirement or has been incorporated into the licensee's license.
 2. GL 89-13 may be cited to establish prior notice in assessing a civil penalty for a particular action.

7.10 Actions Involving Emergency Core Cooling Systems

- a. The significance of emergency core cooling violations is normally determined by the SDP.
- b. To the extent that the SDP does not apply or that the ROP is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the following guidance.
- c. 10 CFR 50.46 enumerates specific steps that must be implemented by a licensee following the discovery of an error in an approved LOCA code.
 1. The effect of the error on predicted peak clad temperature (PCT) must be estimated.
 2. The error must be reported to the NRC on a schedule determined by the magnitude of the change in PCT.
 3. If the impact of correcting the error causes the predicted PCT to exceed the acceptance criterion of 2200 °F, the licensee is required to take immediate action to return to compliance with the regulation.
- d. Enforcement action could be taken against a licensee, related to non-compliance with 10 CFR 50.46 acceptance criteria, in, e.g., the following circumstances:
 1. A licensee discovers an error in an approved ECCS model and does not follow the requirements for assessing and reporting the error.
 2. A licensee discovers an error and assesses its impact, but does not report it or take other action mandated by the regulation as a result of the assessment (e.g., limiting power to stay under 2200 °F; replacing Dougall-Rohsenow correlation per Appendix K requirements).
 3. An error is discovered in an ECCS model by the NRC staff that a licensee (or vendor) could reasonably have been expected to discover had the code been validated properly, in which case enforcement action could be taken against the licensee per the requirements of 10 CFR Part 50, Appendix B, for failure to provide adequate QA.

- e. Although enforcement action might be warranted for violations of 10 CFR Part 50, Appendix B, the staff does not believe that it is normally appropriate to take enforcement action for 10 CFR 50.46 against a licensee who:
 - 1. Discovers an error in an approved LOCA code; and
 - 2. Follows the requirements of 10 CFR 50.46 for assessing, reporting, correcting the error, including whatever steps are needed to stay in compliance with the PCT acceptance criterion.
- f. Enforcement action is generally not taken when errors in the code are not preventable by reasonable QA measures as analogous to failure of a plant component (hardware) resulting from a latent (hidden) flaw that the licensee could not reasonably have been expected to discover prior to the component failure.
 - 1. The NRC would generally require that the failure be evaluated, once identified, to determine if the latent flaw could be generic and, therefore, requires reporting under 10 CFR Part 21.
 - 2. The equipment would also require repair and testing to demonstrate it could meet its functional requirements.
 - 3. Evaluation (including a Part 21 evaluation), repair and testing, are types of actions that are consistent with licensee requirements under 10 CFR 50.46. Accordingly, the staff does not believe that there is a fundamental inconsistency in the way in which enforcement action is taken for software and hardware faults.
- g. Enforcement policy with respect to LOCA codes and 10 CFR 50.46 requirements must be considered in the context of the fundamental differences between “hardware,” i.e., plant equipment, and “software,” i.e., computer codes and analytical results.
 - 1. Determination of whether hardware can accomplish a specific function is, in many cases, a relatively straightforward process.
 - (a) The equipment is operated, its output (e.g., flow from a pump) is measured, and the measured value is compared to a required value, such as that in Technical Specifications, to determine if the equipment meets its functional requirements. (Due consideration must be given to concerns such as instrument uncertainty.)
 - (b) Functionality can be assessed retrospectively, to some extent; if equipment is shown to be out of compliance with its functional requirements, and that it met those requirements during a previous surveillance test. In that case, the assumption is often made that it would not have met its functional requirements for some period prior to the most recent assessment.

2. Computer code assessments are different from hardware assessments. Errors can be extremely subtle, and may not become apparent until a specific part of the analysis package is exercised in a certain way.
 - (a) 10 CFR 50.46 recognizes this aspect of code development and usage, and anticipates that circumstances might arise in which a mathematical model considered to be adequate could be shown, in the light of new information, to be deficient.
 - (b) 10 CFR 50.46 is essentially unique among the NRC's Part 50 requirements, in that it provides specific steps to be taken by a licensee if a LOCA analysis is found not to meet the peak clad temperature (PCT) acceptance criterion by virtue of correction of a newly-discovered error.
 - (1) In such cases, enforcement action against 10 CFR 50.46 or Appendix B would not be taken.
 - (2) However, as noted above, if the errors were preventable by reasonable QA measures, a violation of Appendix B might be warranted.
- h. It must be recognized that there is not a unique, "correct" result for any given plant's LOCA analysis.
 1. If a licensee's analytical model conforms to the requirements of Appendix K of 10 CFR Part 50:
 - (a) The predicted PCT is understood to be substantially higher than that which would be occur in an actual event that followed the licensing basis accident scenario.
 - (1) Appendix K-mandated phenomenological models are known to intentionally over- or under predict specific parameters to bias the PCT result in a conservative direction.
 - (2) A "best-estimate" (or "realistic") calculation of plant response, using identical initial and boundary conditions, would give a much lower PCT.
 - (b) There is no "standard" ECCS analytical model. Beyond Appendix K requirements, each vendor's codes contain different, sometimes proprietary, phenomenological models and modeling approaches (e.g., nodalization, time step), and consequently each would give a somewhat different answer for PCT.

7.11 Actions Involving the Maintenance Rule

- a. Because of the non-prescriptive nature of the rule language, enforcement of the maintenance rule represents a continuing challenge to inspectors.

1. Since implementation of the maintenance rule in July 1996, enforcement of the rule has evolved as lessons were learned.
2. This guidance addresses issues typical of those which are more frequently raised by inspectors; however, it cannot possibly address every conceivable maintenance rule compliance issue.

☛ When a question regarding the application of the Maintenance Rule comes up, the regions can request that such question is paneled. OE will ensure that appropriate NRR staff attend the panel. Others, including the regional inspector, resident inspector, project manager, etc., may be asked to attend the meeting or provide input to the discussions.

- b. **General Enforcement Guidance for Potential Violations of the Maintenance Rule**

1. **A maintenance rule violation can only be cited against the specific language of 10 CFR 50.65.** The most straightforward method to determine whether a violation of the maintenance rule (or any other requirement) exists is to construct a “contrary to” statement that uses parallel language of the rule or requirement in a description of what the licensee did or did not do.
2. [Regulatory Guide \(RG\) 1.160, Monitoring the Effectiveness of Maintenance at Nuclear Power Plants](#) (ML003761662), endorses NUMARC 93-01, Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.
 - (a) NUMARC 93-01 guidance is non-binding and thus, does not represent requirements and can neither be used as the basis for, nor cited in, a maintenance rule violation. NUMARC 93-01 provides methods that are acceptable to the NRC for complying with the provisions of [10 CFR 50.65](#).
 - (b) RG 1.160 and NUMARC 93-01 can be useful to inspectors in understanding how licensees typically implement their maintenance rule programs and in defining terms as they are commonly used with respect to the implementing guidance.

- c. **The Maintenance Rule does not require licensees to establish program procedures.**

1. There cannot be a procedure violation of 10 CFR Part 50, Appendix B, Criterion V, Instructions, Procedures, and Drawings, for failing to establish, implement or to maintain Maintenance Rule process implementing procedures.

2. There cannot be a violation of the administrative section of technical specifications which invokes [RG 1.33, "Quality Assurance Program Requirements."](#)
 - (a) RG 1.33 does not cover the maintenance rule process.
 - (b) The failure to follow a licensee's maintenance rule implementing procedure(s) cannot be cited as part of a maintenance rule violation, although the implementing procedure may be useful in providing insights when evaluating whether a direct violation of 10 CFR 50.65 may have occurred.
- d. There cannot be a violation of Appendix B, Criterion XVI for failure to identify or correct conditions adverse to quality, for failure to identify or correct deficiencies with a licensee's maintenance rule implementation because the maintenance rule process is not safety-related.
 1. This reasoning also applies to violations of Criterion V.
 2. As in the past, a maintenance procedure used for the performance of a maintenance activity on an SSC can be referenced in a technical specification (TS)/RG 1.33 or Appendix B, Criterion V violation, when that maintenance procedure is not adequate, is not maintained, or is not followed and, for use of Appendix B, Criterion V, when the activity was on a safety-related SSC.
- e. **Except in 10 CFR 50.65 (a)(4), there is no distinction in the Maintenance Rule for varying degrees of SSC risk significance.**
 1. The scope of Paragraph (a)(4) assessments may be limited to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.
 2. The scope reduction does not apply to any other section of the Maintenance Rule.
- f. Acronyms and terms have been used which are consistent with those used by licensees to describe maintenance rule-related activities. Acronyms and terms associated with the maintenance rule are described in RG 1.160 and NUMARC 93-01.
- g. The SDP will be used to determine the significance of a violation or maintenance rule finding.

7.11.1 Issues That Are Violations of 10 CFR 50.65 and Issues That Are Not Violations of 10 CFR 50.65

- a. **Paragraph (a)(1)**
 1. Issues that are violations of 10 CFR 50.65 (a)(1):

(a) Failure to establish goals for SSCs in (a)(1). Goals must be:

- (1) Justifiable and defensible.
- (2) Supported by either an adequate Expert Panel determination, adequate use of PRA), or some other reasonable basis and be commensurate with safety.

☞ The activities discussed here, although not violations of the rule, are **indicators** that the licensee's performance demonstration may be invalid which could result in a violation of 10 CFR 50.65. If that is the case, the licensee must recognize the failure to demonstrate performance and, if appropriate, move the SSC to (a)(1).

(b) Failure to monitor performance or condition against established goals.

- (1) The monitoring program must be sufficient in scope and frequency to adequately support a determination as to whether SSCs are meeting their assigned goals.

- (2) Performance monitoring must include tracking of both availability and reliability, where goals of this nature are appropriate, since that provides the maximum assurance that SSCs are capable of fulfilling their intended functions.

(c) Failure to take appropriate corrective action when performance or condition goals are not met.

- (1) Corrective actions should sufficiently address actions to achieve goals, be commensurate with the goals being monitored, be timely and reasonable. The corrective actions of concern are those necessary to meet goals - not necessarily corrective actions to correct individual SSC failures.
- (2) The standard for adequacy of corrective actions is reasonableness. Unless there are significant, credible, differing causes that are not reasonably addressed in the corrective actions, the licensee's actions should be considered adequate.

(d) Failure to consider industry operating experience, where practical, which should include, e.g.:

- Specific vendor recommendations
- Generic communications issued by the NRC or vendors
- Information communicated via industry working groups or owners groups

2. Issues that are not violations of 10 CFR 50.65 (a)(1):

- (a) Failure to meet a goal. If a goal is not met, appropriate corrective action shall be taken.
- (b) Failure to establish goals based on industry-wide operating experience.
 - (1) The words of the rule, “where practical, take into account industry-wide operating experience,” were not intended to force compliance with industry goals, but rather were intended to require licensees to consider industry experience as an information source for setting reasonable goals.
 - (2) A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.
- (c) Failure to subdivide SSCs into high safety significant (HSS) SSCs, low safety significant (LSS) SSCs, and low safety significant (LSS) standby SSCs. (The rule does not require this.)
- (d) Failure to link goals to the licensee’s PRA. (The rule does not require this.)
- (e) Failure to take corrective action as a result of condition monitoring which indicates that an SSC is degrading, but is still capable of performing its intended function. When established goals are not met, either:
 - (1) Appropriate corrective action shall be taken to achieve the goals; or
 - (2) The goals must be changed with adequate justification.
- (f) Failure to perform a cause determination when a performance criterion or goal is exceeded.
 - (1) Unlike Criterion XVI of Appendix B for significant conditions adverse to quality, (a)(1) does not require determination of causes, only that corrective actions be taken when goals are not met; however, if a licensee takes ineffective corrective actions due to fixing the incorrect cause, a corrective action violation could be considered.
 - (2) For corrective action issues involving safety-related SSCs, Appendix B, Criterion XVI, may be more easily used for enforcement purposes.

b. Paragraph (a)(2)

1. Issues that are violations of 10 CFR 50.65 (a)(2):

(a) Failure to move an SSC to (a)(1) when performance indicates that the SSC is not being effectively controlled through appropriate preventive maintenance.

- (1) The performance demonstration must be technically justifiable and reasonable.
- (2) When the performance demonstration is no longer technically justifiable, the demonstration ceases to be valid and the SSC is required to be moved to (a)(1) where the performance of the SSC is monitored against established goals, e.g.:

A repetitive preventive maintenance preventable functional failure would indicate that the licensee has failed to demonstrate the effectiveness of preventive maintenance and consequently that SSC must be moved to (a)(1). For such failures, the time between occurrences and the type of failure should be taken into consideration, e.g., human errors of omission or commission need not be considered repetitive after a reasonable time period. Other component specific preventable failures may be considered repeat despite lengthy periods between failures.

☞ The focus of (a)(2) is on the results achieved through maintenance. For a violation to exist, there must first exist an equipment performance problem which could indicate that preventive maintenance is not being effective. If a performance problem is determined to exist, then the following two questions are relevant to a determination of whether there is a violation: (1) Does that performance problem invalidate the demonstration that the performance of the SSC is being effectively controlled through appropriate preventive maintenance; and (2) If the performance demonstration is invalid, did the licensee move the SSC to (a)(1)?

☞ For enforcement purposes, the (a)(2) “demonstration” is not a one time or periodic evaluation of past SSC performance, but is a continuing requirement. Hence, if the *performance* or condition of an SSC decreases due to, e.g., failures or increased *unavailability*, the demonstration of effective preventive maintenance can be questioned.

(b) Failure to consider both reliability and availability when evaluating whether an SSC’s performance or condition has been demonstrated to be effectively controlled.

- (1) In order for an SSC to remain capable of performing its intended function, it must be both reliable and available.
- (2) If the degree of reliability and availability are not technically justifiable and reasonable, a violation may exist.

2. Issues that are not violations of 10 CFR 50.65 (a)(2):

- (a) Failure to establish performance criteria, establish appropriate performance criteria, link performance criteria to the licensee's PRA, or to meet established performance criteria.
- (b) Failure to move an (a)(2) SSC to (a)(1) **solely** because its performance criteria are not met. (Conversely, just because performance criteria **are** met does not necessarily mean that an (a)(2) demonstration is valid.)
- (c) Failure to correctly characterize a failure as a functional failure (FF) or maintenance preventable functional failure (MPFF).
- (d) Failure to correctly consider a failure or unavailability period as potentially impacting the (a)(2) demonstration, but when considered, the demonstration remains valid.
- (e) Failure to document the demonstration. The rule has no explicit requirements to document the demonstration.
- (f) Failure to consider SSC failures caused by activities other than preventive maintenance.
- (1) Paragraph (a)(2) specifically applies to preventive maintenance.
- (2) Random failures or failures due to errors of design, manufacturing, modifications, or corrective maintenance do not apply in determining whether preventive maintenance is being effective.

10 CFR 50.65 does not dictate by what method the performance is to be demonstrated. However, the licensee must be able to demonstrate, through some reasonable means, that performance is being effectively controlled through appropriate preventive maintenance. RG 1.160 endorses an acceptable method for demonstrating performance. Whatever method the licensee uses to demonstrate performance must be reasonable, technically justifiable, and take into account availability and reliability.

c. **Paragraph (a)(3)**

1. Issues that are violations of 10 CFR 50.65 (a)(3):

- (a) Failure to perform the required periodic evaluation at least every refueling cycle, and in any case, not to exceed 24 months.
- (b) Failure to evaluate (a)(1) activities (performance and condition monitoring activities and associated goals) and (a)(2) activities (preventive maintenance activities).

(c) Failure to make adjustments, where necessary, to goals and monitoring to ensure that unavailability and reliability are balanced.

(1) The licensee's evaluation process must be reasonable and technically justifiable and should include a reasonable basis for making or not making adjustments.

(2) The intent of the evaluation is to provide an opportunity to feedback lessons learned into the process.

☞ As stated previously, the focus of the rule is on the results achieved through maintenance. Consequently, there must first exist an SSC performance problem before the validity of the SSC performance demonstration comes into question. If there is a performance problem which invalidates the licensee's demonstration that the performance of the SSC is being effectively controlled through appropriate preventive maintenance, the SSC must be moved to (a)(1).

2. Issues that are not violations of 10 CFR 50.65 (a)(3):

(a) Failure to document the evaluation.

(1) The rule has no explicit requirements to document the evaluation.

(2) Licensees should use documentation to the extent necessary to assure themselves that the requirement for an evaluation has been acknowledged and performed adequately.

(b) Failure to complete the evaluation in accordance with the licensee's administrative procedure. The licensee's administrative procedure for implementation of 10 CFR 50.65 or for performing evaluations cannot be cited as part of a maintenance rule violation.

(c) Failure to apply industry-wide operating experience.

(1) The words of the rule, "where practical, take into account industry-wide operating experience," were not intended to force compliance with industry practices, but rather were intended to require licensees to consider industry experience as an information source for conducting evaluations.

(2) A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.

d. **Paragraph (a)(4)**

1. Issues that are violations of 10 CFR 50.65 (a)(4):

- (a) Failure to perform a risk assessment prior to performing maintenance activities.
Required assessments:

- (1) May be limited to those SSCs which, singularly or in combination, can be shown (by a risk-informed evaluation process) to have a significant effect on the performance of key plant safety functions
- (2) Are significant to public health and safety.

- (b) Failure to perform an adequate assessment.

- (1) To support a violation, there should be a technically justifiable reason as to why the assessment is determined to be inadequate.

 The Maintenance Rule does not give guidance on what constitutes an adequate assessment.

- (2) The sophistication of the assessment should be commensurate with the complexity of the configuration and should meet the test of reasonableness.
- (3) If the assessment is sufficient in complexity, technically justifiable, and reasonable, it would be difficult to conclude that the assessment was inadequate.
- (4) The information considered should be complete and accurate (e.g., congruence of the assessed configuration to the existing plant configuration and activities) and the assessment tool or process should be used appropriately (e.g., within its capabilities and limitations).

- (c) Failure to update a prior assessment due to emergent work or changing plant conditions that could have an impact on the existing assessment.

- (1) Included in this violation would be the identification of external factors including changed environmental conditions.
- (2) Reasonableness applies when evaluating whether emergent work or changing external factors become impacting. A licensee should not be expected to react at too low a threshold, e.g.:

A typical summer weather forecast for afternoon thunder storms may be too low a threshold for deferring work on an emergency diesel generator, whereas the issuance of a tornado watch due to severe storms in the area may be an appropriate level for a more rigorous reassessment and additional risk management actions.

- (d) Failure to manage the increase in risk that may result from the proposed maintenance activity.
 - (1) The process for managing risk involves using the result of the assessment in plant decision making to control the overall risk impact.
 - (2) The licensee is not bound to keeping risk below some threshold or for taking particular actions when risk exceeds some threshold.
 - (3) The licensee is responsible for making conscious decisions as to how the increase in risk will be handled, then by following their own action plan for handling the increased risk.
- 2. Issues that are not violations of 10 CFR 50.65 (a)(4):
 - (a) Failure to document the assessment.
 - (1) The rule has no explicit requirements that the assessment be documented.
 - (2) Licensees should use documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately.
 - (b) Failure to use probabilistic analyses to perform a risk assessment.
 - (1) See the Statements of Consideration (SOC) in section 7.11.3 of this chapter.
 - (2) Depending on the complexity of the SSCs out of service, a probabilistic assessment may be the most defensible, but is not explicitly required. A violation may exist, however, if a probabilistic assessment of a deterministic risk assessment reaches a significantly different conclusion and indicates that a probabilistic assessment reasonably should have been performed in place of the deterministic assessment.
 - (c) Failing to perform an adequate assessment that is questioned and corrected prior to commencement of maintenance activities.
 - (1) This includes occasions when an NRC inspector questions an assessment prior to the maintenance activity commencing.
 - (2) "Commencement" of maintenance activities is considered the point when the SSCs of concern are disabled or prevented from performing their safety function.

e. Paragraph (b)(1)

1. Issues that are violations of 10 CFR 60.65 (b)(1):

Failure to include a safety-related SSC in scope.

2. Issues that are not violations of 10 CFR 60.65 (b)(1):

Failure to properly classify an SSC as either HSS or LSS. The failure to place within the scope those safety related and non-safety related SSCs as described in (b)(1) and (b)(2) is the violation, not improper classification as HSS or LSS.

 The SOC excerpts provided in this guidance are intended for use as background information only. The SOC excerpts were taken from 56 FR 31308-31310, dated July 10, 1991 and 64 FR 38554-38555, dated July 19, 1999.

f. Paragraph (b)(2)

1. Issues that are violations of 10 CFR 50.65 (b)(2):

Failure to include in the scope those types of non-safety related SSCs described in (b)(2).

2. Issues that are not violations of 10 CFR 50.65 (b)(2):

No specific guidance is provided.

7.11.2 Examples of Violations**a. Paragraph (a)(1)**

1. Failure to set goals and monitor:

10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions. Such goals shall be established commensurate with safety.

Contrary to the above, between (dates), the licensee failed to perform monitoring and failed to established goals for the residual heat removal system although the system was classified as being within the scope of the monitoring program on (dates) after the preventive maintenance program was shown to be ineffective due to repeat preventive maintenance preventable functional failures.

2. Failure to take corrective actions:

10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such structures, systems, and components (SSCs) are capable of fulfilling their intended functions. Such goals shall be established commensurate with safety. When the performance or condition of a SSC does not meet established goals, appropriate corrective action shall be taken.

Contrary to the above, from (date), the time that the Leakage Detection System (LDS) was placed into the scope of the monitoring program, the licensee did not take corrective actions when the performance of LDS did not meet licensee established goals in that the LDS functions were determined not to have met the established goal for reliability on (date) and no changes were made to the preventive maintenance on the LDS system.

b. Paragraph (a)(2)

1. Failure to demonstrate effective preventive maintenance nor set goals and monitor:

Example 1:

10 CFR 50.65 (a)(1), requires, in part, that the holders of an operating license shall monitor the performance or condition of structures, systems, or components (SSCs) within the scope of the rule as defined by 10 CFR 50.65 (b), against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions.

10 CFR 50.65 (a)(2) states, in part, that monitoring as specified in 10 CFR 50.65 (a)(1) is not required where it has been demonstrated that the performance or condition of an SSC is being effectively controlled through the performance of appropriate preventive maintenance, such that the SSC remains capable of performing its intended function.

Contrary to the above, as of (date), the licensee failed to demonstrate that the performance or condition of five primary containment isolation valves and the containment hydrogen analyzers had been effectively controlled through the performance of appropriate preventive maintenance and did not monitor against licensee-established goals. Specifically, the licensee failed to identify, and properly account for five preventive maintenance preventable functional failures of primary containment isolation valves and nine preventive maintenance preventable functional failures of the containment hydrogen analyzers occurring from (date) to (date) which demonstrate that the performance or condition of these SSCs was not being effectively controlled through the performance of appropriate preventive maintenance and, as a result, that goal setting and monitoring was required.

Example2:

10 CFR 50.65(a)(1) requires, in part, that holders of an operating license shall monitor the performance or condition of structures, systems, and components (SSCs) within the scope of the monitoring program as defined in 10 CFR 50.65(b) against licensee-established goals, in a manner sufficient to provide reasonable assurance that such SSCs are capable of fulfilling their intended functions.

10 CFR 50.65 (a)(2) states, in part, that monitoring as specified in 10 CFR 50.65 (a)(1) is not required where it has been demonstrated that the performance or condition of an SSC is being effectively controlled through the performance of appropriate preventive maintenance, such that the SSC remains capable of performing its intended function.

Contrary to the above, the licensee failed to demonstrate that performance of the 480-volt ac electrical distribution system was being effectively controlled through the performance of appropriate preventive maintenance in that a repetitive preventive maintenance preventable failure of a 480-volt ac electrical breaker occurred on (date). Following the failure, the licensee failed to consider placing the 480-volt ac electrical distribution system under 10 CFR 50.65(a)(1) for establishing goals and monitoring against the goals.

c. Paragraph (a)(3)Example 1:

10 CFR 50.65 (a)(3) requires, in part, that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle. Adjustments shall be made where necessary to ensure that the objective of preventing failures of structures, systems, and components (SSCs) through maintenance (reliability) is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

Contrary to the above, the periodic evaluation conducted for the period (dates) did not adequately evaluate the maintenance activities to ensure that reliability was appropriately balanced against unavailability for two emergency diesel generators (EDGs). Specifically, unavailability monitoring of the EDGs during the refueling cycle completed (date) did not consider individual EDG maintenance periods for emergent work on (date) for EDG 1-1 and on (date) for EDG 2-1. As a result, total unavailability was not properly considered and assessed for the EDGs. Without considering this unevaluated unavailability, the balancing of unavailability and reliability was not adequate.

Example 2:

10 CFR 50.65(a)(3) states, in part, that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every

refueling cycle provided the interval between evaluations does not exceed 24 months.

Contrary to the above, as of (date), the licensee had failed to complete the periodic evaluation for the refueling cycle which ended (date).

Example 3:

10 CFR 50.65 (a)(3) requires, in part, that preventive maintenance activities shall be evaluated at least every refueling cycle and these evaluations shall take into account, where practical, industry-wide operating experience.

Contrary to the above, industry-wide operating experience was not taken into account during the evaluation conducted between (dates) for the 22 CVC pump. Specifically, industry-wide operating experience documented previous failures of the CVC pump speed increaser due to wear induced failures of the lubricating oil pump drive pins that could be prevented through performance of vendor recommended preventive maintenance. The PM developed for this activity had never been performed and was indefinitely deferred resulting in failure of the 22 CVC pump on (date).

d. **Paragraph (a)(4)**

Example 1:

10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to perform an assessment prior to conducting maintenance activities between (dates) on the control rod drive (CRD) pump train B and the reactor core isolation cooling (RCIC) system. The failure to perform an assessment occurred during a Division 1 outage in which the residual heat removal (RHR) train A, the low pressure core spray system (LPCS), emergency closed cooling (ECC) train A, emergency service water (ESW) train A, and Division 1 emergency diesel generator (EDG) had already been assessed for risk and removed from service.

Example 2:

10 CFR 50.65(a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to perform an adequate risk assessment in that the overall maintenance risk assessment performed by the licensee for all plant maintenance to

be performed during the week of (date(s)) was inadequate because it failed to account for certain high safety significant structures, systems, and components (HSS SSCs) or others within the licensee-established risk assessment scope) that was/were concurrently out of service.

Example 3:

10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities.

Contrary to the above, the licensee failed to manage the risk associated with the repair of the pipe leak on A train of the essential service water system (ESW), in that, although a risk assessment had been performed for the A train emergent work leak repair, including a provision that isolation and draining of the affected pipe segment not commence until all repair materials and procedures were staged to immediately commence work, isolation was accomplished prior to the correct welding procedure being completed. This resulted in an unnecessary unavailability of A train ESW for 23 hours while the weld procedure was being approved.

e. Paragraph (b)(1)

10 CFR 50.65 (b)(1) requires, in part, that the holders of an operating license shall include within the scope of the monitoring program specified in 10 CFR 50.65 (a)(1) safety-related structures, systems, or components (SSCs) that are relied upon to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, and the capability to prevent or mitigate the consequences of accident that could result in potential offsite exposure comparable to the 10 CFR, Part 100 guidelines.

Contrary to the above, as of (date), the licensee failed to include within the scope of the monitoring program specified in 10 CFR 50.65 (a)(1), the safety-related SSCs that provide the pressurizer level, reactor pressure vessel level, and residual heat removal suction relief valve over-pressure protection functions as applicable for non-Mode 1 conditions. These SSCs are relied upon during and after design basis events to maintain the reactor in a safe shutdown condition.

f. Paragraph (b)(2)

Example 1:

10 CFR 50.65 (b)(2) requires, in part, that the scope of the monitoring program specified in paragraph (a)(1) include non-safety related structures, systems, and components (SSCs) whose failure can prevent safety-related SSCs from fulfilling their safety-related function.

Contrary to the above, from (date) to (date), the Unit 2 turbine building sump system was not included in the scope of the monitoring program specified in 10 CFR 50.65 (a)(1). The inclusion of the turbine building sump in the scope of the monitoring program was necessary because the failure of that system could prevent the emergency feedwater system, a safety-related system, from fulfilling its safety-related function.

Example 2:

10 CFR 50.65 (b)(2) requires, in part, that the scope of the monitoring program specified in paragraph (a)(1) include non-safety related structures, systems, and components (SSCs) that are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (EOPs).

Contrary to the above, as of (date), the licensee failed to include the area radiation monitoring system within the scope of the monitoring program specified in 10 CFR 50.65 (a)(1). The area radiation monitoring system is a non-safety related system used in the plant EOPs. As a result, the preventive maintenance on the system was not assessed following three maintenance preventable functional failures occurring between (dates).

7.11.3 Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants

a. Paragraph 50.65(a)(1)

1. Requires each holder of an operating license under 50.21(b) or 50.22 to monitor the performance or condition of SSCs against licensee-established goals in a manner sufficient to provide reasonable assurance that such SSCs, as defined in paragraph (b), are capable of fulfilling their intended functions.
 - (a) Such goals shall be established commensurate with safety and, where practical, take into account industry-wide operating experience.
 - (b) When the performance or condition of an SSC does not meet established goals, appropriate corrective action shall be taken.
 - (c) For a nuclear power plant for which the licensee has submitted the certifications specified in 50.82(a)(1), this paragraph only shall apply to the extent that the licensee shall monitor the performance or condition of all SSCs associated with the storage, control, and maintenance of spent fuel in a safe condition, in a manner sufficient to provide reasonable assurance that such structures, systems, and components are capable of fulfilling their intended functions.

2. The SOC for paragraph (a)(1) indicates that the licensee establish a monitoring regime which is sufficient in scope to provide reasonable assurance that (1) intended safety, accident mitigation and transient mitigation functions of the structures, systems, and components (SSCs) described in paragraph (b)(1) and (b)(2)(i) can be performed; and (2) for the SSCs described in subparagraphs (b)(2)(ii) and (b)(2)(iii), failures will not occur which prevent the fulfillment of safety-related functions, and failures resulting in scrams and unnecessary actuations of safety-related systems are minimized.
 - (a) Where failures are likely to cause loss of an intended function, monitoring should be predictive in nature, providing early warning of degradation.
 - (b) Monitoring activities for specific SSCs can be performance oriented (such as the monitoring of reliability and availability), condition-oriented (parameter trending), or both.
 - (c) The results of monitoring are required to be evaluated against the licensee-established goals. Goals should be established commensurate with an SSC's safety significance.
 - (d) Where available, the assumptions in and results of probabilistic risk assessments (PRAs) or individual plant examinations (IPEs) should be considered when establishing goals.
3. SSCs which are treated under paragraph (a)(1) may have formally established reliability and availability goals against which they are explicitly monitored, where goals of this nature are appropriate. In addition, and regardless of the nature of the monitoring and goals established to satisfy paragraph (a)(1), reliability and availability over the longer term must be assessed periodically pursuant to the requirements of paragraph (a)(3), as part of the evaluation of goals, monitoring requirements, and preventive maintenance requirements.

b. Paragraph (a)(2)

1. States that monitoring as specified in paragraph (a)(1) of this paragraph is not required where it has been demonstrated that the performance or condition of a structure, system, or component is being effectively controlled through the performance of appropriate preventive maintenance, such that the structure, system, or component remains capable of performing its intended function.
2. The SOC for this paragraph indicates that the purpose of paragraph (a)(2) is to provide an alternate approach (a preventive maintenance program) for those SSCs where it is not necessary to establish the monitoring regime required by (a)(1).

- (a) Under the terms of paragraph (a)(2), preventive maintenance must be demonstrated to be effective in controlling the performance or condition of an SSC such that the SSC remains capable of performing its intended function.
- (b) It is expected that, where one or more maintenance-preventable failures occur on SSCs treated under this paragraph, the effectiveness of preventive maintenance is no longer demonstrated. As a result, the SSCs would be required to be treated under the requirements of paragraph (a)(1) until such time as a performance history is established to demonstrate that reliability and availability are once again effectively controlled by an established preventive maintenance regimen.
- (c) Once such a demonstration has been made, it would be acceptable to return to treating the SSCs under paragraph (a)(2).

c. Paragraph (a)(3)

1. Requires that performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle provided the interval between evaluations does not exceed 24 months. The evaluations shall be conducted taking into account, where practical, industry-wide operating experience. Adjustments shall be made where necessary to ensure that the objective of preventing failures of structures, systems, and components through maintenance is appropriately balanced against the objective of minimizing unavailability of structures, systems, and components due to monitoring or preventive maintenance.
2. The SOC for this paragraph indicates that this provision requires that SSCs performance or condition goals, performance or condition monitoring, and preventive maintenance activities implemented pursuant to paragraphs (a)(1) and (a)(2) be evaluated in light of SSCs' reliabilities and availabilities.
 - (a) In the case of SSCs treated under paragraph (a)(1), adjustments are to be made to goals, monitoring, or preventive maintenance requirements where equipment performance or condition have not met established goals.
 - (b) Conversely, at any time the licensee may eliminate monitoring activities initiated in response to problematic equipment performance or industry experience once the root cause of the problem has been corrected or the adequacy of equipment performance has been confirmed.
 - (c) In the case of SSCs treated under paragraph (a)(2), adjustment of preventive maintenance requirements may be warranted where SSCs availability is judged to be unacceptable.
 - (d) SSCs which are treated under paragraph (a)(1) may have formally established reliability and availability goals against which they are explicitly monitored, where

goals of this nature are appropriate. In addition, and regardless of the nature of the monitoring and goals established to satisfy paragraph (a)(1), reliability and availability over the longer term must be assessed periodically pursuant to the requirements of paragraph (a)(3), as part of the evaluation of goals, monitoring requirements, and preventive maintenance requirements.

d. Paragraph (a)(4)

1. Requires that before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.
2. The SOC for this paragraph indicates that the intent of this requirement is to have licensees appropriately assess the risks related to proposed maintenance activities that will directly, or may inadvertently, result in equipment being taken out of service and then, using insights from the assessment, suitably minimize the out-of-service time resulting from the proposed maintenance activities while also controlling the configuration of the total plant to maintain and support the key plant safety functions.
 - (a) In general, a risk assessment is necessary before all planned maintenance activities. Assessments should also be performed when an unexpected SSC's failure initiates required maintenance activities or when changes to plant conditions affect a previously performed assessment. However, the reevaluation of a previous assessment should not interfere with, or delay, the plant staff's taking timely actions to restore the appropriate SSCs to service or taking compensatory actions necessary to ensure that plant safety is maintained. If the SSC is restored to service before performing the assessment, the assessment need not be conducted.
 - (b) Assessments may vary from simple and straightforward to highly complex. However, the degree of sophistication required for the assessment notwithstanding, the NRC intends that the assessment process will examine the plant condition existing before the commencement of the maintenance activity, examine the changes expected by the proposed maintenance activity, and identify the increase in risk that may result from the maintenance activity. The assessments are expected to provide insights for identifying and limiting risk-significant maintenance activities and their durations.
 - (c) The level of complexity necessary in the assessment would be expected to differ from plant to plant, as well as from configuration to configuration, within a given plant. When a licensee proposes to remove a single SSC from service for maintenance while no other SSC is out of service, a simple deterministic assessment may suffice. If the SSC is covered by TS, then the assessment could be as simple as an expert judgement, along with confirming the relevant requirements of TS. When one SSC is

- out of service and the licensee proposes to remove a second SSC from service for maintenance, the assessment could be simplified through the use of a table of results for pre-analyzed combinations, typically high-safety-significant SSCs paired against each other. However, more detailed assessments are required if a licensee proposes to remove multiple SSCs from service during power operations or to remove from service systems necessary to maintain safe shutdown during shutdown or startup operations. These more detailed assessments are expected to involve probabilistic analyses where possible, and to also include considerations of key plant safety functions to be maintained and defense in depth.
- (d) In general, the NRC expectation regarding managing the risk is a scrutable process for controlling or limiting the risk increase of the proposed maintenance activities. This process should include an understanding of the nature (i.e., affecting the core damage, or large early release frequency) and significance of the risk implications of a maintenance configuration on the overall plant baseline risk level. For example, risk-significant plant configurations should generally be avoided, as should conditions where a key plant safety function would be significantly degraded while conducting maintenance activities. The effective control of potentially significant risk increase due to an unexpected failure of another risk-important SSC can be reasonably assured by planning for contingencies, or coordinating, scheduling, monitoring, and modifying the duration of planned maintenance activities.
- (e) The second sentence in the new (a)(4) paragraph states: “The scope of the assessments may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.” In response to public comments on the proposed rule, this second sentence has been added so that licensees may reduce the scope of SSCs subject to the pre-maintenance assessment to those SSCs which, singularly or in combination, can be shown to have a significant effect on the performance of key plant safety functions. The focus of the assessments should be on the SSCs modeled in the licensee’s *PRA*, in addition to all SSCs evaluated as risk significant (high safety-significant) by the licensee’s maintenance rule expert panel. Typically, these SSCs have been analyzed as causing potential initiating events, if failed, and as accident mitigators, or as high safety-significant SSCs with their support systems. Such SSCs may be identified by operating experience or by deterministic or probabilistic analyses.
- (f) The rule has no explicit documentation requirements. Instead, the rule emphasizes performance. A licensee’s assessment process is expected to identify the impact on safety that is caused by the performance of maintenance. Licensees should use documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately.

e. Paragraph (b)(1)

1. Requires SSCs that are relied upon, to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, and the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 50.34(a)(1) or 100.11 of this chapter, as applicable.
2. The SOC indicates that the scope of SSCs subject to the final maintenance rule includes safety-related SSCs, and certain "non-safety" SSCs in the balance of plant (*BOP*) which meet one or more of four specific criteria, that include one general safety-related criterion described in (b)(1), and three non-safety related criteria described in (b)(2).

f. Paragraph (b)(2)

1. Requires the inclusion of non-safety related SSCs: (i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (*EOPs*); or (ii) Whose failure could prevent safety-related structures, systems, and components from fulfilling their safety-related function; or (iii) Whose failure could cause a reactor scram or actuation of a safety-related system.
2. The SOC indicates that the scope of SSCs subject to the final maintenance rule includes safety-related SSCs, and certain "non-safety" SSCs in the BOP which meet one or more of four specific criteria, that include one general safety-related criterion described in (b)(1), and three non-safety related criteria described in (b)(2).

f. Paragraph (c)

1. Requires that the requirements of this section be implemented by each licensee no later than July 10, 1996.

7.12 Safeguards

This section provides specific guidance concerning enforcement practices for safeguards issues. Supplement III of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

7.12.1 Compliance With the Security Plan Versus 10 CFR Part 73

- a. Licensees subject to the requirements of 10 CFR Part 73.25, 73.26, 73.40, 73.45, 73.46, and 73.55 must submit security plans to the NRC for approval.

1. Once these plans are approved, they are incorporated into the license by amendment and the licensee is required to meet the approved plans.
2. While citations for violations of these plan requirements must be made against the applicable section of the NRC-approved Security Plan and not against Part 73, citations may indicate the connection between the Security Plan and Part 73.
 - (a) This limitation does not apply to orders while they remain in effect.
 - (b) Violations of the requirements in an order may always be cited against the specific requirements contained in the respective order.
3. Changes to the Security Plan that reduce the effectiveness of the plan (that are made without NRC's permission), should be assigned a severity level.

☛ If changes to the Security Plan result in additional issues, these can be assessed and assigned a color using the SDP process.
- b. If there is a conflict between the requirement(s) in a plan, a regulation, or an order, NSIR, NRR or NMSS (as appropriate) should be consulted.
- c. Citations against the general performance criteria of 10 CFR 73.55(a) may be viable. Any such violations should be coordinated with OE and NRR prior to issuance.
- d. Other general sections of Part 73 (e.g., those governing the reporting of safeguards events and the protection of safeguards information) remain in force even when licensees insert references to these requirements in their security plans.

7.12.2 Access Control

- a. **Access control** is not only limited to protected and vital area barriers, but also includes all security measures employed to ensure that unauthorized persons, vehicles, and materials are excluded from entry into the protected and vital areas.
- b. The severity level of an access control violation may be determined by considering the following factors:
 1. The ease of exploitation of the **vulnerability** created by the violation, compounded by its predictability.
 - (a) In determining the vulnerability of a protected or vital area barrier, one must consider whether it could be seen by a potential adversary as being vulnerable based on, e.g., the height of fencing, delay barriers, security force separation from the objective, ease and opportunity to achieve a hostile objective, time and/or opportunity available to execute an assault, etc.

- (b) **Predictability** refers to the ease with which an adversary can anticipate an opportunity, e.g:

Since the operational status of an alarm system is not usually apparent to a potential adversary, the fact that a particular alarm zone would not have detected an unauthorized intrusion for a short period of time will probably not be obvious, and therefore, the vulnerability is less significant.

The absence of a search of particular types of containers by security staff would create predictability that could be exploited by an adversary, and therefore, the vulnerability is more significant.

- (c) **Ease of passage** of a vulnerability refers to the type of opening and the environment in or surrounding a pathway, e.g.:

☞ The significance of a vital area barrier breach is extremely important in that the vital area barrier is the final barrier.

If the pathway is an underground tunnel that has many twists and turns, or one that has sudden vertical drops or climbs, a simple 96-square-inch standard may not be appropriate, since the diameter of such a tunnel would be inadequate to allow an adversary to maneuver along the inside of it. Ease of passage may also refer to whether the opening is under water.

- b. When considering **ease of exploitation**, the following elements of barrier, monitoring, and response should be weighed:

1. **Barrier Integrity:**

- (a) The integrity of the barrier may be compromised by breaches in that barrier, but it may also be compromised by procedural errors or improper design or installation.
- (b) Lost keys and/or lost keycards have the potential to allow unauthorized and undetected access to controlled areas of a plant. The significance of such violations is a function of:
- (1) Whether the keys/keycards were truly lost;
 - (2) Whether the keys/keycards were marked to indicate the areas to which they allowed access;
 - (3) Whether and when the keys/keycards were recovered; and
 - (4) Whether there is any evidence that the keys/keycards has been used before they were recovered.

- (c) The significance of underground pathways allowing access to controlled areas is discussed in Information Notice 86-83 (September 19, 1986).

2. **Compensatory Measures for Unlocked/Unalarmed Portals:**

The significance of security personnel being inattentive while posted as compensatory measures is determined by what functions such personnel are intended to provide.

- (a) If a security force member is posted at a door that is normally alarmed and locked as compensation for the alarm annunciation function, if the security force member is inattentive, only one element of access control is inadequate.
- (b) If a security force member is posted at a door for the controlled access logging function as well as compensation for the alarm annunciation function, if the security force member is inattentive, two elements of access control are inadequate.

7.12.3 Access Authorization Program

- a. A licensee's ability to implement its safeguards security program is based, in significant part, on the its access authorization program.
 - 1. The successful completion of the elements of the access authorization program are critical to ensuring that the safeguards security program can be implemented as required.
 - 2. Violations or licensee requirements implementing 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants," should be assessed using the Physical Protection Significance Determination Process (PPSDP), unless these violations are wilful or deliberate, in which case they should be assessed as discussed in Chapter 6 of this manual.
- b. **Authorization versus Clearance for Access:**
 - 1. Individuals are considered cleared for access as soon as all required background investigations, evaluations, and fitness-for-duty actions have been successfully completed. At that point, however:
 - (a) Individuals do not have authorized unescorted access and do not have such access until they are added to the licensee's authorized access list and are issued a proper badge; and
 - (b) Actual entry of a cleared but as-yet unauthorized individual is a violation. Note, however, that this violation is not as significant as actual entry of an uncleared, unauthorized individual.

c. Improper Access by Authorized or Other Persons:

1. Employees who have been properly cleared and authorized for access to the site must still enter the protected area and vital/material access areas properly.
 - (a) Failing to properly log in to a vital area by tailgating, i.e., following another employee into the area without properly logging in, is a violation although it is usually assessed as a Severity Level IV violation.
 - (b) It is more significant if a person is improperly allowed access to an area where the need for access to that area has not been determined.
 - (c) It is very significant if a person uses another person's identification to gain access to an unauthorized area, or if a person has been terminated for cause and still gains access to a protected or vital area following that termination.

d. Vital Areas Within Vital Areas:

1. Two barriers are required at power reactors, while three barriers are required at Category I fuel facilities, i.e., a parameter barrier and one or two vital area barriers.
2. As a general rule, when vital areas are contained within other vital areas, the barrier and access control requirements are not required at the inner-most barrier.
 - (a) The licensee is only required to have one vital area barrier to protect all vital areas.
 - (b) The inner barrier and access control functions must be fully operative at only the necessary vital area barrier.

☞ If an inner vital area barrier remains intact while the outer vital area barrier is discovered to have vulnerabilities, there is no violation unless the failed outer barrier allows access to vital equipment.

7.12.4 Searches

- a. Searches of individuals, vehicles, and packages are considered inadequate if they are not able to detect the items for which they are conducted, e.g.: a vehicle search must include an examination of the inside of the glove compartment and the undercarriage, motor area, storage areas and the area under the seats.

✓ It is not sufficient to conclude that an item is not contraband or is not otherwise prohibited merely because it cannot be identified through the normal electronic or video search process.

- b. Searches of hand carried items or shipping packages are considered inadequate if they are not able to identify items to the extent that such items can be excluded as contraband or as items that are otherwise prohibited.
- c. When a vehicle that has entered the site is later found to have contained contraband (i.e., weapons, drugs, or explosives of any kind) in an accessible area, the presumption is that the search was inadequate.

7.12.5 Protection of Safeguards Information

- a. When safeguards information is not properly protected from compromise, the severity level of the violation is a function of:
 - 1. The location of the material during the time it was not controlled;
 - 2. The significance of the material;
 - 3. The amount of time left uncontrolled; and
 - 4. The opportunity for compromise of the material while it was uncontrolled.
- b. The following examples illustrate the significance of a violation involving safeguards information that is not properly controlled:
 - 1. If safeguards information had been left in an unlocked container within the locked and continuously-staffed primary access control point, this violation is less significant than if the safeguards information had been left in an uncontrolled area inside the protected area.
 - 2. If safeguards information had been left uncontrolled and outside of a protected area, this violation is more significant than if the safeguards information had been left uncontrolled and inside a protected area.
 - 3. A violation involving safeguards information that has been left uncontrolled is more significant when it is :
 - (a) Sufficiently extensive; or descriptive of the security system as to significantly assist an adversary in an act of radiological sabotage or theft of strategic special nuclear material (SSNM), this violation is more significant than if the safeguards information would not have significantly assisted the adversary.

7.12.6 Protection Against Vehicle Bomb Threats*

- a. 10 CFR 73.55(c)(7) requires licensees to establish vehicle control measures, including vehicle barrier systems, to protect against land vehicle intrusion.
- b. 10 CFR 73.55(c)(8)(I) requires licensees to confirm to the Commission that vehicle control measures established to protect against land vehicle intrusion meet the design goals and criteria specified for protection against a land vehicle bomb.
- c. Under 10 CFR 73.55(c)(8)(ii), licensees may propose alternative measures for protection against a vehicle bomb that would then be subject to review and approval by the NRC.
 1. This is common in the area of physical security and 10 CFR 73.55 already provides for such alternative measures.
 2. By allowing licensees to propose alternative measures for protection against a vehicle bomb, the Commission is allowing them to change the focus of compliance from the rule to the approved plans submitted by licensees.
- d. 10 CFR 73.55(c)(9) requires that licensees submit a summary description of the proposed vehicle control measures within 180 days of the effective date of the rule and fully implement the measures by within 18 months of the effective date.
- e. Violations of 10 CFR 73.55(c)(8)(I) and (9)(I) should be treated in the same manner as any other incomplete and/or inaccurate statement, i.e., under 10 CFR 50.9 and Supplement VII, examples A.1, A.2, B.1, B.2, C.1, C.2, D.1, and D.2.
- f. Violations of 10 CFR 73.55(c)(8)(ii) should also be treated as incomplete and/or inaccurate statements, to the extent that they do not accurately "describe the level of protection that these measures would provide."

* In addition to the 10 CFR 73.55 reference cited above, the NRC has issued [orders](#) modifying license conditions addressing land vehicle assaults as well as waterborne assaults. These orders should be consulted prior to issuing any enforcement action involving these license conditions.

7.12.7 Citations Against 10 CFR Part 50, Appendix B

- a. Appendix B of 10 CFR Part 50 addresses quality assurance criteria for nuclear power plants and fuel reprocessing plants.

✓ Any citations against 10 CFR Part 50, Appendix B in the safeguards area should be coordinated with OE prior to issuance.

1. Appendix B applies to SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

2. The provisions of Appendix B do not generally apply to the safeguards area.
- b. If the region desires to use the Appendix B criteria as the basis for a citation in the safeguards area, it will have to include in the citation sufficient facts and discussion to support the position that the procedure in question is necessary to assure, in the event of an accident, "adequate confidence that a structure, system, or component will perform satisfactorily in service."

7.13 Emergency Preparedness

This section provides specific guidance concerning enforcement practices for emergency preparedness issues.

- a. Normally emergency preparedness findings are evaluated through the SDP and enforcement actions are taken based on the SDP outcome.
- b. If findings are not addressed through the SDP, Supplement VIII of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

7.14 10 CFR 50.54 Deficiency Grace Period

- a. The significant provision of the regulations in this area is 10 CFR 50.54(s)(2)(ii) which provides a four-month grace period for correction of deficiencies that rise to such a level that the Commission may make a finding that the state of emergency preparedness no longer provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.
 1. The grace period represents a recognition by the Commission that many elements of emergency planning involve complex arrangements and interactions with local, State, and Federal entities, much of which is beyond a licensee's direct control.
 2. The grace period reflects an acknowledgment that the licensee's degree of control in the emergency planning area is significantly less than that in the areas of reactor health and safety.
 3. Even where there are significant deficiencies in emergency plans and a formal finding to that effect is made, a grace period should be allowed for corrective action. See County of Rockland v. U.S. Nuclear Regulatory Commission, 709 F.2d 766, 770-771 (2nd Cir. 1983).
- b. The policy underlying the grace period strongly suggests that it was intended to apply to emergency planning deficiencies which can be remedied only in cooperation with State and local officials.

1. If plans are adequate, in place, and capable of implementation, but the licensee failed to implement the plans either during a drill or an actual emergency, no grace period should be necessary to remedy the deficiency.
2. In the Statements of Consideration (SOC) supporting the initial rule (45 FR 55402, August 19, 1980), the Commission discussed how it would apply the grace period, and, in considering plan deficiencies, indicated that it would consider local, State, and licensee plans to see if the features in one plan could compensate for deficiencies in another plan.
 - (a) If an emergency planning deficiency can be remedied only in cooperation with State and local officials, enforcement action should await the expiration of the grace period.
 - (b) The EDO is to be notified before establishing the grace period and should concur on the enforcement action.
 - (c) If the deficiency is of such a nature that cooperation with State and local officials is not necessary to remedy the deficiency, then the grace period does not apply and the matter may be pursued.

7.15 Enforcement Actions Involving Fitness-For-Duty (FFD)

- a. The requirements in 10 CFR Part 26 addressing fitness-for-duty (FFD) programs apply to licensees authorized to:
 1. Operate a nuclear power reactor;
 2. Possess or use formula quantities of SSNM; or
 3. Transport formula quantities of SSNM.
- b. The requirements in 10 CFR Part 55 requires that licensed operators follow FFD programs.
 1. Each FFD issue must be evaluated to determine whether enforcement action should be issued against:
 - (a) The facility licensee for failure to adequately implement a program; or
 - (b) Against the individual licensed operator for failure to follow the program.

7.15.1 Action Against the Facility Licensee for FFD Violations

- a. Licensees subject to 10 CFR Part 26 must establish and implement a FFD program.
 1. The program must provide, among other things, that there is reasonable assurance that nuclear power plant personnel, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM:
 - (a) Will perform their tasks in a reliable and trustworthy manner;
 - (b) Are not under the influence of any substance, legal or illegal; or
 - (c) Mentally or physically impaired from any cause which in any way adversely affects their ability to safely and competently perform their duties.
- b. In citing the facility licensee, it is important to note that it is not the unfit person that establishes the violation but rather the licensee's failures to implement the FFD program, including those of its contractors and vendors, that creates the violation.
- c. Enforcement actions against facility licensees should be prepared and processed in accordance with the standard guidance for escalated and non-escalated actions.
 1. The significance of a FFD finding at an operating power reactor should be assessed by the ROP's SDP.
 2. The significance of a FFD violation for all other licensees should be assessed in accordance with the guiding principles for assessing significance in the Enforcement Policy and the examples in the Enforcement Policy Supplements.
- d. The Enforcement Policy provides examples of violations where the facility licensee failed to meet the requirements of 10 CFR Part 26.
 1. The failure of a licensee to have a FFD program in place is an example of a Severity Level I violation. This violation would be of very significant concern to the NRC because it represents the failure to implement a FFD program.
 2. The failure to take action when there is the potential to have a direct impact on safety-related activities is the basis of the examples for Severity Level II. These are also of very significant concern to the NRC.

☞ If the licensee has effectively implemented its FFD program meeting NRC requirements and, based on behavior observation, identifies and removes a person not fit for duty, there may not be a regulatory violation.

3. Because of failures in an established FFD program that were directly within the licensee's control, an individual who should have been denied access to an area was able to gain access. This is an example of a Severity Level III violation.
 - (a) Typically, these failures would be more significant if the individual improperly granted access is later confirmed to test positive for illegal drug use.
 - (b) A failure to ensure that specimens collected in accordance with 10 CFR Part 26 are not used for purposes other than those provided by the rule without the permission of the tested individual may also be considered a significant violation.
4. Violations which, while requiring corrective action, are less significant to the overall FFD program, are normally assessed as Severity Level IV violations.

7.15.2 Action Against the Licensed Operator for FFD Violations

- a. 10 CFR Part 55 sets forth the requirements for issuance of licenses to individuals to operate nuclear power plants, including the conditions and cutoff levels established pursuant to the Commission's FFD programs, or the licensee's program if the cutoff levels are lower, that are applicable to licensed operators as conditions of their licenses. Therefore, citing the individual operator would be appropriate the determination is made by either the established testing protocols or the Medical Review Officer (MRO), that the individual is unfit for duty.
- b. The Enforcement Policy addresses appropriate enforcement actions against individual licensed operators who fail to meet FFD requirements.
 1. Licensed operator's confirmed positive test for drugs or alcohol:
 - (a) There may be cases where the NRC chooses to exercise discretion and issue a Severity Level IV violation, e.g., where a licensed operator self-reports his or her regulatory noncompliance.

☞ Prior to issuance of an order to the licensed operator, the region should inform him/her of the impending order, and provide an opportunity (typically 10 days) to respond in writing why the order should not be issued.
 - (b) The second time the licensed operator fails a drug test, an order suspending the 10 CFR Part 55 license for up to three years will normally be issued. If the license has less than three years left before it must be renewed, consideration should be given as to whether the license should be renewed.
 - (c) Second and subsequent violations of the licensee's FFD policy involving alcohol should be reviewed to determine if an order should be issued suspending the individual operator's 10 CFR Part 55 license.

2. An order would normally be issued revoking the Part 55 license whenever a licensed operator refuses to participate in the facility licensee's FFD program or is involved in the sale, use, or possession of illegal drugs.
- c. All enforcement actions issued to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level):
1. Are required to be paneled;
 2. Require EA numbers during the review and approval stages; and
 3. Require IA numbers when the actions are issued.

7.15.2.1 Preparing FFD Actions

- a. Fitness-for-duty actions against licensed operators are not processed like other escalated actions.
1. Licensed operators' failures to meet FFD requirements are typically reported to the NRC by facility licensees.
 2. The NRC will normally take enforcement action based on this notification without conducting an inspection.
 3. Despite the normal policy of holding a PEC prior to issuing action against an individual, a PEC is not normally held for FFD issues against a licensed operator.
 4. A PEC is not normally held prior to issuing escalated action against a licensee for a FFD issue.
 - (a) This is, in part, due to the NRC basing its enforcement action on notification from the licensee.
 - (b) Licensed operators are provided an opportunity to contest the action after it has been issued.
 5. The regions should prepare the enforcement package consisting of either the enforcement action transmittal letter and NOV or the combination transmittal letter and NOV (see the forms in Appendix B). The second option would be used when the facility licensee causes the licensed operator's license to expire.
- b. In drafting the citation, it is important to note that the licensed operator may be in violation of Part 55 license conditions, including, e.g., the licensee's:

1. Failure to observe an applicable rule, regulation or order of the Commission (10 CFR 55.53(d));
 2. Use, sale, or possession of illegal drugs or use of alcohol (10 CFR 55.53(j)); or
 3. Refusal to participate in the facility licensee's FFD program (10 CFR 55.53(k)); or
- b. For violations of 10 CFR 55.53(j), i.e, use, sale, or possession of illegal drugs or use of alcohol, two separate situations are possible:
1. The licensed operator uses, possesses, or sells illegal drugs, or consumes alcohol within the protected area; or
 2. The licensed operator performs licensed duties while under the influence of any substance that could adversely affect an operator's ability to safely and competently perform licensed duties.
- c. To have submitted a urine sample that will test positive and then to perform licensed activities are two separate actions; however, given the close relationship between action and result, it is sufficient to cite both requirements and include both violations in the "Contrary to" paragraph as examples of the same Severity Level III violation, e.g.:

☞ Section 55.53(j) states that "under the influence" includes a licensed operator exceeding, "as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A . . . or as established by the facility licensee;" therefore, performing duties immediately before or after submitting a urine sample that later tests positive would be considered performing duties "under the influence."

10 CFR 55.53(j) prohibits the use of (illegal drug used in this case) and prohibits the licensee from performing activities authorized by a license issued under 10 CFR Part 55 while under the influence of (illegal drug used in this case). "Under the influence" is defined in 10 CFR 55.53(j) to mean that the "licensee exceeded, as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A, of this chapter, or as established by the facility licensee."

Contrary to the above, the licensee violated 10 CFR 55.53(j), as evidenced by the following examples:

- a. The licensee used (substance) as evidenced by a confirmed positive test for that drug resulting from a urine sample submitted on (date); and

- b. The licensee performed licensed duties on (date) immediately before (after) the submission of a urine sample which indicated that the licensee was under the influence of alcohol (name of drug).

This is a Severity Level III violation. (Supplement I)

- d. For violations of 10 CFR 55.53(k)), i.e., refusing to participate in the facility licensee's FFD program, the citation should use the following format:

10 CFR 55.53(k) requires that licensed operators participate in the drug and alcohol testing programs established by the Part 50 licensee pursuant to 10 CFR Part 26.

Contrary to the above, on (date), the licensee did not participate in (cooperate with) the Part 50 drug (alcohol) program on (date) in that [describe what happened].

This is a Severity Level III violation. (Supplement I)

7.15.2.2 Coordination and Review for FFD Actions

- a. Fitness-for-duty actions should be coordinated and reviewed according to the following guidelines:
 1. OE, the operator licensing staff in NRR, and NSIR should be consulted early in the process when the region has determined that a reactor operator may have violated the facility licensee's FFD program, refused to participate, or violated other conditions of his or her license with regard to FFD concerns.
 2. All cases when enforcement action is being considered to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level), require:
 - (a) A panel which OE, the operator licensing staff in NRR, and NSIR should participate in;
 - (b) An EA number during the review and approval stages; and
 - (c) An IA number when the action is issued.
- b. Routine cases (i.e., cases where there is no evidence of long-term drug use or alcohol abuse and where the facts do not warrant referral for investigation) that are not required to be sent to headquarters for formal review and approval prior to issuance should be coordinated as follows:
 1. Subsequent to an enforcement panel, OE will complete the Strategy Form and send it to the region and the NRR and NSIR Enforcement Coordinators.

2. The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary).
 3. If there are additional discussions with the Regional Administrator and the Director, OE, the Strategy Form may need to be amended to represent the agreed upon strategy.
 4. If there are disagreements on the overall enforcement strategy, OE may request that the region submit the entire action (including the transmittal letter) to OE for formal review and approval prior to issuance.
 5. Regional Counsel review and statement of no legal objection is required prior to issuance by the region.
 6. The region should send OE the complete enforcement package after it has issued the action.
- c. Non-routine cases (including cases involving an exercise of discretion, requiring DEDO approval or Commission consultation, or involving the misuse of prescription and over-the-counter drugs), are sent to headquarters for full enforcement action package review and approval prior to issuance.
- d. OE may also request that a case be submitted to headquarters for full enforcement action package review and approval prior to issuance subsequent to an enforcement panel.
- e. OGC will not normally provide comments for Severity Level III NOV's without a civil penalty or order.
1. OGC review and statement of no legal objection is required on all orders.
 - (a) OGC will review the proposed order and provide comments to OE within 5 working days of receipt of the package.
 - (b) Immediately effective orders should be expedited.
 2. The NRR Enforcement Coordinator should ensure that the operator licensing staff in NRR reviews the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety has been properly evaluated from an overall agency perspective.
 - (a) Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within five working days. The NRR Enforcement Coordinators normally provide comments for FFD cases.
 - (b) Comments on immediately effective orders should be expedited.
-

3. The NSIR Enforcement Coordinator should ensure that the staff in NSIR reviews the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety has been properly evaluated from an overall agency perspective.
 - (a) Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days. The NSIR Enforcement Coordinator normally provides comments for FFD cases.
 - (b) Comments on immediately effective orders should be expedited.
4. OE will consider timely OGC and program office comments and revise the enforcement action, as appropriate.
5. OE will forward the revised action to the region indicating where and why the action was revised.
6. The region should review the revised action and, if possible, provide concurrence on headquarter's changes by the next day.
7. OE will attempt to resolve any differences among the region, the program office, and OGC (if applicable) and will advise the DEDO during final review and approval.

7.15.2.3 Signature Authority for FFD Actions

FFD actions should be signed and issued according to the following guidelines:

- a. The Regional Administrator (or designee) normally signs and issues NOVs for Severity Level I violations, after review and approval by the Director, OE, the DEDO, and the Commission.
- b. The Regional Administrator (or designee) normally signs and issues NOVs for Severity Level II and III violations after either:
 1. Consultation with OE (usually via an enforcement panel or caucus--note that the Director, or Deputy Director, OE must concur on the Strategy Form); or
 2. Actual enforcement action package review and approval by the Director, OE.
- c. The DEDO normally signs all orders.

7.15.2.4 Licensee Notification, Mailing, & Distribution of FFD Actions

Licensee notification, mailing, and distribution should be made according to the following guidelines:

- a. Enforcement actions against licensed operators should be mailed to individuals by either Certified Mail (Return Receipt Requested) or Express Mail.
- b. **Enforcement actions against licensed operators (including any enclosures) should not be made available to the Public (ADAMS (PARS)) when they are originally issued.**

✓ Due to the personal and medical aspects of FFD violations, it is appropriate to delay making the action available to the Public until the individual has had an opportunity to rebut the conclusion.
- c. Copies of all FFD actions against licensed operators should be sent both to OE and the operator licensing staff in NRR.

7.15.2.5 Licensed Operator Response to FFD Action

- a. Licensed operators are generally required to respond to NOVs within 30 days.
- b. Licensed operators are not required to respond to NOVs where the operator's license has expired, unless the licensed operator contests the action.
- c. A licensed operator's responses to NOVs can either (a) accept the violation or (b) contest the staff's facts and conclusions regarding the NOV.
 1. **If the licensed operator does not dispute that the violation occurred as stated in the NOV:**
 - (a) The regional office is to review the licensed operator's response for the adequacy of the corrective action and should request additional information from the licensed operator if necessary.
 - (b) Licensed operator's responses should normally be acknowledged by the region within 30 days after their receipt.
 - (1) The acknowledgment letter should be sent to the licensed operator.
 - (2) A copy of the NOV, the operator's response, and the acknowledgment letter should be made available to the Public with the home address deleted.

2. If the licensed operator denies the violation:

- (a) The region should coordinate the agency's response to the licensed operator with OE.
- (b) The licensed operator's response should be carefully reviewed to ensure that the staff's initial action was appropriate.
- (c) The region should prepare a response to the licensed operator addressing the licensed operator's points of contention and the acceptability of the corrective action.
 - (1) If the licensed operator's response does not present additional information, then the region will prepare a brief response addressing the licensed operator's points of contention.
 - (2) Even if the licensed operator's response does not present new information, if an error in the enforcement action is identified, it must be corrected.

✓ The licensed operator's home address should be deleted from all documents made available to the Public.
 - (3) If the licensed operator provides a sufficient basis to withdraw the violation, then the violation should be withdrawn and not made available to the Public.
 - (4) The region should normally respond to the licensed operator's responses within 30 days.
- (d) If the staff review of the licensed operator's response concludes that the licensed operator did not provide a sufficient basis to withdraw the violation, or if the licensed operator has not replied within 30 days, the letter and NOV (without enclosures), and the operator's response, should then be made available to the Public.