NRC ENFORCEMENT MANUAL

Office of Enforcement
U.S. Nuclear Regulatory Commission
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Abstract

The NRC Enforcement Manual (Manual) is designed to assist the NRC staff in implementing the Commission's enforcement program. It is intended for internal use only by the NRC. As such, failure to follow the guidance in this Manual does not invalidate an enforcement action.

The Manual contains procedures, requirements, and background information that are essential to those who develop or review enforcement actions for the NRC. This Manual provides guidance consistent with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

This Manual revises and supersedes Rev. 3, "NRC Enforcement Manual," published in June 2000.

The Manual is intended to serve as a guidance tool for the professional staff who prepare, review, and coordinate enforcement actions. The Manual provides information relevant to each step in the escalated and non-escalated enforcement process for various NRC enforcement actions. Because some of the information for processing a particular action is similar to other actions, there is some repetition of information. This format was selected to be most helpful to users because it allows them to find all the needed information concerning a particular action in one place rather than having to follow a system of cross references.

The Manual also contains a variety of information, including standard formats and standard citations for NRC enforcement actions that should prove helpful to administrative, program support, and clerical personnel involved in the preparation or tracking of enforcement packages.

Because the enforcement process changes from time to time, the Manual is designed as a living document maintained on the NRC's public Web site www.nrc.gov (select **What We Do**, then **Enforcement**, then **Guidance Documents**). This strategy ensures that users will apply the most current guidance associated with various enforcement issues and activities. Change Notices are announced and individual changes that have been made in the Manual are identified and summarized in the Change Notice Index posted on the **Enforcement** Web site.

Questions concerning the use of the Manual, suggestions for improving the content or format of the Manual, or corrections of any errors or inconsistencies in the Manual, should be directed to Renée M. Pedersen, Senior Enforcement Specialist, Office of Enforcement.

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- APPENDICES -

Appendix A: Temporary Enforcement Guidance

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Abbreviations

ADAMS Agencywide Document Access and Management System
AEA Atomic Energy Act
AIT Augmented Inspection Team
ALJ Administrative Law Judge
ASLBP Atomic Safety and Licensing Board Panel (NRC)
CAL Confirmatory Action Letter
CEL "Chilling Effect" Letter
CFR Code of Federal Regulations
DEDE Deputy Executive Director for Regulatory Effectiveness
DEDO May refer to either the Deputy Executive Director for Regulatory Effectiveness or the Deputy Executive Director for Regulatory Programs
DEDR Deputy Executive Director for Regulatory Programs
DFI Demand for Information
DHR decay heat removal
DOJ Department of Justice
DOL Department of Labor
DOT Department of Transportation
EA enforcement action
EATS Enforcement Action Tracking System
EDO Executive Director for Operations
EGM enforcement guidance memorandum
EN Enforcement Notification
ERA Energy Reorganization Act
FFD Fitness-For-Duty
FOIA Freedom of Information Act
FR *Federal Register*
FSAR final safety analysis report
GDC general design criterion
IA individual action
I&C instrumentation and control
IFS Inspection Finding System
IIT Incident Investigation Team
LER licensee event report
LOR Letter of Reprimand
MC NRC Manual Chapter
MC&A material control and accounting
MD NRC Management Directive
MOU Memorandum of Understanding
NCV Non-Cited Violation
NMSS Office of Nuclear Materials Safety and Safeguards
NOD Notice of Deviation
NOED Notice of Enforcement Discretion
NON Notice of Nonconformance
NOV Notice of Violation
NRC Nuclear Regulatory Commission
NPR Non-Power Reactor
NRR Office of Nuclear Reactor Regulation
NSIR Office of Nuclear Security and Incident Response

OE	Office of Enforcement
OGC	Office of the General Counsel
OI	Office of Investigations
OIG	Office of the Inspector General
OL	operating license
OPA	Office of Public Affairs
OSHA	Occupational Safety and Health Administration
PARS	Publicly Available Records System
PCRM	primary containment radiation monitoring
PIM	Plant Issues Matrix
QA	quality assurance
RCS	reactor coolant system
ROP	reactor oversight process
RPAO	Regional Public Affairs Officer
RSO	radiation safety officer
SALP	systematic assessment of licensee performance
SAR	safety analysis report
SDP	significance determination process
SEN	Special Enforcement Notification
SER	safety evaluation report
TS	technical specification
VA	Department of Veterans Affairs

Introduction

The Commission has developed an enforcement program and Enforcement Policy to support the NRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement action should be used as a deterrent to emphasize the importance of compliance with regulatory requirements, and to encourage prompt identification and prompt, comprehensive correction of violations.

Violations are identified through inspections and investigations. All violations are subject to civil enforcement action and may also be subject to criminal prosecution. After an apparent violation is identified, it is assessed in accordance with the Commission's Enforcement Policy. The Policy is published as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions," to provide widespread dissemination. Because it is a policy statement and not a regulation, the Commission may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

There are three primary enforcement sanctions available: Notices of Violation, civil penalties, and orders. A Notice of Violation (NOV) identifies a requirement and how it was violated, and formalizes a violation pursuant to 10 CFR 2.201. A civil penalty is a monetary fine issued under authority of Section 234 of the Atomic Energy Act (AEA) or Section 206 of the Energy Reorganization Act (ERA). Section 234 of the AEA provides for penalties of up to $100,000 per violation per day; but that amount has been adjusted by the Debt Collection Improvement Act of 1996 to be $120,000. The Commission's order issuing authority under Section 161 of the AEA is broad and extends to any area of licensed activity that affects the public health and safety. Orders modify, suspend, or revoke licenses or require specific actions by licensees or persons. As a result of a rulemaking in 1991, the Commission's regulations now provide for issuing orders to persons who are not themselves licensed. NOVs and civil penalties are issued based on violations. Orders may be issued for violations, or in the absence of a violation, because of a public health or safety issue.

The first step in the enforcement process is assessing the significance of a violation or issue. In assessing significance, the NRC considers four specific issues: actual safety consequences; potential safety consequences, including the consideration of risk information; potential for impacting the NRC's ability to perform its regulatory function; and any willful aspects of the issue. For certain types of violations at commercial nuclear power plants, the enforcement process relies on information from the reactor oversight process's Significance Determination Process (SDP). The SDP is used to evaluate the actual and potential safety significance of inspection *findings* to provide a risk-informed framework for discussing and communicating the significance of inspection findings. The final disposition of violations associated with findings that have been evaluated through the SDP is contingent on the risk significance attributed to the findings (assigned the colors of green, white, yellow, or red with increasing risk). Other violations are assigned a severity level to reflect their significance which then factors into the how the violation should be dispositioned. Severity Levels range from Severity Level I, for the most significant violations, to Severity Level IV for those of more than minor concern. Minor violations are so insignificant that they do not warrant enforcement action.

A predecisional enforcement conference may be conducted with a licensee before making an enforcement decision if escalated enforcement action (i.e., Severity Level I, II, or III violations, civil penalties or orders) appears to be warranted, and if the NRC concludes that it is necessary or the licensee requests it. If the NRC concludes that a conference is not necessary, it may provide a licensee with an opportunity to respond to the apparent violations before making an enforcement decision or issue the enforcement action if a civil penalty is not warranted. The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, such as: (1) a

common understanding of facts, root causes and missed opportunities associated with the apparent violations, (2) a common understanding of corrective action taken or planned, and (3) a common understanding of the significance of issues and the need for lasting comprehensive corrective action. The decision to hold a conference does not mean that the agency has determined that a violation has occurred or that enforcement action will be taken. In accordance with the Enforcement Policy, conferences are normally open to public observation.

Civil penalties are considered for Severity Level III violations and are normally assessed for Severity Level I and II violations and knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act.

The NRC imposes different levels of civil penalties based on a combination of the type of licensed activity, the type of licensee, the severity level of the violation, and (1) whether the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past 2 years or past 2 inspections, whichever is longer; (2) whether the licensee should be given credit for actions related to identification; (3) whether the licensee's corrective actions are prompt and comprehensive; and (4) whether, in view of all the circumstances, the matter in question requires the exercise of discretion. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or twice the base civil penalty.

If a civil penalty is to be proposed, a written Notice of Violation and Proposed Imposition of Civil Penalty is issued and the licensee has 30 days to respond in writing, by either paying the penalty or contesting it. The NRC considers the response, and if the penalty is contested, may either mitigate the penalty or impose it by order. Thereafter, the licensee may pay the civil penalty or request a hearing.

In addition to civil penalties, orders may be used to modify, suspend, or revoke licenses. Orders may require additional corrective actions, such as removing specified individuals from licensed activities or requiring additional controls or outside audits. Persons adversely affected by orders that modify, suspend, or revoke a license, or that take other action may request a hearing.

The NRC issues a press release with a proposed civil penalty or order. All orders are published in the *Federal Register*.

A graphical representation of the NRC's graded approach in assessing and dispositioning violations is included in Appendix D.

CHAPTER 1
GENERAL

1.1 Purpose of the Manual

This Manual promulgates detailed guidance and procedures to implement the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) published as NUREG-1600. Enforcement sanctions are issued in accordance with the Enforcement Policy and should be used as a deterrent to emphasize the importance of compliance with requirements, and to encourage prompt identification and prompt comprehensive correction of violations. The Enforcement Policy is published as NUREG-1600.

1.2 Applicability of the Manual

a. The NRC Enforcement Manual (Manual) applies to the Office of Enforcement (OE), the regional offices, the program offices (Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), and Office of Nuclear Security and Incident Response (NSIR)), and all other groups (special teams or task forces) involved in enforcement activities. It also describes the enforcement role of the Office of the General Counsel (OGC), with particular reference to the Associate General Counsel for Hearings, Enforcement, and Administration, and the Assistant General Counsel for Materials Litigation and Enforcement.

b. Most enforcement activities are initiated from the regional offices. For the purpose of structuring this Manual, therefore, it has been assumed, for the most part, that the regional office is the office initiating, recommending, or issuing enforcement action. However, all other offices that conduct inspections and determine compliance are to follow the appropriate guidance in this Manual. Therefore, the term region generally means in this Manual, the office initiating the action.

c. This Manual uses both mandatory and permissive terms. Permissive terms recognize the flexibility needed in the enforcement process. Terms such as "should" and "normally" establish the customary or expected course of action. To provide the necessary oversight and agency wide consistency, deviations from the guidance in this Manual are authorized as follows:

    1. Regional Administrators, the Associate Director for Inspection and Programs, NRR (for enforcement actions that NRR issues), and the Deputy Director, NMSS (for enforcement actions issued by NMSS), may authorize deviations from permissive provisions provided these deviations are discussed with OE. However, significant deviations require the prior approval of the Director, OE. This will permit OE the opportunity to monitor the adequacy of this guidance and consider whether a change to the existing guidance is necessary.

    2. The Director, OE, may authorize deviations from either the permissive or mandatory provisions. Where appropriate or necessary, the Director will consult and obtain approval of the Deputy Executive Director for Reactor Programs (DEDR),the Executive Director for Operations (EDO), and the Commission (through the EDO).

d. The guidance in this Manual is intended for internal use by the NRC. As such, **failure to follow the guidance in this Enforcement Manual does not invalidate an enforcement action**.

1.3 Distribution of the Manual

The Manual is no longer published in the NUREG series nor distributed in paper. In an effort to improve efficiency and effectiveness, the Manual is available to all employees as a living document maintained on the NRC's public Web site (select **What We Do**, then **Enforcement**, the **Guidance Documents)**. This approach ensures that users will apply the most current guidance associated with various enforcement issues and activities. While individuals may find it necessary to print out pages from this electronic text from time to time, given it's changing nature, the intent is not to have individuals printing out the entire document.

1.4 Enforcement Manual Changes

The Director, OE, may make changes to this Manual by announcing an NRC Enforcement Manual Change Notice. Changes to the Manual may add new enforcement guidance, clarify or amplify existing guidance, delete enforcement guidance, add temporary guidance, or correct administrative mistakes. Change Notices will be numbered sequentially from the issuance of a new Manual revision. Individual changes that have been made in the Manual are identified and summarized in the Change Notice Index posted with the Manual on the **Enforcement** Web site.

1.4.1 Enforcement Guidance Memoranda (EGMs) and Temporary Guidance in Appendix A

Because the enforcement process changes from time to time, expedited enforcement guidance may need to be issued. The normal method for the Director, OE, to issue expedited enforcement guidance is through the issuance of an EGM. EGMs may add guidance for Enforcement Policy application, revise existing guidance on processing enforcement actions, or transmit temporary guidance. EGMs normally introduce the new guidance with a brief background discussion and provide details of the new guidance and a discussion of application. Depending on the nature, complexity, and urgency of a proposed EGM, the Director, OE, will provide internal and external stakeholders an opportunity to comment on proposed EGMs before their issuance.

EGMs will be numbered sequentially during the year of issuance (e.g., 99-01, 99-02). Addendums or revisions to EGMs should retain the same EGM number and indicate the revision status and revision date. EGMs may identify the section of the Manual affected by the new guidance in parentheses after the subject title. To expedite the dissemination of new enforcement guidance, EGMs will be mailed to addressees and electronically transmitted to the Regional Administrators and the Regional and Program Office Enforcement Coordinators on the day of issuance. EGMs are distributed to the Commission, SECY, Regional Administrators, program offices, OGC, OI, and the EDO's office. EGMs are made available to the Public and posted on the **Enforcement** Web site.

The Director, OE, may also issue temporary guidance through memoranda to the staff on issues in early developmental stages in an attempt to develop permanent guidance.

EGMs and temporary guidance that are in effect at the time of a full revision of the Manual that are not otherwise addressed in the Manual, will be included in Appendix A. EGMs and other temporary guidance will be routinely reviewed to determine whether they should be retained as temporary guidance, issued as permanent guidance, or discontinued. Permanent guidance will subsequently be addressed in a Change Notice.

1.5 Application of the Enforcement Policy During Periods of Change

The General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy) is published as NUREG-1600. While this Manual provides detailed guidance on the implementation of the enforcement program, the Enforcement Policy represents the agency's official statement of policy for enforcement actions, and as such, takes precedence over this Manual. In the event the agency finds it necessary to revise the Enforcement Policy, the revised Enforcement Policy will be published in the *Federal Register* and will take precedence over the version published in the latest bound edition of NUREG-1600. Normally the Enforcement Policy in effect at the time a violation occurs is the policy that is applied. However, if the revised Enforcement Policy reduces the significance and/or civil penalty amount for a particular case, the NRC may choose to apply the latest version of the Enforcement Policy, regardless of whether the violation occurred before the policy change. Exercise of this discretion requires prior consultation with OE. Guidance related to the proper method of citing the Enforcement Policy in enforcement actions is provided in Appendix B of this Manual.

1.6 Definitions

The following terms are applicable to the enforcement program.

Apparent violation: A potential noncompliance with a regulatory requirement (regardless of possible significance or severity level) that has not yet been formally dispositioned by the NRC. Apparent violations may end up dispositioned as Non-Cited Violations, cited in Notices of Violation, or issued in conjunction with civil penalties or various types of orders. The NRC may also choose to exercise mitigation discretion in accordance with Section VII.B of the NRC Enforcement Policy and refrain from issuing enforcement action.

Deviation: A licensee's failure to satisfy a written commitment, such as a commitment to conform to the provisions of applicable codes, standards, guides, or accepted industry practices when the commitment, code, standard, guide, or practice involved has not been made a requirement by the Commission.

Escalated Enforcement Action: A Notice of Violation or civil penalty for any Severity Level I, II, or III violation (or problem); a Notice of Violation associated with an inspection finding that the reactor oversight's significance determination process characterizes as having low to moderate, or greater, safety significance (i.e., white, yellow, or red); or any order based upon a violation.

Event: As used in the enforcement program, an "event" means (1) an event characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, or (2) a radiological impact on personnel or the environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above NRC limits, or a loss of radioactive material. For example, an equipment failure discovered through a spill of liquid, a loud noise, the failure to have a system respond properly, or an annunciator alarm would be considered an event; a system discovered to be inoperable through a document review would not.

Intended Safety Function: The total safety function of a system. Where redundancy exists, the loss of one component or subsystem does not defeat the intended safety function as long as an equivalent component or subsystem is operable.

Licensee Official: First-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material (whether or not listed on a license).

Minor Violation: A violation that is less significant than either a Severity Level IV violation or a violation associated with a finding that the significance determination process characterizes as green. Although minor violations must be corrected, they are not usually described in inspection reports or inspection records.

Non-Cited Violation (NCV): A method for dispositioning a Severity Level IV violation or a violation associated with a finding that the significance determination process characterizes as green. Provided applicable criteria in the Enforcement Policy are met, issues are documented as violations, but are not cited in Notices of Violation which normally require written responses form licensees.

Noncompliance: Violations (regardless of whether they are cited or not) , nonconformances, and deviations.

Nonconformance: A vendor's or certificate holder's failure to meet contract requirements related to NRC activities (e.g., 10 CFR Part 50, Appendix B, Part 71, or Part 72) where the NRC has not placed requirements directly on the vendor or certificate holder.

Notice of Violation (NOV): A formal written citation in accordance with 10 CFR 2.201 that sets forth one or more violations of a legally binding regulatory requirement.

Person: Broadly defined in Section 11s of the Atomic Energy Act to include individuals, a variety of organizations, and any representatives or agents of those organizations.

Repetitive or Similar Violation: A violation that reasonably could have been prevented by a licensee's corrective action for a previous violation (normally occurring within the two years before the inspection at issue, or within the last two inspections, whichever is longer).

Requirement: A legally binding obligation, such as a statute, regulation, license condition, technical specification, or order.

Significance: As used in the enforcement program, significance involves the consideration of: (1) actual safety consequences; (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the NRC's ability to perform its regulatory function; and (4) any willful aspects of the violation.

Significance Determination Process (SDP): The process used to determine the risk significance of pertinent findings within the reactor oversight process.

System: Includes administrative and managerial control systems, as well as physical systems.

Unauthorized Individual: As used in the safeguards area, someone not authorized for entrance into the area in question, or not authorized to enter in the manner entered. As used in other areas, someone not authorized in accordance with a specific requirement (e.g., regulation or license condition) to conduct a certain licensed activity.

Vendor: A supplier of products or services to be used in an NRC-licensed facility or activity. In some cases, the supplier may be an NRC or Agreement State licensee (e.g., nuclear fuel fabricator, radioactive waste broker) or the supplier's product may be required to have an NRC Certificate of Compliance (e.g., certain transport packages such as spent fuel casks, waste casks, or radiography devices).

Violation: The failure to comply with a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

Vital Area: As used in safeguards, includes both vital areas and material access areas.

Willfulness: An attitude toward compliance with requirements that ranges from the careless disregard for requirements to a deliberate intent to violate or to falsify. Willfulness does not include acts that do not rise to the level of careless disregard (e.g., inadvertent clerical errors).

Withdraw: To take away, as to retract, all or part of an enforcement action, such as withdrawing the civil penalty but leaving the Notice of Violation in effect. Cf: rescind, which means to abrogate, annul, or set aside as though it never existed. Rescind is used for those situations in which it is concluded that because of a basic mistake of law or fact, the action should not have been issued at all.

1.7 Enforcement References and Resource Documents

There are many documents that provide useful enforcement information and background. These documents are listed below:

NUREGs:

- NUREG-1499, "Reassessment of the NRC's Program for Protecting Allegers Against Retaliation."
- NUREG-1525, "Assessment of the NRC Enforcement Program." This report provided the foundation for the 1995 Enforcement Policy revision.
- NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions."
- NUREG-1622, "NRC Enforcement Policy Review (July 1995-July 1997)." This report provided the foundation for the 1998 Enforcement Policy revision.

Rulemaking Considerations:

- Completeness and Accuracy of Information: Statements of Consideration.
  This document (52 FR 49362, 12/31/87), is located in the NRC Rules and Regulations under Part 2.
- Deliberate Misconduct Rule: Statements of Consideration. This document (56 FR 40664, 08/15/91), is located in the NRC Rules and Regulations under Part 2.

Policy Statements:

- Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation. This document (61 FR 24336, May 14, 1996) is located in the NRC Rules and Regulations under Policy Statements, Administration.

Memorandums of Understanding (MOUs):

- MOU between NRC and DOJ: 53 FR 50317 (12/14/88) Effective 11/23/88
- MOU between NRC and DOL: 47 FR 54585 (12/03/82) Effective 6/25/82
- MOU between NRC and DOT: 44 FR 38690 (07/02/79)

These documents are also located on the **Enforcement** Web site.

Systems of Records:

- NRC-3 Enforcement Actions Against Individuals
- NRC-6 Discrimination Cases

The notices published for these systems are located in NRC Rules and Regulations, Volume IV.

CHAPTER 2
RESPONSIBILITIES AND AUTHORITIES

2.1 Scope of the Chapter

This chapter details the responsibilities and authorities for enforcement activities established in the Enforcement Policy and in various NRC Management Directives (MDs) for the Deputy Executive Director for Regulatory Programs (DEDR); the Deputy Executive Director for Materials, Research and State Programs (DEDMRS); the Office of Enforcement (OE); the regional offices; the Office of the General Counsel (OGC); the Office of Nuclear Reactor Regulation (NRR); the Office of Nuclear Material, Safety, and Safeguards (NMSS); the Office of Nuclear Security and Incident Response (NSIR); the Office of Public Affairs (OPA); and the Office of the Chief Financial Officer. This chapter also discusses requirements for Commission notification and consultation.

2.2 Deputy Executive Directors for Operations (DEDOs)

In accordance with NRC MD 9.17, "Organization and Functions, Office of the Executive Director for Operations":

a. The DEDR is authorized to approve or issue all escalated enforcement actions involving 10 CFR Part 50 or 55 licensees, including orders and civil penalties pursuant to 10 CFR Part 2, Subpart B. The DEDR is responsible to the EDO for NRC enforcement programs.

b. The DEDMRS is authorized to approve or issue all escalated enforcement actions except those involving 10 CFR Part 50 or 55 licensees, including orders and civil penalties pursuant to 10 CFR Part 2, Subpart B.

Hereinafter, the phrase “appropriate Deputy Executive Director” and “DEDO” will refer to either of these individuals, as appropriate.

2.3 Office of Enforcement (OE)

In accordance with NRC MD 9.19, "Organization and Functions, Office of Enforcement," the Office of Enforcement exercises oversight of NRC enforcement programs, provides programmatic and implementation direction to regional and headquarters offices conducting or involved in enforcement activities, and ensures that regional enforcement programs are adequately carried out.

2.3.1 Delegation of Authority to the Director, OE

a. In accordance with NRC MD 9.19, "Organization and Functions, Office of Enforcement," the Director is authorized to:

   1. Prepare enforcement actions including Notices of Deviations, Notices of Violation (NOVs), Notices of Violation and Proposed Impositions of Civil Penalty, orders, and settlement agreements, and issue these actions in the DEDO's absence or under the DEDO's direction.

2. Manage major enforcement actions (civil penalties, orders, and significant NOVs) and, in the DEDO's absence or under the DEDO's direction, approve or direct enforcement action to be taken by regional or headquarters offices.

3. Prepare letters requesting investigations, confirming actions, or obtaining information under sections 161(c) or 182 of the Atomic Energy Act, prepare subpoenas for alleged violations of regulatory requirements, and issue those actions in the DEDO's absence or under the DEDO's direction.

4. Take necessary or appropriate action in accordance with the decision of an Administrative Law Judge, an Atomic Safety and Licensing Board, or the Commission after enforcement hearings pursuant to 10 CFR Part 2.

5. Recommend to the EDO through the DEDO changes to rules and policies for Commission consideration concerning enforcement matters.

6. Provide guidance and training on implementation of the Commission's Enforcement Program.

b. In accordance with the February 7, 1997; June 2, 1998; and June 2000, redelegations of authority issued by the DEDO, and subject to paragraph 4 of this section, the Director, OE is authorized to approve or issue enforcement actions involving:

1. Part 30, 40, 70, and 76 licensees and certificate holders:

   a. Notices of Violations and Proposed Imposition of civil penalties for violations (or problems) categorized no higher than Severity Level II.

   b. Orders imposing civil penalties for violations (or problems) categorized no higher than Severity Level II.

   c. Confirmatory Orders.

   d. Demands for Information.

   e. Exercise of Discretion:

      (1) pursuant to Section VII.A.1.g of the Enforcement Policy for penalties no higher than the applicable base civil penalty, and

      (2) pursuant to Section VII.B.6, to refrain from issuance of enforcement actions against Agreement State licensees who perform work in areas under exclusive Federal jurisdiction without filing for reciprocity, provided that the Agreement State licensee was not aware, or could not reasonably have been expected to be aware, that such activity is under NRC jurisdiction.

2. Part 50 licensees:

   a. Notices of Violations and Proposed Impositions of civil penalties for violations (or problems) categorized no higher than Severity Level III.

b. Notices of Violation for violations associated with findings characterized through the reactor oversight process's significance determination process as green, white, or yellow.

c. Confirmatory Orders.

d. Demands for Information.

3. Individual Actions pursuant to Parts 30, 40, 50, 70, and 76, and actions to licensed operators pursuant to Part 55:

   a. Notices of Violations without civil penalties no higher than Severity Level II (Commission consultation is required for Severity Level I actions).

   b. Confirmatory Orders.

   c. Demands for Information.

4. The delegations of paragraphs 1, 2, and 3 do not apply to cases where:

   a. the Director, OE, or the Director, NRR, or the Director, NMSS, or the Regional Administrator are in disagreement on a proposed action; or

   b. the DEDO advises the Director, OE, that in a particular case or matter the DEDO wishes to retain approval authority.

5. The Director, OE, shall keep the DEDO informed of the escalated actions approved pursuant to the delegations of paragraphs 1, 2, and 3., and consult with the DEDO in any case involving novel issues, or substantial legal, programmatic, or policy issues raised during the review process, or where the Director, OE, believes warrants consultation.

2.3.2 Redelegation of Authority by the Director, OE

The Director, OE may redelegate his or her authority according to the following guidelines:

a. Subject to the limitations and stipulations in MD 9.19, the Director may, except where expressly prohibited, redelegate to others the authority delegated to the Director, OE.

b. The authority discussed in Sections 2.3.1.b.1, 2.3.1.b.2, and 2.3.1.b.3 is not to be further delegated without written approval of the DEDO, and the Office of the General Counsel.

2.3.3 Deputy Director, OE

In accordance with MD 9.19, the Deputy Director, OE, assists the Director in overseeing, managing, and directing the development of enforcement policies and programs, and in issuing enforcement actions. He or she also acts for the Director, OE, in the Director's absence. However, the approval of enforcement actions under Sections2.3.1.b.1, 2.3.1.b.2, and 2.3.1.b.3 r requires prior coordination with the DEDO.

2.3.4 OE Staff

As directed by the Director, OE, the OE staff:

a. Assists the Director, OE, in developing and implementing the enforcement program and Enforcement Policy.

b. Participates in enforcement panels and SDP panels whenever practical and as directed by the Director, OE, to provide enforcement perspectives.

c. Assigns enforcement action (EA) and individual action (IA) numbers to proposed enforcement actions as appropriate and prepares and maintains SDP/EA Request & Strategy Forms.

d. Assigns EA numbers to all findings addressed in a SDP/enforcement panel, regardless of whether a potential violation is involved. (This allows the agency to keep track of SDP issues.)

e. Reviews the enforcement strategy for proposed escalated enforcement actions to ensure technical adequacy and conformance to established policy, guidance, and precedents.

f. Participates in predecisional enforcement conferences and regulatory conferences whenever practical and as directed by the Director, OE, to provide enforcement perspectives.

g. Participates in enforcement caucuses and SDP caucuses whenever practical and as directed by the Director, OE, to provide enforcement perspectives.

h. Coordinates the headquarters review and concurrence process for escalated enforcement actions proposed by the regions (including those associated with the reactor oversight process's SDP) and those proposed by the program offices.

i. Prepares Enforcement Notifications (ENs) for civil penalty actions submitted to OE, orders, and the exercise of enforcement discretion described in Section VII.B.6 of the Enforcement Policy.

j. Prepares Regulatory Notifications (RNs) for significant regulatory actions, such as a Final Significance Determination for a white, yellow, or red finding (that does not include an NOV) or an order that requires additional safety measures beyond the regulatory framework (versus an order based on compliance issues, e.g., 2002 security orders).

k. Coordinates press releases and State notification for actions issued by the program offices.

l. Coordinates and reviews press releases for significant enforcement issues, such as revisions to the Enforcement Policy.

m. Reviews Office of Investigations (OI) reports and coordinates with the region, OGC, and the applicable program office to determine whether enforcement action is appropriate.

n. Assists the Director, OE, in preparing letters requesting investigations, confirming actions, or obtaining information under sections 161(c) or 182 of the Atomic Energy Act, and in preparing subpoenas with respect to alleged violations of regulatory requirements.

o. Evaluates the enforcement program as carried out by the regional offices.

p. Participates in regularly scheduled conference calls with the Regional Enforcement Coordinators and the Program Office Enforcement Coordinators to discuss enforcement issues and cases.

q. Maintains and revises the Enforcement Policy and the NRC Enforcement Manual, as directed by the Director, OE.

r. Maintains the Enforcement Action Tracking System (EATS) and Individual Action Tracking System (IATS).

s. Maintains the enforcement-related information on the NRC's internal and external Web sites.

t. Prepares an annual report for the enforcement program.

u. Develops and provides training on the enforcement program.

v. Serves as petition manager for 10 CFR 2.206 petitions assigned to OE.

w. Coordinates with the Occupational Safety and Health Administration (OSHA) on the resolution of enforcement issues involving both the NRC and OSHA jurisdiction at NRC facilities.

2.4 Regional Offices

In accordance with NRC MD 9.29, "Organization and Functions, Regional Offices", the regional offices are responsible for implementing the enforcement program subject to the overall policy, program, and implementation guidance of OE. The regional offices normally prepare and issue non-escalated enforcement actions; schedule and conduct enforcement and SDP panels, predecisional enforcement conferences and regulatory conferences, and enforcement and SDP caucuses; prepare and issue escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required; evaluate licensees' responses to enforcement actions and prepare appropriate responses; track the status of enforcement actions; conduct regional staff training; issue regional enforcement procedures; and audit regional enforcement actions. (Note that the regional offices are generally responsible for enforcement activities associated with on-site contractors.)

2.4.1 Delegation of Authority to the Regional Administrators

In accordance with the responsibility for supervising and directing the enforcement functions of the region, subject to the overall policy, program, and implementation guidance of OE, Regional Administrators:

a. Approve, sign, and issue non-escalated enforcement actions.

b. Recommend all escalated enforcement actions to headquarters either (1) through consultation (usually via an enforcement or SDP panel) or (2) by submitting the actual enforcement action package for review and approval.

c. Sign and issue escalated enforcement actions (other than orders) after either (1) consultation with OE (usually via a panel or caucus) or (2) actual enforcement action package review and approval by the Director, OE (and the DEDO and Commission, as appropriate).

d. Signs and issues enforcement actions or letters exercising discretion in accordance with Sections VII.B.2 - 6 of the Enforcement Policy, after consultation with OE, (and the DEDO, when required). These cases require EA numbers.

e. Review licensees' responses to proposed escalated enforcement actions and recommend appropriate action to the Director, OE.

f. Conduct enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses.

g. Contact the Director, OE as soon as possible, and normally no later than 24 hours after receiving the SDP/EA Request & Strategy Form, if they disagree with an enforcement strategy (or SDP conclusion) arrived at during an enforcement or SDP panel or enforcement or SDP caucus.

h. Notify OE when an enforcement action involves significant disagreement within the region, including disagreement by the Regional Counsel.

i. Ensure that the Regional Counsel (when available) reviews and provides legal advice on all regional escalated enforcement action recommendations submitted to headquarters for review and approval.

j. Review Office of Investigations (OI) reports promptly and notify OE whenever an OI field director concludes during or after an investigation that willfulness is involved (even if a report has not yet been issued); in addition, make recommendations to OE for enforcement action, including immediate action, when warranted.

k. Ensure that appropriate training and instructions are provided to regional staff to implement the enforcement program and that region-based enforcement actions (including NRC Form 591s) are periodically audited. Copies of regional instructions and procedures should be provided to OE.

l. Ensure, for cases in which the regional licensing staff receives notice of a licensee bankruptcy action, that the regional enforcement staff determines whether any outstanding civil penalties exist and, if so, promptly notifies the Director, OE, so that an appropriate claim can be filed to preserve the NRC's interest.

m. Ensure that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE.

n. Ensure that copies of Task or Technical Interface Agreements that involve potential violations are sent to the Director, OE and e-mailed to “OEMAIL.”

o. Recommend to the Director, OE, as appropriate, changes to the Enforcement Policy or guidance within this Manual.

2.4.2 Redelegation of Authority by the Regional Administrator

The Regional Administrator may redelegate his or her authority according to the following guidelines:

a. The Regional Administrator may redelegate the authority to issue non-escalated enforcement actions to Branch Chiefs and above and may redelegate the authority to issue NRC Form 591s to qualified inspectors.

b. The Regional Administrator may redelegate the authority to issue Notices of Violation including Severity Level III violations that do not include civil penalties to the Deputy Regional Administrator.

c. The Regional Administrator may redelegate the authority to issue Notices of Violation associated with white and yellow SDP findings to the Deputy Regional Administrator.

d. The Regional Administrator may redelegate the authority to conduct enforcement panels, predecisional enforcement conferences, and enforcement caucuses to regional management. This delegation should normally not be to individuals below a Deputy Division Director.

e. The Regional Administrator may redelegate the authority to sign and issue Confirmatory Action Letters (CALs) to Division Directors and above.

f. The Regional Administrator may redelegate the authority to sign and issue cases exercising Section VII.B.2 - 6 discretion for matters that would otherwise be Severity Level IV violations to Division Directors and above. OE should be consulted (by telephone or e-mail "OEMAIL") prior to exercising this discretion.

2.4.3 Regional Counsel

As directed by the Regional Administrator, the Regional Counsel:

a. When available, reviews and provides legal advice on all regional escalated enforcement action recommendations in either draft or final form prior to being submitted to headquarters for review and approval.

b. Reviews other enforcement actions, as requested.

2.4.4 Regional Enforcement Coordinators

As directed by the Regional Administrator, the Regional Enforcement Coordinators:

a. Prepare or review all escalated enforcement actions prepared by the regional staff to ensure technical adequacy and conformance to established policy, guidance, and precedents.

b. Prepare an SDP/Enforcement Panel Worksheet (Panel Worksheet) (included in Appendix D) for all proposed enforcement issues and for all operating reactor findings (even those without associated violations) that will be discussed during an enforcement or SDP panel.

c. Compile supporting documents for issues to be addressed in an enforcement or SDP panel.

d. Serve as point of contact for regional reviews, comments, and concurrence for subsequent changes or revisions made to enforcement actions and final SDP letters submitted to headquarters for review and approval.

e. Ensure that all enforcement actions issued by the region that were the subject of an enforcement or SDP panel are subsequently sent to OE (e-mail "OEMAIL").

f. Prepare and issue Enforcement Notifications (ENs) for those escalated enforcement actions that are issued by the region that have not been submitted to headquarters for enforcement action package review and approval.

g. Review Office of Investigations (OI) reports and coordinate with regional and headquarters staff to determine whether enforcement action is appropriate.

h. Prepare draft Commission papers for escalated enforcement actions requiring Commission consultation, or review those prepared by the regional staff.

i. Track the progress of all escalated enforcement actions and final SDP letters while in preparation in the region and strive to achieve timely actions.

j. Maintain necessary records and statistics on enforcement actions taken by the region.

k. Monitor, audit, and assist in processing non-escalated enforcement actions to ensure that they are consistent with the Enforcement Policy, other guidance, and precedents.

l. Ensure that disputed minor violations, Severity Level IV violations, or violations associated with green SDP findings (regardless of whether they were dispositioned as NCVs or in NOVs) are coordinated with OE.

m. Attend enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses, as appropriate.

n. Participate in regularly scheduled conference calls with OE to discuss enforcement issues and cases.

o. Train regional personnel in enforcement matters.

p. Revise regional enforcement procedures, as appropriate.

q. Review press releases for enforcement actions to ensure that they conform to the guidance in this Manual.

2.4.5 Regional Supervisors and Managers

As directed by the Regional Administrator, regional supervisors and managers:

a. Review inspection and investigation findings in accordance with regional procedures and recommend appropriate enforcement action.

b. Approve and sign non-escalated enforcement actions, as authorized by the Regional Administrator.

c. Conduct enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses when authorized to do so by the Regional

Administrator. (The level of regional management conducting the meetings should normally not be below a Division Director.)

d. Evaluate licensees' responses to enforcement actions and provide recommendations to the Regional Administrator regarding imposition or mitigation of sanctions.

In addition, Division Directors are responsible to the Regional Administrator for recommended escalated enforcement actions. The recommendation should include evaluation of the significance of the violation, whether a civil penalty or order should be proposed, and whether mitigation or escalation of the civil penalty is appropriate.

2.4.6 Resident and Region-Based Inspectors

As directed by regional management, resident and region-based inspectors:

a. Identify violations of regulatory requirements and recommend enforcement action.

b. Appropriately document findings and enforcement action.

c. Recommend to appropriate regional management the severity level of an apparent violation and provide information that bears on the mitigation or escalation of a civil penalty, if proposed.

d. Sign and issue NRC Form 591s (if so qualified and authorized) for Severity Level IV violations and Non-Cited Violations (NCVs).

e. Review responses to NOVs submitted by licensees to determine whether corrective actions are adequate.

f. Prepare, or provide input to, evaluations of licensees' responses to proposed civil penalties and orders, as appropriate, for submittal to regional management.

g. Attend enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses, as appropriate.

2.4.7 Senior Reactor Analysts

As directed by regional management, senior reactor analysts support NRC objectives related to improving the utilization of risk insights in the reactor inspection and enforcement programs.

2.5 Office of the General Counsel (OGC)

In accordance with NRC MD 9.7, "Organization and Functions, Office of the General Counsel," the General Counsel supervises and directs the performance of all legal and administrative functions necessary to carry out the assigned responsibilities of the Office.

2.5.1 Associate General Counsel for Hearings, Enforcement, and Administration

In accordance with MD 9.7, the Associate General Counsel for Hearings, Enforcement, and Administration:

a. Reviews and provides legal advice on: civil penalty actions, enforcement actions involving OI findings, enforcement-related orders, enforcement-related Commission papers, and other enforcement actions upon request.

b. Represents staff in NRC adjudicatory hearings on enforcement actions.

2.5.2 Assistant General Counsel for Materials Litigation and Enforcement

As directed by the Associate General Counsel for Hearings, Enforcement, and Administration, the Assistant General Counsel for Materials Litigation and Enforcement serves as the principal OGC contact for all enforcement matters. As such, the Assistant General Counsel:

a. Reviews and provides legal advice on: civil penalty actions and Demands for Information as requested, enforcement actions involving OI findings, enforcement-related orders, enforcement-related Commission papers, and other enforcement actions upon request.

b. Provides additional OGC review or concurrence (or statement of no legal objection) for complex and novel cases and enforcement-related OI matters when requested by OE.

c. Provides OGC review and concurrence (or statement of no legal objection) on all orders as well as enforcement actions included in Commission papers.

d. Represents the staff in NRC adjudicatory hearings on enforcement actions.

2.6 Office of Nuclear Reactor Regulation (NRR)

NRR is responsible for supporting the enforcement program in several ways. For all areas in which NRR evaluates, directly manages, or conducts inspections (vendors and non-power reactors), NRR is responsible (similar to a regional office) for implementing the enforcement program and Enforcement Policy subject to the overall policy, program, and implementation guidance from OE. Specifically, NRR normally prepares and issues non-escalated enforcement actions; schedules and conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses; prepares and issues escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required; evaluates licensees' responses to enforcement actions and prepares appropriate responses; tracks the status of enforcement actions; conducts NRR staff training; and audits NRR enforcement actions. NRR is responsible for developing and directing the implementation of policies, programs, and procedures for regional application of the SDP in the evaluation of findings and issues associated with the reactor oversight process. The output of the SDP provides a direct input into the enforcement program in terms of how a violation will be dispositioned. For issues that are not evaluated by the SDP, NRR reviews the enforcement strategy for escalated enforcement actions for Part 50 and 55 licensees to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

2.6.1 Delegation of Authority to the Director, NRR

The Director, NRR is authorized to act according to the following guidelines:

a. In accordance with NRC MD 9.27, "Organizations and Function, Office of Nuclear Reactor Regulation," the Director, NRR has been authorized to issue orders and Demands for Information. However, as stated in the Enforcement Policy, normal use of this authority is expected to be confined to actions not associated with violations.

b. In accordance with delegation from the Director, OE, dated July 17, 1987 and February 3, 1998, for enforcement issues involving vendors and non-power reactors, the Director, NRR:

   1. Approves, signs, and issues non-escalated enforcement actions.

   2. Recommends <u>all</u> escalated enforcement actions to headquarters either (1) through consultation (usually via an enforcement panel) or (2) by submitting the actual enforcement action package for review and approval.

   3. Signs and issues escalated enforcement actions (other than orders) <u>after</u> either (1) consultation with OE (usually via a panel or caucus) or (2) actual enforcement action package review and approval by the Director, OE (and the DEDO and Commission, as appropriate).

   4. Signs and issues enforcement actions or letters exercising discretion in accordance with Sections VII.B.2 - 6 of the Enforcement Policy, after consultation with OE, (and the DEDO, when required). These cases require EA numbers.

   5. Reviews licensees' responses to proposed escalated enforcement actions and recommends appropriate action to the Director, OE (e-mail “OEMAIL”).

   6. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

   7. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE.

   8. Ensures that the enforcement activities conducted under this delegation are consistent with established policy, guidance, and precedents.

c. The delegations listed above do not apply to cases where the Director, OE, or the director, NRR or the Regional Administrator are in disagreement on a proposed action; or the DEDO advises the Director, OE that he or she wishes to retain approval authority.

d. For all areas in which the region evaluates, directly manages, or conducts inspections, the Director, NRR ensures that the NRR staff reviews the enforcement strategy for escalated enforcement actions recommended by the regional offices to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

e. In accordance with the responsibility for supervising and directing all enforcement-supporting functions of NRR, the Director, NRR:

   1. Contacts the Director, OE as soon as possible, and normally no later than 24 hours after receiving the SDP/EA Request & Strategy Form, if they disagree with an enforcement strategy arrived at during an enforcement panel or enforcement caucus.

   2. Ensures that OI reports are reviewed and that recommendations are made to OE for enforcement action, including immediate action, when warranted.

   3. Ensures that NRR staff receives appropriate training and instructions to implement the enforcement program and that NRR-based enforcement actions are periodically audited.

   4. Ensures that disputed non-escalated actions (NCVs and NOVs) are coordinated with OE.

   5. Ensures that copies of Task or Technical Interface Agreements that involve potential violations are sent to the Director, OE (e-mail "OEMAIL").

   6. Ensures that the enforcement activities conducted under this function are consistent with established policy, guidance, and precedents.

   7. Recommends to the Director, OE, as appropriate, changes to the Enforcement Policy or guidance within this Manual.

f. In accordance with guidance provided in Part 9900 of the NRC Inspection Manual, the Director, NRR is responsible for issuing guidance to implement Section VII.C of the Enforcement Policy related to issuance of NOEDs.

2.6.2 Redelegation of Authority by the Director, NRR

The Director, NRR may redelegate his or her authority according to the following guidelines:

a. The Director, NRR may redelegate the authority to sign and issue non-escalated enforcement actions to Section Chiefs and above.

b. The Director, NRR may redelegate to the applicable Division Director, NRR, the authority to sign and issue, after coordination with OE, Severity Level III NOVs without civil penalties.

c. The Director may redelegate, to Division Directors and above, the authority to sign and issue actions and letters exercising discretion in accordance with Sections VII.B.2 - 6 of the NRC Enforcement Policy for matters that would otherwise be Severity Level IV violations. OE should be consulted by telephone or e-mail prior to exercising this discretion. These actions require EA numbers.

d. The Director may redelegate the authority to conduct predecisional enforcement conferences to NRR management. This delegation should not normally be to individuals below a Deputy Division Director.

e. The Director, NRR, will forward copies of further redelegations to OE.

2.6.3 Associate Director For Inspection and Programs, NRR

As directed by the Director, NRR, the Associate Director for Inspection and Programs:

a. Serves as the principal NRR manager responsible for enforcement matters involving Part 50 and 55 licensees.

b. Ensures that the enforcement strategy for escalated enforcement actions and cases involving Commission papers for Part 50 and 55 licensees are reviewed to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

c. Ensures that comments are provided (verbally, electronically ("OEMAIL"), or in writing) based on the review in paragraph (b) of this section to the Director, OE, normally within 5 working days of receipt of the enforcement package in headquarters.

d. Ensures that the NRR Enforcement Coordinator and project, technical, and management personnel attend enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses, as appropriate.

e. Contacts the Director, OE as soon as possible, and normally no later than 24 hours after receiving the SDP/EA Request & Strategy Form, if he or she disagrees with an enforcement strategy arrived at during an enforcement panel or enforcement caucus.

f. Reviews applicable OI reports to identify immediate safety issues and provide NRR perspective in determining appropriate enforcement action.

g. Recommends to the Director, OE, initiation of proposed enforcement action, as appropriate.

h. Ensures that response to task interface agreements are coordinated with OE, as appropriate.

i. Recommends to the Director, OE, changes to the Enforcement Policy or guidance within this Manual, as appropriate.

2.6.4 NRR Enforcement Coordinator

As directed by the Associate Director for Inspection and Programs:

a. Serves as the principal NRR contact for enforcement matters involving 10 CFR Part 50 and 55 licensees.

b. Participates in the weekly regional enforcement and SDP panels considering all 10 CFR Part 50 and 55 licensee cases.

c. Leads the NRR review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies the Associate Director for Inspection and Programs of the enforcement strategy, especially in cases where the Enforcement Coordinator disagrees with the strategy.

d. Obtains necessary technical support from other NRR divisions to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that reactor safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions.

e. Participates in predecisional enforcement conferences and regulatory conferences with enforcement implications, when the issues warrant.

f. Consolidates NRR views on the enforcement strategy for proposed escalated actions and forwards the NRR comments (verbally, electronically, or in writing) to the Director, or Deputy Director, OE for enforcement actions submitted to headquarters.

g. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) involving vendors and non-power reactors are coordinated with OE.

h. Participates in regularly scheduled conference calls with OE, the regions, and the other program office Enforcement Coordinators to discuss enforcement issues and cases.

i. Reviews applicable OI reports to identify immediate safety issues, coordinates with appropriate NRR staff, and provides NRR perspective in determining appropriate enforcement action.

2.6.5 NRR Staff

a. In accordance with delegations of authority for areas in which NRR evaluates, directly manages, or conducts inspections (vendors and non-power reactors) the NRR staff:

    1. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedents.

    2. Issues non-escalated enforcement actions, including Notices of Nonconformance, NOVs, and NCVs.

    3. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

    4. Prepares a Panel Worksheet and compiles supporting information for enforcement or SDP panels.

    5. Requests EA numbers for all contemplated escalated enforcement actions.

    6. Submits all escalated enforcement actions to OE for review and approval.

    7. Reviews vendor responses to enforcement actions to determine whether corrective actions are adequate.

    8. Reviews OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted.

b. As directed by the Director, NRR, NRR staff and management personnel support enforcement activities as follows:

1. Inspection Program Branch (IIPB) provides oversight and representatives as necessary to support SDP/enforcement panels.

2. Appropriate project, technical, and management personnel should participate in enforcement and SDP panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

3. The Probabilistic Safety Assessment Branch (SPSB) supports assessment of the safety significance of the event(s) on which the proposed enforcement action is based. This support will include probabilistic risk assessment (PRA) and Accident Sequence Precursor calculations, where appropriate, as part of the integrated process considering all facets surrounding the violation in support of enforcement decisions.

4. Appropriate project, technical, and management personnel should attend predecisional enforcement conferences and regulatory conferences.

5. Appropriate project, technical, and management personnel should participate in enforcement and SDP caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

6. Project, technical, and management personnel will review applicable OI reports to identify immediate safety issues and provide NRR perspective in determining appropriate enforcement action.

7. Project, technical, and management personnel will coordinate with OE on task interface agreements that have the potential for enforcement implications.

2.7 Office of Nuclear Material Safety and Safeguards (NMSS)

NMSS is responsible for supporting the enforcement program in two ways. First, for all areas in which NMSS evaluates, directly manages, or conducts inspections, NMSS is responsible (similar to a regional office) for implementing the enforcement program and Enforcement Policy subject to the overall policy, program, and implementation guidance from OE. Currently, this includes violations involving:

- MC&A and chemical, fire protection, and criticality safety activities at fuel facilities
- gaseous diffusion plants
- transportation shipping packages
- independent spent fuel storage installations
- dry storage systems for spent fuel
- decommissioning activities
- low-level waste licensees
- uranium recovery licensees

In these cases, NMSS normally prepares and issues non-escalated enforcement actions; schedules and conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses; prepares and issues escalated enforcement actions when authorized to do so, or after concurrence by the Director, OE, and approval by the DEDO, as required; evaluates licensees' responses to enforcement actions and prepares appropriate responses; tracks the status of enforcement actions; conducts NMSS staff training; and audits NMSS enforcement actions.

Second, for all areas in which the region evaluates, directly manages, or conducts inspections, NMSS reviews the enforcement strategy for escalated enforcement actions recommended by the regional offices to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

2.7.1 Delegation of Authority to the Director, NMSS

The Director, NMSS is authorized to act according to the following guidelines:

a. In accordance with MD 9.26, "Organization and Functions, Office of Nuclear Materials Safety and Safeguards", the Director, NMSS has been authorized to issue orders and Demands for Information. However, as stated in the Enforcement Policy, normal use of this authority is expected to be confined to actions not associated with violations.

b. In accordance with a delegation of authority issued by the Director, OE, dated November 8, 2001, for all areas in which NMSS evaluates, directly manages, or conducts inspections, the Director, NMSS:

   1. Approves, signs, and issues non-escalated enforcement actions.

   2. Recommends <u>all</u> escalated enforcement actions to headquarters either (1) through consultation (usually via an enforcement panel) or (2) by submitting the actual enforcement action package for review and approval.

   3. Signs and issues escalated enforcement actions (other than orders) <u>after</u> either (1) consultation with OE (usually via a panel or caucus) or (2) actual enforcement action package review and approval by the Director, OE (and the DEDO and Commission, as appropriate).

   4. Signs and issues enforcement actions or letters exercising discretion in accordance with Sections VII.B.2 - 6 of the Enforcement Policy, after consultation with OE, (and the DEDO, when required). These cases require EA numbers.

   5. Reviews licensees' responses to proposed escalated enforcement actions and recommends appropriate action to the Director, OE.

   6. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

   7. Ensures that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE.

   8. Ensures that the enforcement activities conducted under this delegation are consistent with established policy, guidance, and precedents.

c. The delegations listed above do not apply to cases where the Director, OE, or the director, NMSS, or the Regional Administrator are in disagreement on a proposed action; or the DEDO advises the Director, OE that he or she wishes to retain approval authority.

d. For all areas in which the region evaluates, directly manages, or conducts inspections, the Director, NMSS ensures that the NMSS staff reviews the enforcement strategy for escalated enforcement actions recommended by the regional offices to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

e. In accordance with the responsibility for supervising and directing all enforcement-supporting functions of NMSS, the Director, NMSS:

   1. Contacts the Director, OE as soon as possible, and normally no later than 24 hours after receiving the SDP/EA Request & Strategy Form, if they disagree with an enforcement strategy arrived at during an enforcement panel or enforcement caucus.

   2. Ensures that OI reports are reviewed and that recommendations are made to OE for enforcement action, including immediate action, when warranted.

   3. Ensures that NMSS staff receives appropriate training and instructions to implement the enforcement program and that NMSS-based enforcement actions (including NRC Form 591s) are periodically audited.

   4. Ensures that disputed non-escalated actions (NCVs and NOVs) are coordinated with OE.

   5. Ensures that copies of Task or Technical Interface Agreements that involve potential violations are sent to the Director, OE.

   6. Ensures that the enforcement activities conducted under this function are consistent with established policy, guidance, and precedents.

   7. Recommends to the Director, OE, as appropriate, changes to the Enforcement Policy or guidance within this Manual.

f. In accordance with guidance provided in Part 9900 of the NRC Inspection Manual, the Director, NRR is responsible for issuing guidance to implement Section VII.C of the Enforcement Policy related to issuance of NOEDs.

2.7.2 Redelegation of Authority by the Director, NMSS

The Director, NMSS may redelegate his or her authority according to the following guidelines:

a. The Director may redelegate authority to sign and issue non-escalated enforcement actions to Section Chiefs and above and may redelegate the authority to issue NRC Form 591 to qualified inspectors.

b. The Director may redelegate to the Deputy Director, NMSS, the authority to sign and issue, after coordination with OE, Severity Level III NOVs without civil penalties.

c. The Director may redelegate, to Division Directors and above, the authority to sign and issue actions and letters exercising discretion in accordance with Sections VII.B.2 - 6 of the NRC Enforcement Policy for matters that would otherwise be Severity Level IV violations. OE should

be consulted by telephone or e-mail prior to exercising this discretion. These actions require EA numbers.

d. The Director may redelegate the authority to conduct predecisional enforcement conferences to NMSS management. This delegation should not normally be to individuals below a Deputy Division Director.

e. The Director, NMSS, will forward copies of further redelegations to OE.

2.7.3 NMSS Regional Coordinators

As directed by NMSS management, the Regional Coordinators:

a. Participate in the weekly regional enforcement panels considering all material licensee cases.

b. Request EA numbers for NMSS escalated enforcement actions not assigned during weekly panels.

c. Provide assistance to the lead division, on request, in reviewing inspection and investigation findings to identify apparent violations that may warrant escalated enforcement action.

d. Provide assistance to the lead division, on request, in developing enforcement action worksheets, agendas for enforcement panels with OE, and issuing background information to all participants at least 48 hours in advance.

e. Schedule matters to be considered by OE enforcement panels.

f. Review and coordinate comments within NMSS, after OE review, on escalated enforcement actions for all material cases submitted by the regions or prepared by OE.

h. Participate in all NMSS predecisional enforcement conferences and regional predecisional enforcement conferences, when the issues warrant.

i. Determine whether the licensee has been the subject of previous escalated enforcement action for purposes of the civil penalty assessment process.

j. Provide assistance to the lead Division, upon request, in drafting escalated enforcement actions, including cover letters, orders, demands for information, proposed civil penalties, orders imposing civil penalties, and Commission papers to ensure technical adequacy and conformance to established policy guidance and precedents; and coordinate with OE during the process.

k. Serve as point of contact for NMSS reviews, comments, and concurrence for subsequent changes or revisions made to enforcement actions.

l. Provide assistance to the lead Division, upon request, in arranging and conducting predecisional enforcement conferences, including developing opening remarks on the Enforcement Policy and process.

m. Provide policy advice to NMSS Divisions and SFPO concerning enforcement matters, including information on enforcement actions in similar cases.

n. Provide training on enforcement matters within NMSS.

o. Track progress of all escalated enforcement actions while in preparation in NMSS and strive to achieve timely actions.

p. Ensure that disputed non-escalated enforcement actions (NCVs and NOVs) are coordinated with OE.

q. Participate in regularly scheduled conference calls with OE, the regions, and the other program office Enforcement Coordinators to discuss enforcement issues and cases.

r. Coordinate with appropriate NMSS Division concerning possible enforcement action based on OI reports.

2.7.4 NMSS Staff

a. In accordance with delegations of authority for areas in which NMSS evaluates, directly manages, or conducts inspections, the NMSS staff:

1. Ensures that the enforcement activities conducted under current delegation(s) are consistent with established policy, guidance, and precedents.

2. Identifies violations of regulatory requirements and recommends enforcement action.

3. Appropriately documents enforcement actions.

4. Issues non-escalated enforcement actions, including Notices of Nonconformance, NOVs, and NCVs.

5. Signs and issues NRC Form 591s (if so qualified and authorized) for Severity Level IV violations and Non-Cited Violations (NCVs).

6. Recommends the severity level of an apparent violation and provides information that bears on the mitigation or escalation of a civil penalty, if proposed.

7. Prepares a Panel Worksheet and compiles supporting information for enforcement or SDP panels.

8. Conducts enforcement panels, predecisional enforcement conferences, and enforcement caucuses.

9. Requests EA numbers for all contemplated escalated enforcement actions.

10. Submits all escalated enforcement actions to OE for review and approval.

11. Reviews responses to enforcement actions to determine whether corrective actions are adequate.

12. Reviews OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted.

b. In accordance with guidance from the Director, NMSS, to support the enforcement program, the NMSS staff:

   1. Participates in enforcement panels to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

   2. Attends predecisional enforcement conferences.

   3. Participates in enforcement caucuses to provide additional agency perspectives associated with the enforcement strategy for potential escalated enforcement actions.

   4. Reviews the enforcement strategy for regional escalated enforcement actions for material licensees to ensure that the violations have been adequately established and that the safety significance of the violations has been properly evaluated from an overall agency perspective.

   5. Provides comments (verbally, electronically (e-mail "OEMAIL") or in writing) based on the review in paragraph (d) of this section to the Director, OE, normally within 5 working days of receipt of the enforcement package.

   6. Reviews applicable OI reports and makes recommendations to OE for enforcement action, including immediate action, when warranted.

2.8 Office of Nuclear Security and Incident Response (NSIR)

NSIR reviews the enforcement strategy for escalated enforcement actions involving security at nuclear facilities and security of nuclear materials and nuclear activities (including fitness-for-duty and access authorization issues) to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

2.8.1 Director, Division of Nuclear Security, NSIR

As directed by the Director, NSIR, the Division Director of Nuclear Security:

a. Serves as the principal NSIR manager responsible for enforcement matters involving security at nuclear facilities and security of nuclear materials and nuclear activities.

b. Ensures that the enforcement strategy for escalated enforcement actions and cases involving Commission papers involving security at nuclear facilities and security of nuclear materials and nuclear activities are reviewed to ensure that the violations have been adequately established and that the significance of the violations has been properly evaluated from an overall agency perspective.

c. Ensures that comments are provided (verbally, electronically ("OEMAIL"), or in writing) based on the review in paragraph (b) of this section to the Director, OE, normally within 5 working days of receipt of the enforcement package in headquarters.

d. Ensures that the NSIR Enforcement Coordinator and project, technical, and management personnel attend enforcement and SDP panels, predecisional enforcement conferences, regulatory conferences, and enforcement and SDP caucuses, as appropriate.

e. Contacts the Director, OE as soon as possible, and normally no later than 24 hours after receiving the SDP/EA Request & Strategy Form, if he or she disagrees with an enforcement strategy arrived at during an enforcement panel or enforcement caucus.

f. Reviews applicable OI reports to identify immediate safety issues and provide NSIR perspective in determining appropriate enforcement action.

g. Recommends to the Director, OE, initiation of proposed enforcement action, as appropriate.

h. Ensures that response to task interface agreements are coordinated with OE, as appropriate.

i. Recommends to the Director, OE, changes to the Enforcement Policy or guidance within this Manual, as appropriate.

2.8.2 NSIR Enforcement Coordinator

As directed by NSIR management:

a. Serves as the principal NSIR contact for enforcement matters involving security at nuclear facilities and security of nuclear materials and nuclear activities.

b. Participates in the weekly regional enforcement and SDP panels considering all cases involving security at nuclear facilities and security of nuclear materials and nuclear activities.

c. Leads the NSIR review of the enforcement strategy for enforcement actions discussed during panels and caucuses and notifies appropriate NSIR management of the enforcement strategy, especially in cases where the Enforcement Coordinator disagrees with the strategy.

d. Obtains necessary technical support from other NSIR divisions to ensure that the enforcement strategy for actions proposed by the regions are technically adequate and that reactor safety aspects of the violation have been properly evaluated from an overall agency perspective and are consistent with previous actions or staff positions.

e. Participates in predecisional enforcement conferences and regulatory conferences with enforcement implications, when the issues warrant.

f. Consolidates NSIR views on the enforcement strategy for proposed escalated actions and forwards the NSIR comments (verbally, electronically ("OEMAIL"), or in writing) to the Director, or Deputy Director, OE for enforcement actions submitted to headquarters.

g. Participates in regularly scheduled conference calls with OE, the regions, and the other program office Enforcement Coordinators to discuss enforcement issues and cases.

h. Reviews applicable OI reports to identify immediate safety issues, coordinates with appropriate NSIR staff, and provides NSIR perspective in determining appropriate enforcement action.

2.9 Office of Public Affairs

The Office of Public Affairs (OPA), including the regional Public Affairs Officer (RPAO), generally issues press releases for proposed civil penalties, orders modifying, suspending, or revoking a license and orders imposing civil penalties (if the civil penalty has been withdrawn or substantially mitigated) and in other enforcement cases as appropriate, such as imposition of a particularly large or significant civil penalty. Press releases are also normally issued to announce predecisional enforcement conferences and regulatory conferences that are open for public observation. These press releases should be brief and carefully worded so as not to prejudge the outcome. They should include an explicit description of the nature of the conference as a predecisional opportunity for the licensee to present any additional material information before the NRC arrives at a decision.

Although press releases are not normally issued for escalated NOVs proposed without a civil penalty, there are two situations in which a press release should be issued. Press releases should be issued for escalated NOVs proposed without a penalty, where, but for the 5-year statute of limitations, a civil penalty would have been proposed. Press releases should also be issued for escalated NOVs proposed without a penalty, where, but for the limitation of proposing a civil penalty against a vendor (i.e., could not establish that the violation was a knowing and conscious failure to notify the NRC in accordance with 10 CFR Part 21), a civil penalty would have been proposed. OPA may choose to issue a press release for escalated NOVs associated with an SDP finding.

OPA may also choose to issue press releases for other enforcement actions that they view as newsworthy.

2.10 Office of the Chief Financial Officer

The Chief Financial Officer has been delegated authority to issue orders to licensees who violate Commission regulations by nonpayment of license and inspection fees.

2.11 Office of State Programs

The Office of State Programs, including the Regional State Liaison Officer, work in conjunction with the regional offices and the program offices to ensure proper transmittal of enforcement actions issued to individuals licensed by the State and enforcement actions issued to Agreement State Licensees.

2.12 Commission Notification and Consultation

a. The Commission is provided written Enforcement Notification (EN) (Form 26-I, 26-II, or 26-III) prior to issuing an enforcement action as follows:

   1. Same-day EN:

      a. all immediately effective orders;

      b. any case on which the Commission was previously consulted;

      c. all enforcement actions that are being withdrawn or rescinded and the Commission was previously notified of their issuance; and

d. all NOEDs issued involving natural events, such as severe weather conditions. (See NOED guidance in Part 9900 of the Inspection Manual for format.)

2. Three-day EN:

a. all escalated NOVs associated with white, yellow, or red SDP findings;

b. all enforcement actions involving civil penalties or orders (except orders for non-payment of fees) that are not subject to a same-day EN;

➜ **NOTE**: ENs should include a detailed discussion of the basis for assessing a civil penalty for any violation that is characterized through the SDP in accordance with the ROP. [SRM 8/2/2001; SECY-01-0114]

c. actions involving exercise of discretion under Section VII.A.1, if discretion is being exercised and the deviation in the amount of the civil penalty proposed under this discretion from the amount that would be assessed under the normal process is greater than two times the base civil penalty in Tables 1A and 1B, the EN should specifically note this exercise of discretion; and

d. actions involving exercise of discretion under Section VII.B.2 of the Enforcement Policy the first time that it is exercised for that plant shutdown.

3. Five-day EN:

Exercising discretion under Section VII.B.6 of the Enforcement Policy, regarding violations involving special circumstances and issuance of the EN is appropriate based on the uniqueness or significance of the issue. In approving use of Section VII.B.6 discretion, OE will review the decision as to whether to issue an EN.

4. In General:

a. OE prepares and issues ENs for enforcement actions that are submitted to and reviewed by OE. The Region prepares ENs for cases that are not submitted to OE for review (i.e., cases where OE previously agreed to the enforcement strategy through a panel or caucus). The Region should subsequently submit these ENs to OE for issuing.

b. If an order is issued to a non-licensee or to a licensed operator, the EN should so state.

c. The Commission should receive a more detailed and earlier explanation of an enforcement action than an EN provides if the action is likely to have implications for broader sanctions (i.e., where the staff contemplates significant additional enforcement action in the near future) or involves issues that are of substantial public interest. [SRM 11/26/96; SECY-96-222]

- **The Region should ALWAYS consult with OE prior to issuing an action involving an EN to ensure that (any) comments from the Commission are considered prior to issuance.**

b. The Commission is provided written Regulatory Notification (RN) (Form 27-I or 27-II) prior to issuing a significant regulatory action, such as a Final Significance Determination for a white, yellow, or red finding (that does not include an NOV) or an order that requires additional safety measures beyond the regulatory framework (versus an order based on compliance issues, e.g., 2002 security orders) as follows:

1. Same-day RN:

   a. all immediately effective orders;

   b. any case on which the Commission was previously consulted;

   c. all significant regulatory actions that are being modified, withdrawn or rescinded, and the Commission was previously notified of their issuance.

2. Three-day RN:

   a. all Final Significance Determination letters with a white, yellow, or red finding (that does not include an NOV).

3. In General:

   a. OE prepares and issues RNs for significant regulatory actions in a manner similar to the issuance of ENs. (See Section 5.5.3 for specific implementing guidance.) OE prepares and issues RNs using the standard format in Appendix B (Form 27-I or 27-II) and assigns the RN the next sequential number from the EN system.

   b. The Commission should receive a more detailed and earlier explanation of a significant regulatory action than an RN provides if the action is likely to have implications for broader sanctions or involves issues that are of substantial public interest.

   c. **The Region should ALWAYS consult with OE prior to issuing an action involving an RN to ensure that (any) comments from the Commission are considered prior to issuance.**

c. The Commission is consulted[1] (SECY paper or memorandum) prior to taking action in the following situations (unless the urgency of the situation dictates immediate action):[2]

1. An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation.

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[1] If the Commission paper relates to discrimination based on a Department of Labor finding, see Section 7.7.6 for additional guidance.

[2] Commission papers should normally be negative consent matters. The recommendation block should read "If the Commission does not direct otherwise within 2 weeks from the date of this paper, the staff intends to issue the proposed enforcement action as discussed herein."

2. Proposals to impose a civil penalty for a single violation or problem that is greater than three times the Severity Level I value shown in Table 1A of the Enforcement Policy for that class of licensee.

3. Any proposed enforcement action that involves a Severity Level I violation.

4. Any action the EDO believes warrants Commission involvement.

5. For enforcement cases involving an OI report where the NRC staff (other than the OI staff) disagrees with the conclusions of the OI report concerning issues of intent, Commission consultation is needed unless the Director, OI agrees that it is not warranted. If the Commission is not consulted, OE should document in the case file the nature of the disagreement, how it was resolved, and the concurrence of OI in proceeding with the enforcement action without Commission consultation (see Section 7.5.4.1.d).

6. Any proposed enforcement action on which the Commission asks to be consulted.

7. Cases involving deliberate misuse of licensed material and in which the staff concludes that discretion should be exercised and no enforcement action issued. [SRM 8/13/97; SECY-97-153]

8. Any enforcement action initiated more than 18 months after a violation is initially identified (based on the completion date of the inspection), or more than 18 months after referral of a potential violation to OI where the enforcement action in the case was affected or modified as a result of the age of the action and the EDO believes that Commission consultation is warranted. The region should draft a Commission paper for headquarters' review that explains the reasons for the delay (with input from OI, as necessary), and explains the rationale for the staff's proposal with a specific focus on what effect the delay has on the proposed action. This would include consideration of factors such as, but not limited to:

   a. How is the effectiveness of the proposed enforcement action likely to be affected by the delay?

   b. Should the focus of the action be modified as a result of the delay? (If we have observed several years of good performance in the area in question, perhaps the action should focus on sending a message to individual wrongdoers rather than to the licensee.)

   c. Has the delay affected our ability to find or obtain credible evidence from organizations or individuals?

   d. Are the expected benefits to public health and safety justified by using limited NRC resources to pursue this action?

   If the enforcement action in the case was <u>not</u> affected or modified as a result of the age of the action, or, if the enforcement action was affected by the age of the action but the EDO does not believe that Commission consultation is warranted, then a Commission paper need not be written. Instead, OE should draft a memorandum (using Form 37 in Appendix B) from the Director, OE to the DEDE that explains the reasons for the delay (with input from OI and the applicable regional office, as necessary), and explains the rationale for the staff's proposal with a specific focus on what effect the delay has on the proposed action and brief consideration of the factors included in paragraphs a through d above.

A copy of this memorandum should also be provided to the Commissioner's assistants at least 5 days before the action is to be taken.

2.13 Special Task Forces

From time to time, NRC management may choose to establish a special task force to investigate or otherwise review circumstances for which agency enforcement action is a possible outcome. A special task force can serve a valuable purpose by bringing special expertise and insight into the investigative and enforcement processes.

At its inception, any special task force formed to investigate or otherwise review circumstances for which agency enforcement action is a possible outcome should have its role within the agency's existing investigative and enforcement processes clearly delineated in a charter or tasking memorandum. In particular, the charter or tasking memorandum should address whether the special task force's activities and work products should be independent or integrated within the existing investigative and enforcement processes and should include a clear strategy for how the special task force's work will ultimately be used by the agency. For example, should the special task force prepare an independent report or should they prepare input for an OI, NRR, NMSS, or region-based report? Should they participate in enforcement decision-making activities, such as participating in enforcement panels, conferences, and caucuses? Clearly defining the responsibilities of the special task force and establishing a work plan at the outset should preserve its usefulness and avoid confusion regarding the documentation and follow-up of task force findings.

CHAPTER 3
DISPOSITIONING NONCOMPLIANCES

3.1 Scope of the Chapter

This chapter provides guidance to the staff to address the initial stages of the enforcement process. It provides guidance for: maintaining a proper focus on protecting public health and safety; identifying and gathering facts for noncompliances; assessing the significance of violations and issues (including the use of information from the reactor oversight process's significance determination process (SDP)); assigning severity levels; tracking enforcement and SDP issues; conducting enforcement and SDP panels; documenting noncompliances; and handling predecisional enforcement information. Once the staff has determined how a noncompliance should be dispositioned (e.g., Non-Cited Violation, non-escalated or escalated enforcement action, or treated under discretion), the guidance in Chapters 4, 5, 6, and 7 should be used to process the appropriate enforcement action.

3.2 Protecting Public Health And Safety

When an inspector identifies what appears to be a significant safety issue, his or her first response should be to ensure that corrective actions are initiated to protect the public health and safety. Whether the issue warrants potential enforcement action is a secondary consideration.

If the public is likely to be endangered by continued operations, or there is a concern involving the lack of integrity of those involved in licensed activities, the region should initiate immediate action to correct the condition and consider, depending on the circumstances, issuing a Confirmatory Action Letter (CAL) or immediately effective order.

Based on the circumstances of the case, an expedited inspection report may be prepared limited in scope to the issue, or enforcement action may be taken before an inspection report is issued or a predecisional enforcement conference is held.

3.3 Identifying Noncompliances and Gathering Facts

Potential noncompliances may be identified through NRC inspection activity, NRC investigation, licensee identification (such as through internal audits, employee reports, or a self-disclosing event), or through an allegation supported by an NRC inspection or investigation. For the purposes of the enforcement program and this Manual, noncompliances include violations, deviations, and nonconformances.

a. A **violation** is defined as a licensee's failure to comply with a legally binding requirement, such as a rule, order, license condition, or technical specification. The manner in which a violation is dispositioned, i.e., as a Non-Cited Violation (NCV), in a Notice of Violation (NOV), or the subject of an exercise of enforcement discretion, does not change the fact that the issue is a violation. Failure to comply with a Regulatory Guide or Generic Letter is not by itself a violation (unless they have been incorporated into a license condition) because Regulatory Guides and Generic Letters are not substitutes for requirements. For example, if a Generic Letter or Demand for Information requests information from a licensee pursuant to the provisions of 10 CFR 50.54(f) and the licensee does not respond, then it would be a violation of 10 CFR 50.54(f). A licensee's failure to comply with its procedures is not a violation unless the licensee's procedures have been made a legally

binding requirement. Violations should be considered and referred to as "apparent" until the NRC formally dispositions them.

b. A **deviation** is defined as a licensee's failure to satisfy a written commitment or conform to the provisions of code, standard, guide, or accepted industry practice when the commitment, code, standard, guide, or practice involved has not been made a legally binding requirement by the Commission, but is expected to be implemented. Written commitments include statements made by the licensee providing information on how NRC requirements will be met relative to facility design, construction, and operation. Examples of licensee commitments include responses to bulletins, generic letters, or 10 CFR 50.54(f) requests. Although the failure of a reactor licensee to meet a commitment in the final safety analysis report (FSAR) may constitute a deviation, the failure may also be a violation of 10 CFR 50.59 or a violation of a technical specification, a general design criterion, or a quality assurance requirement.

c. A **nonconformance** is defined as a vendor's or certificate holder's failure to meet contract requirements related to NRC activities (e.g., 10 CFR Part 50, Appendix B) where the NRC has not placed requirements directly on the vendor or certificate holder.

The first step in the enforcement process is to ensure that specific information is gathered about the potential noncompliance. This information will help the agency to:

- determine whether a noncompliance has occurred (the fact that an event with safety consequences occurs does not necessarily mean that a noncompliance has occurred),
- assess the safety significance of the noncompliance,
- categorize the severity level of the noncompliance (if appropriate), and
- determine the appropriate enforcement action.

This information is also used to subsequently document the potential noncompliance. Therefore, it is important that the information be accurate and complete. The questions listed below are intended to serve as a guideline for gathering enforcement information. However, they should not be considered prescriptive, nor all encompassing.

- What requirement or commitment was violated?
- How was the requirement or commitment violated?
- When was the requirement or commitment violated and how long did it exist?
- How, when, and by whom (licensee or NRC) was the violation discovered?
- What is the apparent significance of the issue (actual or potential consequences, potential for impacting regulatory process, willfulness)?
- What information is necessary to complete the SDP (if applicable)?
- What was the root cause?
- What corrective actions have been taken or planned (if known)?
- Did the licensee place the place the issue in its corrective action program (if applicable)?
- Was the violation required to be reported and, if so, what was the applicable reporting requirement?

3.4 Assessing Significance

Before the staff decides how a violation should be dispositioned, it should first assess the significance of the violation or issue. In assessing significance, the NRC considers four specific issues:

- actual safety consequences;
- potential safety consequences, including the consideration of risk information;
- potential for impacting the NRC's ability to perform its regulatory function; and
- any willful aspects of the issue.

For certain types of violations at commercial nuclear power plants, the enforcement process relies on information from the reactor oversight process's Significance Determination Process (SDP). The SDP is used to evaluate the actual and potential safety significance of inspection *findings* to provide a risk-informed framework for discussing and communicating the significance of inspection findings. The final disposition of violations associated with findings that have been evaluated through the SDP is contingent on the risk significance attributed to the findings. See Section 3.5 for additional guidance on using information from the SDP.

Other violations are assigned a severity level to reflect their significance which then factors into the how the violation should be dispositioned. See Section 3.6 for additional guidance on assigning severity levels.

Some violations are so insignificant that they do not warrant enforcement action. See Section 3.9 for additional guidance on these minor violations.

The following paragraphs provide a general discussion of the guiding principles in assessing significance.

a. **Actual Safety Consequences.** In evaluating actual safety consequences, the NRC considers issues such as actual onsite or offsite releases of radiation, onsite or offsite radiation exposures, accidental criticalities, core damage, loss of significant safety barriers, loss of control of radioactive material or radiological emergencies. (See Section 3.5 for guidance on violations that are associated with SDP findings with actual consequences.)

b. **Potential Safety Consequences.** In evaluating potential safety consequences, the NRC considers the realistic likelihood of affecting safety, i.e., the existence of credible scenarios with potentially significant actual consequences. The NRC will use risk information wherever possible in assessing significance and assigning severity levels. A higher severity may be warranted for violations that have greater risk significance and a lower severity level may be appropriate for issues that have low risk significance. Duration is an appropriate consideration in assessing the significance of violations. See the additional guidance on using risk considerations in Section 3.7.

c. **Impacting the Regulatory Process.** The NRC considers the safety implications of noncompliances that may impact the NRC's ability to carry out it statutory mission. Noncompliances may be significant because they may challenge the regulatory envelope upon which certain activities were licensed. These types of violations include failures such as: failures to provide complete and accurate information, failures to receive prior NRC approval for changes in licensed activities; failures to notify NRC of changes in licensed activities; failure to perform 10 CFR 50.59 analyses; failures associated with the change process provisions in 10 CFR 50.54(a) (involving quality assurance programs), 10 CFR 50.54(p) (involving safeguards plans), 10 CFR 50.54(q) (involving emergency plans); and reporting failures, etc., Even inadvertent reporting failures are important

because many of the surveillance, quality control, and auditing systems on which both the NRC and its licensees rely in order to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting. The existence of a regulatory process violation does not automatically mean that the issue is safety significant. In determining the significance of a violation, the NRC will consider appropriate factors for the particular regulatory process violation. These factors may include: the significance of the underlying issue, whether the failure actually impeded or influenced regulatory action, the level of individuals involved in the failure and the reasonableness of the failure given their position and training, and whether the failure invalidates the licensing basis. Factors to consider for failures to provide complete and accurate information are addressed in Section IX of the Enforcement Policy.

Unless otherwise categorized in the Supplements to the Enforcement Policy, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

d. **Willfulness.** Willful violations are by definition of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. Willful violations cannot be tolerated by either the Commission or a licensee. Therefore, a violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness. The term "willfulness" as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., negligence or inadvertent clerical errors in a document submitted to the NRC. In determining the significance of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official[3] or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the significance assessment will be dependent on the circumstances of the violation. However, if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be considered at least more than minor. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances such that it demonstrates the seriousness of the violation thereby creating a deterrent effect within the licensee's organization.

All willful violations must be coordinated with OE. Additional guidance on willful violations is included in Chapter 7.

[3]The term "licensee official" as used in the enforcement program means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license. Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

3.5 Using Information From the Significance Determination Process (SDP)

The reactor oversight process uses an SDP to evaluate the actual and potential safety significance of most inspection *findings* to provide a risk-informed framework for discussing and communicating the significance of inspection findings. Specific guidance on the reactor oversight process is included in NRC Inspection Manual Chapter 2515 and guidance on the SDP is described in the NRC Inspection Manual, Chapter 0609. Depending on their significance, inspection findings are assigned colors of:

- green (very low safety significance),
- white (low to moderate safety significance),
- yellow (substantial safety significance), or
- red (high safety significance).

The reactor oversight process uses an Agency Action Matrix to determine the appropriate agency response for findings whether or not violations are involved. If violations that are more than minor (i.e., green, white, yellow, or red) are associated with these inspection findings, they will be documented and normally dispositioned as NCVs or in NOVs depending on the safety significance. These violations are not normally assigned severity levels, nor are they normally subject to civil penalties. Instead of using civil penalties as a deterrent, enforcement actions in this approach are but one part of the agency's overall regulatory response. The reactor oversight process's Agency Action Matrix will cause the staff to consider specific regulatory actions based on the risk significance of the issue. Actions might include increased inspections, Demands for Information (DFIs), or orders.

However, civil penalties (and the use of severity levels) will be considered for issues with actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, failure to make the required notifications that impact the ability of Federal, State and local agencies to respond to an actual emergency preparedness (site area or general emergency), transportation event, or a substantial release of radioactive material.

Civil penalties and severity levels will also be used to address violations that are willful or that have the potential for impacting the regulatory process.

The use of civil penalties in these instances remains appropriate as a deterrent for these types of issues. To the extent that the SDP can provide an assessment of the significance of the underlying violation or issue, it should be used as a first step in resolving the violation. This will ensure a consistent approach for significance determinations. The staff should consider the SDP output in conjunction with the guiding principles for assessing significance and the guidance included in the Supplements of the Enforcement Policy to determine the appropriate severity level. For example, a procedural violation associated with an inspection finding characterized by the SDP as green may be categorized at Severity Level IV based on the risk significance and ultimately assigned a Severity Level III categorization because the violation was willful.

3.6 Assigning Severity Levels and Using Enforcement Policy Supplements

For those issues that are not assessed through the SDP, the staff should use severity levels as a way of distinguishing the significance of violations that warrant enforcement action. Severity levels also help to determine the appropriate enforcement action. The Enforcement Policy establishes four severity levels:

- Severity Level I (most significant; very significant)
- Severity Level II (very significant)
- Severity Level III (significant)
- Severity Level IV (least significant; more than minor; not significant based on risk)

Severity Level I and II violations usually involve actual or high potential consequences on public health and safety. Severity Level III violations are significant enough to warrant consideration of civil penalties. Enforcement actions including Severity Level III violations (with or without civil penalties) are considered escalated actions to reflect the level of regulatory concern. Although Severity Level IV violations are not significant based on risk, it does not mean that they have no risk significance.

The Commission recognizes that there are other violations of minor safety or environmental concern that are below the level of significance of Severity Level IV violations. While licensees must correct these minor violations, they don't normally warrant documentation in inspection reports or inspection records and do not warrant enforcement action. To the extent such violations are described, they will be noted as violations of minor significance that are not subject to enforcement action. See Section 3.9 for additional guidance on minor violations.

Supplements I through VIII of the Enforcement Policy provide examples of violations in eight different activity areas and serve as guidance for determining severity levels. However, the examples are neither exhaustive nor controlling. If a violation fits an example contained in a supplement, it should normally be evaluated at that severity level. If, however, the region believes that a different severity level categorization is warranted and the circumstances are not addressed by this Manual, the region should either explain the rationale in the Panel Worksheet when the case is sent to headquarters, or consult with OE prior to issuing the enforcement action in the region. If the staff chooses to categorize a violation at a severity level different from the examples in the supplements, the cover letter to the licensee should address the staff's rationale for categorizing the severity level. If a violation does not fit an example in the supplements, it should be assigned a severity level commensurate with its safety significance. Additional guidance on severity level categorization for the different activity areas is addressed in Chapter 8.

Consistent with the guiding principles for assessing significance, the severity level for a violation may be increased if it includes willfulness. This does not apply to those examples in the supplements where willfulness is already factored in.

3.7 Using Risk Information

Risk is a relevant consideration in enforcement decisions concerning significance, severity levels, appropriateness of sanctions, and the exercising of enforcement discretion.

The uncertainties associated with risk assessment are recognized as PRA models utilized by the staff and licensees vary in quality, creating the potential for differing views on the risk significance of events. In addition, some PRA limitations do exist, particularly in the area of human reliability analysis. In utilizing the results of PRA, the staff should not generally base an enforcement decision wholly on quantitative risk numbers; rather, risk significance should be an input in the consideration of the final enforcement action.

In determining the appropriate enforcement action, the staff should continue to balance risk information against the guidance currently provided in the Enforcement Policy and the Enforcement Policy Supplements. The staff should routinely consider the risk implication of each reactor case considered for escalated action.[4] Depending on the circumstances of the case, this assessment may be qualitative, relying primarily on engineering judgment based on qualitative risk insights; or quantitative risk analysis, or some combination of the two. However, if the staff is to use specific, quantitative PRA results or qualitative risk insights to support an enforcement decision, it should be reviewed by an NRC PRA specialist prior to issuance of the action, generally the Senior Reactor Analysts (SRAs). The Regional SRA is the preferred point for this review, due to the plant specific design and operational information available to the regional staff. In addition, any quantitative PRA results provided as a basis for an enforcement action should explicitly reference the source (e.g., IPE, specific analysis) so that all assumptions, conditions, and methods are retrievable for subsequent review, if needed. The basis for qualitative assessment should be briefly described.

Judgment must be exercised in the use of risk significance as a factor in decisions regarding the appropriateness of the sanction. There may be cases where, due to increased risk significance, it is appropriate to both escalate the severity level and the sanction[5] in order to convey the correct regulatory message to the licensee and the use of enforcement discretion may be warranted to reach the proper enforcement action. Based on risk information it may be warranted to treat violations normally considered a Severity Level IV violation at a higher severity level.

While a higher severity level and sanction is warranted for violations that have greater risk significance; it may also be appropriate to consider a lower severity level or enforcement action for issues that have low risk significance. However, low risk does not excuse noncompliance. If a licensee believes an issue is of low risk and not worthy of being a requirement, the licensee may seek a change to the requirement. However, until the requirement is changed, compliance is required.

At each weekly enforcement or SDP panel meeting, OE will ask whether the violation involves a risk significant issue. The region is expected to have a position on risk significance or be able to describe

[4] Some reactor cases involve issues or events that do not lend themselves to PRA insights. For example security, health physics, and emergency preparedness issues are typically not amenable to current methods of risk assessment. In these cases, risk insights from a PRA perspective will not be needed.

[5] The Supplementary Information section to the December 1996 policy change stated that "[I]n developing higher civil penalties, the Commission intends to consider, where appropriate, assessing civil penalties for each violation that is aggregated into a Severity Level II problem.

what steps should be taken to obtain a view on risk if the matter may be risk significant.[6] To the extent known, the licensee's position on risk for the violations at issue should be discussed. While regional input is normally the first step in the considerations, this should not be considered only a regional responsibility. NRR should also be prepared to provide a view of risk.

Following the decision at the enforcement or SDP panel to pursue escalated enforcement on a particular issue where risk may be relevant to the enforcement decision, an assignment will be made to obtain additional risk information as necessary. A repanel will be held as warranted.

Assuming the event is of sufficiently increased risk significance to warrant escalated action, the issue of risk significance should normally be addressed in the correspondence with the licensee that arranges a predecisional enforcement conference or regulatory conference or in the "choice letter," i.e., we should note that the apparent violations appear to be risk significant and that if the licensee differs in that view, the licensee should provide a brief explanation of its position. Conferences should normally be held for risk significant cases.

3.8 Factors That do Not Affect Significance

Whether the licensee finds and reports a problem, or whether the licensee takes prompt and extensive corrective actions, is normally not considered in determining significance, unless these items are part of the violation itself. In addition, the **significance of a violation should not be increased if it is repetitive**. Similarly, **the staff should not view the significance of a group of related programmatic violations as being greater than the individual violations (i.e., aggregation)**. While these issues may be considered in developing the appropriate enforcement action and agency response (increased inspections, management meetings, etc.,), they should not be used to increase significance.

In addition, the actions of a public utility commission or other State or local regulatory agency in response to a proposed NRC enforcement action are not matters to be considered in applying the Enforcement Policy. Specifically, the possible impact from the reaction of a public utility commission or other State or local regulatory agency should not be considered in determining potential severity level, civil penalty amount, (if a civil penalty is proposed) or nature and context of an order. Examples of potential impacts that might occur include not allowing recovery of the cost of a civil penalty or cost of the replacement power for an outage necessitated by the violations at issue. However, if a State regulatory agency has taken enforcement action against a licensee for a transportation issue, the NRC should consider that action before determining appropriate enforcement action. (See Section 8.5.2 for additional guidance on NRC action in conjunction with State action for a transportation violation.)

[6] After completion of training, and when made available on a full-time basis, the region should, to the extent practical, use the Senior Reactor Analysts to assist them. These individuals should be consulted for risk significance insights prior to each respective Regional Enforcement Panel, in order for the panel to have some assessment of the risk significance of the events discussed. To the extent these individuals are not available, risk insights should be gathered from the Events Assessment and Generic Communications Branch in the weekly meeting, IPE's, and core PRA knowledge. Assistance from Research should be sought as needed. OE is available to assist the Region in obtaining Headquarters assistance in this effort.

3.9 Minor Violations

Minor violations are below the significance of Severity Level IV violations and violations associated with green SDP findings and are not the subject of enforcement action. The failure to implement a requirement that has insignificant safety and regulatory consequences should normally be categorized as a minor violation. While licensees **must correct minor violations**, minor violations **do not normally warrant documentation** in inspection reports or inspection records and **do not warrant enforcement action**. See Section 3.12.1 for specific guidance and sample language for the few exceptions when documenting minor violations is warranted.

Inspection Manual Chapter 0612 provides guidance for determining whether issues identified under the reactor oversight process are minor. Where a licensee does not take corrective action or willfully commits a minor violation, the circumstances will result in categorization at least at Severity Level IV or associated with a least a green SDP finding and consideration of an NOV requiring a formal written response from the licensee.

Examples of different categories of violations that may be considered minor include, but are not limited to:

a. Record keeping issues - issues that do not preclude the licensee from being able to take appropriate action on safety-significant matters or properly assessing, auditing, or otherwise evaluating its safety-significant activities.

b. Licensee administrative requirement/limit issues - cases where licensees exceed administrative limits, limits that licensees impose upon themselves that are more conservative than regulatory limits.

c. Insignificant dimensional, time, calculation, or drawing discrepancies - characterized by minor discrepant values referred to in either the licensee's Final Safety Analysis Report (FSAR) or design documents.

d. Insignificant procedural errors - procedural errors or inadequate procedures that have no impact on safety equipment or personnel safety.

e. Work in progress findings - for the purposes of enforcement, "work in progress" is defined as any violation occurring and identified in the course of performing work or maintenance on equipment that is out of service or declared inoperable per the technical specifications and has no safety consequences, and the violation is identified and corrected prior to returning the equipment to service and/or declaring the equipment operable. Errors that occur on non-designated pieces of equipment, such as inadvertently or mistakenly operating a different train of the equipment, or errors that cause another requirement (e.g., technical specifications) to be violated, are not considered minor by this definition.

f. Minor changes to requirements - a failure to meet 10 CFR 50.59 requirements that involves a change to the FSAR description or procedure, or involves a test or experiment not described in the FSAR, where there was not a reasonable likelihood that the change would ever require NRC approval per 10 CFR 50.59. A failure to meet 10 CFR 50.71(e) by not updating the FSAR, where the failure would not have a material impact on safety or licensed activities. The focus of the minor violation is not on the actual change, test, or experiment, but on the potential safety role of the system, equipment, etc. that is being changed, tested, or experimented on.

In all cases, minor violations should have negligible actual safety consequences, little to no potential to impact safety, little to no impact on the regulatory process, and no willfulness. The following examples apply the above guidance and demonstrate a thought process that can be used in making the determination of whether a violation is minor. In all cases, this determination is based on the judgement of the inspector who identified the issue and the regional management involved and will depend on the circumstances of the particular issue.

3.9.1 Record Keeping Issues

a. In a licensee event report, the licensee reported that a particular problem had occurred twice before. The NRC later discovered that the problem had actually occurred three times before.

   The violation: Under 10 CFR 50.9, the licensee is required to provide complete and accurate information in all material respects.

   Minor because: This is a failure to include accurate information that has no safety consequences.

   Not minor if: The omission was shown to be deliberate.

b. In a records storage vault, the licensee observes a ceiling leak. Temporary containers were used to collect water during rainstorms. This "work around" continued for a year. However, the containers overflowed during a heavy weekend rainstorm when no one was available to monitor the containers and some safety-related records were damaged, but were still readable.

   The violation: The licensee failure to correct the water intrusion problem in a prompt manner which resulted in damage to and potential loss of records violated the 10 CFR 50.71 requirement to maintain adequate safeguards against tampering with and loss of records.

   Minor because: This was failure had no safety consequences because, although records were damaged and placed at risk, no records were lost.

   Not minor if: Required records were irretrievably lost.

c. The licensee's leak test records were not complete for all sources.

   The violation: A leak test is required by license conditions or by 10 CFR 34.27.

   Minor because: The leak tests were performed but not documented, or the last documented test revealed no radiological contamination or signs of leakage.

   Not minor if: The leak tests were not performed or a subsequent test showed leakage had occurred and the contamination was discovered later.

d. An inspector found that a licensee was missing area radiation survey records or weekly area contamination (smear) records.

   The violation: Area radiation surveys and contamination surveys are required by license conditions, 10 CFR 20.2103, or 10 CFR 35.

Minor because: The record of the survey is missing, but the survey was actually performed. No unexpected contamination or exposure resulted from the violation.

Not minor if: An unexpected contamination or exposure resulted from the violation.

3.9.2 Licensee Administrative Requirement/Limit Issues

a. NRC inspectors identified that a high radiation door was not locked as required by plant procedures. While the licensee's procedurally controlled administrative limit for area postings was exceeded, the door to the area was conservatively classified and did not exceed regulatory radiation levels that warrant posting as a locked high radiation area.

The violation: The licensee is committed to follow plant procedures (i.e., through License Condition, Technical Safety Requirements, or Technical Specifications). Site procedures require activities to be accomplished in accordance with procedures.

Minor because: The requirement was a licensee administrative limit. The area was conservatively posted and no regulatory limits requiring posting were exceeded.

Not minor if: The area radiation levels exceeded the limits such that the area should have been a locked high radiation area.

b. The NRC requires licensees to maintain the total effective dose equivalent (TEDE) to five rem per year. The licensee established by procedure an administrative limit of two rem per year. Radiation safety officer approval was required for any individual to exceed the procedural limit. Contrary to the licensee’s program, a technician received 2.7 rem in one year without approval from the radiation safety officer.

The violation: The licensee is required to follow their procedures per license conditions.

Minor because: This was a licensee administrative limit. The worker was within federal limits.

Not minor if: Multiple examples were identified of failures to satisfy station radiation protection procedures indicating a failure to maintain and implement programs to keep exposures as low as reasonably achievable.

3.9.3 Nonsignificant Dimensional, Time, Calculation, or Drawing Discrepancies

a. An inspector found that a few radiological survey instruments were beyond the required calibration frequency. The instruments were actually in calibration tolerance (when later checked).

The violation: The licensee is required to calibrate radiological survey instruments at specified intervals.

Minor because: The instruments were actually in tolerance and this was an isolated occurrence.

Not minor if: There is a programmatic problem in instrument calibration (i.e., multiple examples of not having instruments calibrated at the proper intervals) or the

instruments were out of calibration tolerance, resulting in a lack of reasonable assurance that the surveys performed were representative of the actual radiological conditions.

b. An inspector noted that the required training for a worker who ships radioactive materials was not completed as required.

The violation: The licensee is required to provide recurrent training every three years to workers who ship radioactive materials per 49 CFR and license conditions.

Minor because: The recurrent training was not yet performed, but the initial training had been performed and training had been scheduled. There was no actual consequence during the radioactive material shipments.

Not minor if: An actual consequence occurred that was attributed, in whole or in part, to the lack of training.

3.9.4 Insignificant Procedural Errors

a. An inspector discovered a small pile of low level radioactive material from a milling operation that was not properly posted with the words "Caution, Radioactive Materials." This problem occurred because of an oversight by the licensee.

The violation: The material should be posted as per 10 CFR 20.1902.

Minor because: This is a small area with low level radioactive material and access was restricted by a fence around the area. Other areas were sufficiently posted.

Not minor if: Other areas were also not posted or the radioactive material presented an accessible hazard.

b. An NRC inspector did not find an NRC Form - 3, "Notice to Employees" posted at a licensee facility.

The violation: The posting of the NRC Form-3 is required by 10 CFR 19.11.

Minor because: The safety significance is minor.

Not minor if: The licensee had already been told repeatedly about the requirement or it was a repeat violation.

c. A licensee reported to an NRC inspector that a shipment had been picked up by the shipper before the package had been surveyed by the licensee.

The violation: The survey of the radioactive material shipment is required by 49 CFR.

Minor because: This was the last of several surveys required in the licensee's procedures and the event resulted in no contamination or exposure potential (very low level radioactive material within the allowable regulatory limits).

Not minor if: This was the only required survey, a programmatic problem existed, the package was suspected to be very close to the regulatory limits, there was a history of contamination on the outside of similar packages, or there was a contamination event.

3.9.5 Work in Progress Findings

a. Prior to system operation following a modification, the licensee determined that the modification package that installed piping and cold traps to remove residual uranium hexaflouride from cylinder filling lines did not include the correct size orifice to reduce air flow as called for by the original system design. Due to the location of the orifice, a large airflow could occur that would render the cold traps useless in removing the uranium hexaflouride before it was exhausted to the environment, potentially resulting in an excessive release of uranium above technical specification requirement limits.

The violation: The orifice design was not translated into work instructions and drawings (or the drawings were not implemented) as required.

Minor because: This was work in progress. The error was identified and corrected during post modification testing prior to the system being declared operational.

Not minor if: The system is put in service without installing the correct size orifice or performing a calculation to show that the installed size will still meet the design requirements.

3.9.6 Minor Changes to Requirements

a. The licensee developed and approved a preventive maintenance task (not required to be reviewed by the plant onsite review committee) that required that a change be made to the plant technical specifications. A 10 CFR 50.59 screening was not performed. When requested to perform the task, control room operators identified that the task would violate technical specifications and did not perform it.

The violation: A task was changed that required a change to the technical specifications and no 10 CFR 50.59 screening was completed.

Minor because: The licensee's established process identified the problem prior to implementation. The problem did not affect any equipment and had no safety consequences.

Not minor if: The task had been performed.

b. FSAR steps for transferring to the recirculation phase following a loss of coolant accident required that the transfer be performed by first using Train A then using Train B. The emergency operating procedures were changed to allow concurrent use of both trains.

The violation: The 10 CFR 50.59 screening review performed to change the procedures did not recognize that it resulted in a change to the FSAR.

Minor because: There is not a reasonable likelihood that the change to procedure would ever be a change requiring prior NRC approval. This is a failure that has no safety consequences. A subsequent evaluation concluded that concurrent use of both trains was acceptable

Not minor if: The evaluation determined concurrent use of both trains was unacceptable.

c. The FSAR stated that each column of ice condenser baskets consisted of four baskets. The licensee modified the columns to add a fifth basket without performing a 10 CFR 50.59 review. The addition of the fifth basket did not affect the thermal hydraulic performance of the ice condenser.

The violation: It is a change to the facility as described in the FSAR and no 10 CFR 50.59 screening was performed.

Minor because: There is not a reasonable likelihood that the change would ever be a change requiring prior NRC approval. This is a failure that has no safety consequences.

Not minor if: The fifth basket caused changes in steam flow following a LOCA that would have resulted in containment design pressure being exceeded or other event where the necessary change would require Commission review and approval prior to implementation.

d. The licensee approved a temporary procedure to flush the shell side of a steam generator blowdown heat exchanger. The 10 CFR 50.59 screening found that the procedure did not affect the facility as described in the FSAR. However, the procedure change opened a valve that bypassed a steam generator blowdown radiation monitor which was described in the FSAR. In the event of a steam generator tube rupture, the emergency operating procedure directed operators to line up to the monitored tank, so no unmonitored release would occur.

The violation: The 10 CFR 50.59 screening was inadequate in that it incorrectly found that the procedure change did not affect the facility as described in the FSAR.

Minor because: This is a failure to meet 10 CFR 50.59 requirements that involves a change to the FSAR description, where there was not a reasonable likelihood that the change to procedure would ever be a change requiring prior NRC approval. There is no safety consequences because there is not reliance for safety on the radiation monitor during the heat exchanger flush evolution.

Not minor if: The procedure lined up the radioactive water to an unmonitored release path such that a release could occur.

e. The technical specifications required that the members of the offsite safety review board have, at a minimum, a bachelor degree in a technical field. One member had a degree in business only.

The violation: The technical specification is violated.

Minor because: This is a failure to implement a requirement that has no safety consequences.

Not minor if: The licensee fails to revise the technical specification.

3.10 Tracking Enforcement and SDP Issues

The staff tracks various enforcement and SDP issues through the use of OE's Enforcement Action Tracking System (EATS). Under this system, enforcement action (EA) numbers are assigned to a variety of issues. The guidance on when EA numbers should be used and how to request them is addressed in Section 3.10.1 and 3.10.2 respectively. Section 3.10.3 discusses the use of individual action (IA) tracking numbers to track enforcement actions issued to individuals. In addition to EATS, the Reactor Program System (RPS) provides a source of enforcement information.

3.10.1 Enforcement Action (EA) Numbers

Enforcement action (EA) numbers are assigned by OE as a method of administratively tracking and filing a variety of enforcement issues. As a matter of convenience, **EA numbers are also assigned to SDP issues that are addressed in SDP/enforcement panels**. **EA numbers are also assigned to program office orders imposing additional regulatory requirements (see paragraph (s)).** EA numbers are normally assigned when cases are discussed during enforcement or SDP panels, whether or not the case results in enforcement action. During or subsequent to an enforcement or SDP panel, OE will assign an EA number to each individual issue being considered for enforcement action or to each individual inspection finding being assessed by the SDP that does not have enforcement implications by completing the SDP/EA Request & Strategy Form (see the next section). In particular, OE will assign an **EA number to each enforcement issue (each individual violation or problem)** or SDP issue as noted below. (This enables OE to track individual violation/problem assessments.) OE will then send the form to the region. If additional related escalated violations or problems or SDP issues are identified subsequent to an enforcement or SDP panel, EA numbers will be assigned. If violations, problems, or issues are dropped subsequent to an enforcement or SDP panel, the related EA numbers should be closed. EA numbers are assigned sequentially according to the year of issuance (e.g., EA-00-011). Once an EA number has been assigned to a proposed violation, all subsequent documents involving the violation should include the complete five-digit EA number. EA numbers are assigned as follows:

a. Any issue that is discussed during an enforcement or SDP panel, regardless of whether the issue results in an enforcement action.

b. Any case in which a predecisional enforcement conference or Regulatory Conference is scheduled.

c. Any case in which the region issues an inspection report giving a licensee the choice of responding to apparent violations or requesting a predecisional enforcement conference (i.e., "choice letter").

d. All escalated enforcement issues. This includes those cases that require headquarters' review prior to issuance and those that do not. **EA numbers are assigned to each individual Severity Level I, II, or III violation or problem and to each individual violation associated with a white, yellow, or red SDP finding.** (This enables OE to track individual violation/problem assessments.) Multi-sanction cases receive individual EA numbers for each sanction (e.g., a case that includes both a proposed civil penalty and a separate (stand-alone) Demand For Information (DFI) would have one EA number for the proposed civil penalty and a separate EA number for the DFI). Orders that impose civil penalties retain the same EA number as the action that proposed the civil penalty.

e. Any case involving willfulness whether or not escalated or non-escalated enforcement action is to be issued, including willful cases where the staff proposes to exercise discretion and refrain from issuing enforcement action (e.g., NCV).

f. Severity Level IV NOVs and NOVs associated with green SDP findings involving power reactors. EATS will track why an NOV was issued in terms of the Section VI.A.1 Enforcement Policy criteria that was met.

g. Non-escalated enforcement actions requiring headquarter's review, including:

   1. Any enforcement action requiring Commission approval.
   2. Any non-escalated enforcement action involving an individual, other than an individual licensed by 10 CFR Parts 30, 40, and 70.
   3. Any enforcement action resulting from an AIT, IIT, or DET inspection, regardless of whether the issue will be dispositioned in an NOV or NCV.
   4. Any non-escalated enforcement action which, by the examples in the Supplements, could be categorized at Severity Level III or characterized as white by the SDP.
   5. Any non-escalated enforcement action related to a current proposed escalated enforcement action, unless there has been prior approval for separate issuance by the Director, OE.

h. Any case involving an exercise of discretion as addressed in Sections VII.B.2 - 6 of the Enforcement Policy.

i. Any case in which the staff proposes to exercise discretion and refrain from issuing an enforcement action for a transportation cask contamination violation that could be categorized at Severity Level III or above (see Section 8.5.4).

j. Any case in which a Notice of Enforcement Discretion (NOED) is issued, and the root cause that results in the need to request the NOED was a violation in itself (regardless of whether the violation will be dispositioned as an NCV or in an NOV). The EA number should be included on the subsequent enforcement action and should not be included on the NOED when it is issued.

k. Any case involving an OI report where enforcement action appears warranted (i.e., whether the action is based on willfulness or not and whether the action is escalated, non-escalated, or an NCV). OE will assign an EA number to the case when it determines enforcement action is warranted or when it requests an OGC analysis of whether enforcement action is supportable.

l. Any case in which the staff proposes to issue a Demand for Information (DFI). The DFI should be given an individual EA number even if issued together with another enforcement action. If another enforcement action is issued after the response to the DFI, a new EA number is also to be obtained.

m. Any case (during review and approval) in which the region proposes to issue any action to an individual (i.e., NOV, civil penalty, DFI, order, close out letter, Letter of Reprimand (LOR) or similar letter) (see Section 3.10.3 for further guidance on tracking individual actions).

n. Any case (during review and approval) in which the NRC proposes to issue an enforcement action (regardless of severity level) to a licensed operator for failure to comply with a facility licensee's fitness-for-duty (FFD) program.

o. Any case in which the NRC issues a "chilling effect" letter (CEL) for discrimination for engaging in protected activities. The region should request an EA number when it is determined that a CEL should be issued. The EA will be closed upon issuing the CEL itself. Any subsequent enforcement action proposed will be given a new EA number.

p. Any case where two investigative findings of discrimination by the same licensee are made within 18 months by the Department of Labor Area Director.

q. Any case referred to DOJ in which the NRC is considering escalated enforcement action.

r. Any disputed minor violation, Severity Level IV violation, or violation associated with a green SDP finding (regardless of whether it was dispositioned as an NCV or in an NOV) that did not have an EA number when it was originally dispositioned. Actions (including escalated) that were originally issued with an EA number should be tracked using the existing EA number. Appropriate keywords should be used to identify the violation as disputed in EATS.

s. An order (issued by the program office) imposing additional requirements beyond the existing regulatory requirements (e.g., 2002 security orders). One EA number may be used in the event the same order is issued to multiple licensees. The program office should contact OE (normally through their office Enforcement Coordinator) as soon as they believe an order should be issued.

t. Any issue that OE , the region, or the program office believes is warranted.

3.10.2 Preparing and Maintaining SDP/EA Request & Strategy Forms (Strategy Forms)

SDP/EA Request & Strategy Forms (Strategy Forms) are used to request an EA number from OE and to summarize the agency's strategy for dispositioning SDP and enforcement issues. Strategy Forms also serve as aids during case deliberations. Because the agency's strategy for an issue may evolve over time, Strategy Forms also serve to record the conduct of enforcement or SDP meetings and discussions about the strategy and document the basis for any change in enforcement or SDP approach. A Strategy Form is included in Appendix D.

To ensure that Strategy Forms fully serve their purposes, the following guidance should be implemented:

a. Every issue paneled in an enforcement or SDP panel will get an EA number whether or not the case results in enforcement action. For example, an inspection finding characterized as white by the SDP will be assigned an EA number even if there are no violations associated with it. If a violation is associated with the white issue, only one EA number needs to be issued to address the case. EA numbers simply serve as a tracking and filing references.

b. The region will request an EA number from OE for cases that have not been paneled by submitting a completed Strategy Form for those cases that require an EA number (see Section 3.10.1 for a complete listing of cases that require an EA number).

c. A Strategy Form should be prepared following each panel. In addition to the necessary information to support EATS, the form should briefly state:

- what was agreed to at the meeting;

- if there was not agreement at the meeting, a brief description of the disagreement and what actions are being taken to resolve the difference;
- whether actions need to be taken to obtain the views of others (briefing of the managers in the normal decision chain need not be stated);
- whether additional investigation, interviews, or inspection activities are needed;
- whether there is a need to revisit the agreement after further reviews of the evidence or research is conducted; or
- any other actions needed to resolve the issue.

d. The Strategy Form should list the principal participants involved in the discussions. For multi-office panels, at a minimum, it should include regional and OE Enforcement Specialists, Enforcement coordinators from NRR, NMSS, and NSIR, and the lead manager or staffer from each office represented (including OGC). It should also list any OI investigator, technical specialist, or other individual who provided substantial insights to the discussion.

e. Subsequent to an SDP or enforcement panel, OE will provide the Strategy Form to the region, the program office (through the NRR, NMSS, or NSIR Enforcement Coordinator), the Associate General Counsel for Hearings, Enforcement, and Administration, and to any OGC attorney or OI representative who participated in the panel.

f. The Strategy Form should normally be completed within one working day of the panel, subsequent panel, enforcement caucus, or other substantiative communication where the enforcement strategy is discussed.

g. Copies of the Strategy Forms are retained by OE in the official EA case files, with regional work sheets and other background documents, until the file is placed in storage (usually 2 years after the case is closed), at which time the Forms may be discarded. The original Strategy Form is filed by EA number and region in a consolidated file maintained by OE.

h. After a subsequent panel, caucus, or substantiative discussion, the Strategy Form should be updated by noting the original EA number, the date of the meeting or discussion, the form revision number, and the outcome of the meeting, including a brief explanation of the reason for any change in strategy. The background information need not be restated unless it changed. The updated Strategy Form is approved, distributed, and filed like the original Strategy Form.

3.10.3 Individual Action (IA) Numbers

Individual Action (IA) numbers are assigned by OE to administratively track and file **all** correspondence issued to an individual, if that individual is being considered for or has been issued an enforcement action.

Use of IA numbers enables the NRC to maintain a list of individuals who have been considered for individual enforcement action. With the assignment of an IA number, all external correspondence is included in a separate system of records (NRC-3, "Enforcement Actions Against Individuals"). By the notice establishing this system of records, individual actions and correspondence with individuals may be maintained by personal identifier in NRC offices.

a. IA numbers are assigned to any case in which correspondence is addressed to an individual concerning potential enforcement action. IA numbers should be used on all close-out letters. IA numbers should be used on conference or choice letters. The region should use an EA number for the review and approval stages and get an IA number from OE when the correspondence is

ready to be issued. The EA number should not appear on the correspondence issued with an IA number and should not appear in the ADAMS profile. The same IA is used through an individual's case, including any subsequent action, e.g., Letter of Reprimand (LOR), Non-Cited Violation (NCV), NOV, civil penalty, Demand for Information (DFI), order, or close-out letter. This includes NOVs issued to licensed operators for FFD violations, (regardless of severity level). Like the original correspondence, the region should use the EA number for the draft action through the review and approval stages and include the IA number on the final action when it is ready to be issued. The EA number should not appear on the action issued with an IA number and should not appear in the ADAMS profile. The EA file should be closed upon issuing the final IA action. The EA file should be reopened for tracking purposes if the individual requests a hearing.

b. IA numbers are **not** assigned to cases in which a DFI or order involving an individual is issued to the licensee, unless the correspondence is directed to an individual concerning his or her performance, in which case, paragraph "a." applies.

c. OE includes copies of significant enforcement actions issued against individuals on the **Enforcement** Web site. Significant Enforcement Actions (NOVs with Severity Level I, II, or III violations, civil penalties, and orders) are listed alphabetically since 1995 in the enforcement document collection in the electronic reading room.

d. OE includes summaries of all enforcement actions (NOVs with Severity Level I, II, III, or IV violations, DFIs, civil penalties, and orders) issued to individuals in its annual report (available in the enforcement document collection in the electronic reading room).

e. Individuals prohibited or restricted by order in their employment in NRC licensed activities (previously included on the "Restricted Individuals List") are included in the Significant Enforcement Actions Issued to Individuals in the enforcement document collection in the electronic reading room of the NRC's public Web site.

Appendix D includes a matrix that summarizes tracking and publication information regarding actions against individuals. Chapter 7 includes guidance on distribution of individual actions, including when and when not to make actions available to the public through ADAMS (PARS).

3.11 Enforcement and SDP Panels

Enforcement panels are meetings to discuss and reach agreement on an enforcement approach for certain violations of NRC requirements, and to assure consistency in the resolution of such violations.

SDP/enforcement panels are meetings to discuss and reach agreement on the significance of inspection findings at power reactors that appear to be more significant than green under the SDP. Because the outcome of the SDP provides an input into the enforcement process, a secondary purpose for such panels is to discuss and reach agreement on an enforcement approach for any violations that might be associated with the inspection findings. Although these panels are similar to enforcement panels in many respects, specific guidance for SDP/enforcement panels is included in NRC Inspection Manual Chapter 0609.

The following types of violations and related issues should be brought to an enforcement panel unless specifically exempted by current enforcement guidance in the Manual or an EGM. For example, if enforcement guidance gives the region the authority to classify a potentially escalated violation at Severity Level IV based on specific criteria, and those criteria are met, the issue need not be brought to a panel.

If a regional office does not believe a panel is necessary for one of the listed items, the Regional Enforcement Coordinator should consult with OE. The Director, OE, may make exceptions to this guidance in cases where the proposed resolution of the issue is noncontroversial and is consistent with recent precedent and current policy. In addition, an Office Director or Regional Administrator may request a panel to discuss any issue that is not specifically covered by this list. Unless specified, the following list applies to all types of NRC licensees.

a. Violations for which escalated enforcement action is recommended, i.e., any violation for which an order, an NOV at Severity Level I, II or III, an NOV associated with a white, yellow, or red SDP finding, or a civil penalty is being recommended.

b. Violations involving a finding of wrongdoing or discrimination by OI, a licensee or DOL, including cases that OI has referred to DOJ. These violations should be discussed regardless of the apparent severity level.

c. Violations normally classified at Severity Level I, II or III or associated with a white, yellow, or red SDP finding for which enforcement discretion in accordance with Sections VII.B.2-6 is being recommended. OE should be consulted by telephone for Severity Level IV issues.

d. Violations normally classified at Severity Level I, II or III or associated with a white, yellow, or red SDP finding for which non-escalated action is being recommended.

e. Cases in which enforcement action is being considered against an individual, including a licensed reactor operator, regardless of the severity level of the violation.

f. Cases in which a Demand for Information is being recommended prior to making a final enforcement decision.

g. Cases where information obtained during a predecisional enforcement conference or in response to a choice letter or Demand for Information needs to be considered in determining enforcement action.

h. Violations at power reactors where a departure from the NCV policy is proposed, i.e., to issue an NOV when the NCV criteria are met and vice versa.

i. Licensee-disputed violations, violations of 10 CFR 50.59, violations of 10 CFR Part 55, or violations of 10 CFR 50.65 that cannot be resolved via coordination between the involved offices.

3.11.1 Participating in Enforcement Panels

Participation in enforcement panels should be in accordance with the following guidelines:

a. **Region**: The region should schedule cases on the regular weekly panel conference call with OE. In addition to OE, the region should notify either the NRR or NMSS Enforcement Coordinator. The region should also invite the Assistant General Counsel for Materials Litigation and Enforcement and the applicable OI investigator and Regional Field Office Director for cases involving willfulness. The region should strive to provide participants with **one weeks notice of the meeting**. The region is responsible for chairing the panel and presenting the pertinent facts of the case.

   The regions may choose to conduct internal meetings prior to the scheduled enforcement panel as they see the need. These internal meetings are often useful to review the details of the incident

to focus the subsequent panel discussion on the major issues and for the region to develop its position for efficient presentation during the panel call.

It is expected that the region will be represented on the panel call by a person at the Division Director level or higher. It is important to recognize that the regional participants provide a recommendation to the Regional Administrator and that their position does not represent the final region position. (See Section 3.11.3.h for additional guidance on enforcement strategy disagreements.)

b. **OE**: To achieve timely decision-making, either the Director or Deputy Director, OE will normally participate in panels in addition to the OE Enforcement Specialist. OE should help facilitate discussions and should focus on ensuring that violations are accurate and that strategies are consist with the Enforcement Policy, EGMs and other guidance, and past practice.

c. **Program Office**: The program offices should be invited to participate in panels (attendance is not necessarily mandatory). The NRR, NMSS, and NSIR Enforcement Coordinators are responsible for arranging for participation by the appropriate and necessary program office staff and for ensuring that the staff has briefing materials in advance of the meeting. (See Section 3.11.2 for guidance on briefing materials.)

In evaluating the appropriateness of the proposed enforcement strategy, program office participants should focus on whether the violations are technically accurate and factual and whether the enforcement strategy is consistent with the program office's policy, guidance, position, or past practice. If program office participants disagree with the enforcement strategy discussed during the panel, they are responsible for elevating their concerns to program office management (the Associate Director for Inspection and Programs for NRR cases, and the applicable Division Director for NMSS and NSIR cases). (See Section 3.11.3.h for additional guidance on enforcement strategy disagreements.)

d. **OGC/OI**: OGC (Assistant General Counsel for Materials Litigation and Enforcement) should be invited to panels involving willfulness and other cases with potential issues of legal significance. OI (applicable investigator and Regional Field Office Director) should be invited if there are questions as to OI findings.

3.11.2 Preparing for Enforcement Panels

In order for enforcement panels to be effective, the regions need to ensure that they are appropriately prepared. Although it is recognized that these meetings are conducted during the preliminary stages of the enforcement process, sufficient information should be gathered to support the meeting's purpose, i.e., to discuss the apparent violations, severity levels, violation groupings, escalated history, preliminary civil penalty assessment, etc. If sufficient information is not available, the enforcement panel will likely need to be rescheduled. The regions may choose to conduct internal meetings prior to the scheduled enforcement panel as they see the need. These internal meetings are often useful to review the details of the incident to focus the subsequent panel discussion on the major issues and for the region to develop its position for efficient presentation during the panel call.

The regions should send **SDP-related information** to OE and the NRR Enforcement Coordinator (and the NSIR Enforcement Coordinator, if applicable) at least **72 hours in advance of an SDP/enforcement panel**. (See Inspection Manual Chapter 0609 for specific details on SDP-related information.)

The regions are to send **briefing materials to OE (e-mail "OEMAIL"), OGC, the NRR, NMSS, or NSIR Enforcement Coordinator, and the EDO regional coordinator, at least 48 hours in advance of the meeting**.

Briefing materials for proposed actions should include:

- a draft inspection report (or draft report excerpt or other draft document that addresses the circumstances of the case),
- other available information, such as an LER,
- a case summary (the region may use the SDP/Enforcement Panel Worksheet (Panel Worksheet) (included in Appendix D) or comparable summary),
- a draft NOV,
- factors for the Sanction in Actions Against Individuals (included in Appendix D), if applicable, and
- a written analysis of the evidence that may support each element of a discrimination case, if applicable (included in Appendix D).

Briefing information for an imposition should include the licensee's response to the proposed civil penalty action.

All briefing materials should be appropriately marked as predecisional information. Briefing materials sent to OE should either be faxed or sent by e-mail to "OEMAIL" as well as to the individual OE participants.

3.11.3 Enforcement Panel Outcome

Depending on the discussions in the enforcement panel, the staff will determine one of several outcomes.

a. **If the staff concludes that no violation occurred**, OE will document the disposition of the issue by completing the Strategy Form (no violation or SDP finding without a violation). OE will send the form to the region and make it available to the program office and OGC.

b. **If the staff concludes that non-escalated enforcement should be proposed**, OE will assign an EA number to the case and document the disposition of the issue by completing the Strategy Form (including why an NOV vs. an NCV was issued). OE will send the form to the region and make it available to the program office and OGC. Thereafter, the regions may generally issue the enforcement action without prior coordination or review with OE. In special cases, OE may request that the action be coordinated or reviewed prior to issuance.

c. **If the staff concludes that a predecisional enforcement conference should be conducted**, the region should proceed to issue the inspection report (2 weeks in advance of the conference) using the transmittal letter in Appendix B (Form 1-I...**"conference letter"**). (See Section 5.2 for additional guidance on conferences.)

d. **If the staff concludes that a predecisional enforcement conference need not be conducted, but that additional information about the licensee's corrective action is necessary to decide on enforcement action or that a civil penalty is warranted**, the region should proceed to issue the inspection report requesting a licensee response using the transmittal letter in Appendix B (Form 1- II...**"choice letter"**). Issuing a "choice letter" may be appropriate where a licensee appears to understand the significance of the violation and the need for corrective action at the

inspection exit, but that the inspector may not be aware of all of the corrective actions subsequent to the inspection exit. This is more likely to be the case for materials licensees' inspections because inspectors are not stationed at the materials facilities. Issuing a choice letter may provide the emphasis to the licensee to develop and implement comprehensive corrective actions to avoid the potential for a civil penalty. Following receipt of the licensee's response to the inspection report, the region should arrange for OE consultation (with the Enforcement Specialist) or another enforcement panel, if warranted. The purpose of the meeting is to discuss whether new information or perspectives were obtained that may warrant reconsidering the preliminary enforcement strategy for the case, including whether a predecisional enforcement conference is necessary. The discussion should include, among other things, the reasonableness of the licensee's corrective action. If the staff concludes that a conference is necessary, the region should arrange for a conference with the licensee as soon as possible. If the staff concludes that a conference is not necessary, the meeting in essence evolves into an enforcement caucus meeting, whereby the staff determines the final enforcement strategy for the case. (See Section 5.4 for additional guidance on enforcement caucuses.)

e. **If the staff concludes that a predecisional enforcement conference need not be conducted and that sufficient information exists to conclude that a civil penalty is not warranted**, the region may choose to issue the inspection report requesting a licensee response using the transmittal letter in Appendix B (Form 1-II...**"choice letter"**) including the additional paragraph informing the licensee that a civil penalty does not appear warranted. This approach should reduce resource expenditures by the licensee if the licensee understands in advance that the agency does not plan to issue a civil penalty. Following receipt of the licensee's response to the inspection report, the region should arrange for OE consultation (with the Enforcement Specialist) or another enforcement panel, if warranted. The purpose of the meeting is to discuss whether new information or perspectives were obtained that may warrant reconsidering the preliminary enforcement strategy for the case, including whether a predecisional enforcement conference or civil penalty is necessary. The discussion should include, among other things, the reasonableness of the licensee's corrective action. If the staff concludes that the documented corrective action is not sufficiently prompt and comprehensive such that a civil penalty may be warranted, an enforcement conference may be necessary. If the staff concludes that a conference is necessary or if the licensee requests a conference, the region should arrange for a conference with the licensee as soon as possible. If the staff concludes that a conference is not necessary, the meeting in essence evolves into an enforcement caucus meeting, whereby the staff determines whether the draft NOV should be modified or withdrawn.

f. **If the staff concludes that a predecisional enforcement conference need not be conducted and that sufficient information exists to conclude that a civil penalty is not warranted**, the region may choose to make a **"choice call"** to the licensee. In such cases, the license will be contacted by telephone and informed that the NRC does not see a need for a predecisional enforcement conference or a written response prior to issuing the enforcement action. However, during the telephone call, the licensee is provided the option of attending a conference or submitting a written response to the apparent violations in the inspection report. The letter to the licensee transmitting the Notice of Violation (Form 3-I or 3-II) will document the conversation.

   If the licensee indicates during the choice call that it does desire to have a conference or provide a written response before the NRC issues its enforcement action, then the staff should follow the applicable guidance for issuing a choice letter and then reviewing the licensee's response afterwards.

g. **If the staff concludes that an additional panel or discussion is necessary**, the same principal panel participants should attend if practicable. The other participants, to the extent that they might have information relevant to the issues to be discussed, should also attend if practicable. However, all of the participants need not be present to conduct a subsequent panel or discussion. The Enforcement Specialist should bring the previous Strategy Form(s) to subsequent panels for the case. It is not always necessary to hold a new panel to change a past agreement recorded on a Strategy Form. OE management can agree to change an agreement as a result of telephone calls or meetings outside the panel process. After a subsequent panel or substantiative discussion, the Strategy Form will be updated noting the outcome of the meeting, including a brief explanation of the reason for any change in enforcement strategy and distributed so that the region, program office, and OGC are aware of the change and can comment, if desired. Following receipt of the revised Strategy Form, it is the responsibility of the principal participants to verify that the revised strategy is acceptable to the office or region. The principal participants are responsible for discussing, as warranted, changes to previously agreed upon strategy with the prior panel participants from their office or region who may not have been involved in the subsequent panel or discussion. The regional principal participants should discuss, as warranted, the issues with OI. Disagreements with the revised strategy should be handled as discussed below.

h. **If, after being briefed on the enforcement panel outcome, the Regional Administrator, the Associate Director for Inspection and Programs for NRR cases, or the applicable Division Director for NMSS or NSIR cases, disagree on enforcement strategy issues** such as severity level, SDP characterization, civil penalty assessment, or whether a predecisional enforcement conference is necessary, they should contact the Director, OE as soon as possible, and no later than 24 hours after receiving OE's summary of the enforcement strategy documented on the Strategy Form. In the case of a regional disagreement, the Regional Administrator and Director, OE should confer and either resolve their differences or promptly escalate the matter to the DEDO. (Depending on the nature of the regional disagreement, OE may arrange for program office participation.) In the case of a program office disagreement, the Associate Director for Inspection and Programs for NRR cases, or the applicable Division Director for NMSS or NSIR cases, should confer with the Director, OE, and the Regional Administrator to resolve their differences or the Director, OE will promptly escalate the matter to the DEDO. Based on the outcome of these discussions, if warranted, OE will revise the summary of the agreed upon enforcement strategy on the Strategy Form and send it to the region and program office.

i. **Re-exiting**. If, as a result of the panel discussion, a substantive change is made to the apparent violations or message given at the exit, a re-exit should be held. This may be done by the branch chief by telephone.

3.12 Documenting Noncompliances

Noncompliances (other than minor violations) are normally documented in inspection reports or, in certain cases involving material licensees, inspection records or by using NRC Form 591, "Safety and Compliance Inspection." See the guidance in Section 4.4 of this Manual for detailed guidance on the use of NRC Form 591 to document noncompliances. In addition, detailed guidance on preparation of inspection reports and use of inspection records is contained in the NRC Inspection Manual, Chapter 0610, "Inspection Reports," Chapter 0612, “Power Reactor Inspection Reports,” and Chapter 87100, "Licensed Materials Program," respectively.

➜ **NOTE**: Inspection Manual, Chapters 0610 and 0612 address thresholds for documentation in inspection reports.

The manner in which a noncompliance is documented in an inspection report or inspection records depends on how the noncompliance will be dispositioned. Inspection reports or inspection records must contain a sufficiently detailed discussion of the inspection findings to substantiate the significance and support any enforcement sanction the NRC may choose to issue. The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance. The inspection report or inspection records should include information, as appropriate, that was previously gathered considering the issues in Section 3.3.

With the exception of inspection reports associated with potential escalated enforcement action, inspection reports are generally to be issued within the timeliness goals established in Chapters 0610 and 0612 of the Inspection Manual (i.e., 30 calendar days after the completion of an inspection for regional or resident inspector reports and 45 calendar days after the completion of an inspection for integrated and major team inspection reports).

➜ **NOTE**: If an issue is described in an inspection report in sufficient detail to conclude that a noncompliance has occurred, then that observation **must be dispositioned** as a violation, an apparent violation, or an NCV. To simply document a noncompliance as a "weakness," "licensee failure," "observed discrepancy," "minor violation," or similar characterization without dispositioning it is inappropriate. If a noncompliance has not occurred, to avoid any confusion, it may be appropriate in certain situations to include a statement such as, "this issue does not constitute a violation of NRC requirements."

3.12.1 Documenting Minor Violations

Although minor violations must be corrected and discussed with the licensee (normally during the inspection exit), **minor violations should not normally be documented in inspection reports**. Although minor violations should not normally be documented, there are a very few exceptions when documentation is **warranted**.

- Documenting a minor violation may be warranted as part of closing out a Licensee Event Report, where it would be obvious to a member of the public that a violation is involved (e.g., “failure to follow procedures,” in the body of the LER or as part of the title). Documentation in this case helps to provide public confidence that the agency is not blatantly ignoring a violation. In contrast, documenting a minor violation would not be warranted where a violation is identified because of questions raised by an inspector or because of an inspector’s training and expertise.

- Documenting a minor violation may be warranted if the associated technical information relates directly to an issue of agency-wide concern (e.g., to document the results of am NRC temporary instruction (TI)).

To the extent such violations are described, they will be noted as violations of minor significance that are not subject to enforcement action. For example:

> Although this issue should be corrected, it constitutes a violation of minor significance that is not subject to enforcement action in accordance with Section IV of the Enforcement Policy.

In these types of cases, minor violations should not normally be discussed in inspection report cover letters. The documentation in inspection reports and inspection records should briefly describe the violation circumstances. A discussion of the corrective actions is not necessary. Minor violations documented in inspection records **should not be cited on NRC Form 591**.

If a licensee disputes that a minor violation is a violation, the region should respond by following the procedures in Section 4.2.6 Licensee Denial of NCV.

3.12.2 Documenting Non-Cited Violations (NCVs)

In accordance with Section VI.A of the Enforcement Policy, the NRC may disposition certain Severity Level IV violations and violations associated with a green SDP findings as NCVs. (See Section 4.2 for additional guidance for dispositioning violations as NCVs.) NCVs should be discussed in the report details and the summary of findings sections of the report and noted in the inspection transmittal letter in accordance with the following general guidance. See the specific guidance below for documenting reactor licensee NCVs and all other licensee NCVs.

Inspection report details should briefly describe the requirement and how the requirement was violated. Even though the issue may warrant disposition as an NCV, the staff must still provide sufficient detail to substantiate the existence of a Severity Level IV violation or violation associated with a green SDP finding (see applicable guidance in Inspection Manual Chapter 0612). Although the degree of detail necessary to support a violation is a function of the significance and the complexity of the noncompliance, the supporting detail for a given Severity Level IV violation or violation associated with a green SDP finding should be the same, whether it is dispositioned as an NOV or NCV.

NCVs should be addressed in the inspection report transmittal letter (cover letter) after any cited violations. The staff should use the cover letter in Form 2, as applicable. The discussion should simply note how many NCVs were identified, and include "appeal" process language (see Section 4.2.6 for guidance on the NCV appeal process). Cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.

The details of specific NCVs should not normally be discussed in inspection report cover letters. However, there may be instances where a brief discussion of an NCV is warranted, such as cases where categorization at Severity Level III or association with a white issue was seriously considered and where it is important to emphasize the importance of corrective action.

Cover letters should not be used as a substitute for an NOV. In particular, cover letters should not normally seek additional information about an NCV.

The following discussion provides specific guidance for documenting reactor licensee NCVs and all other licensee NCVs.

a. **Power Reactor Licensees**: Section VI.A.1of the NRC Enforcement Policy provides that most Severity Level IV violations and violations associated with green SDP findings involving a power reactor be dispositioned as NCVs unless they meet one of the exceptions that may warrant citation in an NOV. The inspection report should also include the licensee's corrective action program file reference. In many cases, the licensee will not have yet developed the corrective actions at the time of the inspection report's issuance. If the inspector is aware of the licensee's corrective actions, they may choose to document them in the inspection report. Documentation of the licensee's corrective actions is not required for enforcement purposes. An applicable conclusion should be included that the issue will not be cited, as follows:

> This Severity Level IV violation is being treated as a Non-Cited Violation, consistent with Section VI.A.1 of the NRC Enforcement Policy. This violation is in the licensee's corrective action program as (include file reference).

> This violation is associated with an inspection finding that is characterized by the Significance Determination Process as having very low risk significance (i.e., green) and is being treated as a Non-Cited Violation, consistent with Section VI.A.1 of the NRC Enforcement Policy. This violation is in the licensee's corrective action program as (include file reference).
>
> Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this violation is being treated as a Non-Cited Violation, consistent with Section VI.A.1 of the NRC Enforcement Policy. This violation is in the licensee's corrective action program as (include file reference).

b. **All Other Licensees**: Licensee-identified Severity Level IV violations that satisfy the remaining criteria in Section VI.A.8 of the Enforcement Policy may be dispositioned as NCVs. Documentation in inspection reports and inspection records should also briefly describe the corrective actions to provide a basis for a repetitive violation if the corrective actions are inadequate or not implemented.

   NCVs documented in inspection reports should be cited in inspection reports as NCVs, while NCVs documented in inspection records should be cited as NCVs on NRC Form 591. In both cases, a conclusion should be included that the violation will not be cited, as follows (depending on whether or not the violation was willful):

> This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.
>
> Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.

3.12.3 Documenting Non-Escalated Enforcement Actions

Severity Level IV violations and violations associated with green SDP findings that are cited in an NOV may be documented in an inspection report or inspection records and should be addressed throughout the documentation as "violations" versus "apparent violations," (since an actual NOV is included). The violations should be addressed in the report details and summary of findings, and conclusion sections of the inspection report. Inspection report details should briefly describe the requirement and how the requirement was violated. The staff must provide sufficient detail to substantiate the existence of a Severity Level IV violation or violation associated with a green SDP finding (see applicable guidance in Inspection Manual Chapter 0610). The degree of detail necessary to support a violation is a function of the significance and the complexity of the noncompliance. The cover letter transmitting the non-escalated NOV should be prepared in accordance with the guidance in Section 4.3 and Form 2 in Appendix B. The cover letter MUST address why an NOV is being issued in terms of the Section VI.A Enforcement Policy criteria they met.

Severity Level IV violations may also be dispositioned through the use of NRC Form 591. (See Section 4.4 for guidance on the use of NRC Form 591.)

Deviations and nonconformances are generally issued as part of non-escalated enforcement actions and may be documented in inspection reports or inspection records. The deviations or nonconformances should be addressed in the executive summary, report details, observations and

findings, and conclusion sections of the inspection report. The cover letter transmitting a Notice of Deviation should be prepared using Form 2 in Appendix B with appropriate modifications to reflect the Notice of Deviation as the enforcement action versus an NOV. Notices of Deviation involving FSAR issues require the approval of the Director, OE. The cover letter transmitting a Notice of Nonconformance should be prepared using Form 9 in Appendix B.

3.12.4 Documenting Potential Escalated Enforcement Actions

Issues being considered for potential escalated enforcement action should be documented in inspection reports (inspection records should not be used) and should refer to the potential noncompliances as "apparent violations" throughout the report and **should not include any specific conclusions regarding the safety significance or severity level of the apparent violations or SDP characterizations.** The discussion of an apparent violation in the inspection report should address the facts supporting the significance of the issue without making any specific conclusions about the "safety significance." For example, in a particular case involving a procedure violation, it would be appropriate to include the following sentence in the inspection report, "Although the apparent violation of the failure to follow procedures did not result in an actual safety consequence, it could have (under the circumstances) resulted in an overexposure." However, for the same case, it would not be appropriate to say, "The apparent violation of the failure to follow procedures was not safety significant." First, the latter conclusion does not capture the full set of circumstances of the issue (i.e., that there was a potential safety consequence). Second, although this sentence does not specifically include a severity level categorization, the conclusion could be construed as not meeting the threshold for escalated action.

The safety significance and severity level or SDP characterization of issues being considered for escalated action is not normally made until after an enforcement or SDP panel, a predecisional enforcement conference or regulatory conference, and enforcement or SDP caucus. A premature conclusion of the safety significance and severity level or SDP characterization for an apparent violation in the inspection report has the potential for confusion if views change based on a subsequent review of the facts.

Apparent violations should be addressed in the executive summary, report details, observations and findings, and conclusion sections of the inspection report. The staff should use the applicable version of Form I, to transmit the inspection report and apparent violations, depending on whether a conference or choice letter is appropriate.

3.12.5 Documenting Violations That Potentially Involve Willfulness

The discussion of noncompliances in inspection reports or inspection records **should not include any conclusions about the intent of a violation, such as whether it was deliberate, willful, or due to careless disregard.** The discussion in the inspection report should address the circumstances surrounding the apparent violation without making a conclusion about the intent of the violator. For example, it would be appropriate to include the following sentence in an inspection report (presuming the facts are clear), "Despite informing the inspector that he was aware of the need to use an alarming dosimeter when performing radiography, the radiographer failed to activate his alarming dosimeter." It would not be appropriate to say, "The radiographer deliberately failed to activate his alarming dosimeter." Conclusions about the willfulness of an apparent violation represent agency decisions that are normally not made until after OI has performed an investigation and a predecisional enforcement conference has been held.

The staff needs to be cautious about describing facts associated with apparent willfulness. For example, if the person says he was aware of a requirement, was he aware at the time of committing the violation, or did he become aware after the violation? Complete and accurate discussion of the facts that support willfulness of an apparent violation in the inspection report is important. If during an inspection indications of willfulness are identified, regional management and OI should be promptly notified.

Inspection reports that include apparent violations that may involve willfulness are to be coordinated with OI, and OE should be notified prior to the issuance of the report.

3.12.6 Documenting Violations That Warrant Mitigation Enforcement Discretion

In accordance with Sections VII.B.2 through VII.B.6 of the Enforcement Policy, the NRC may choose to exercise discretion and refrain from issuing an NOV or civil penalty for a Severity Level I, II, III, or IV violation. When discretion is being considered for a violation and the agency has not yet reached a formal enforcement decision, the inspection report narrative should refer to the violation as an "apparent violation." Conversely, when the agency concludes that discretion should be exercised for a violation that meets the criteria of Sections VII.B.2 through VII.B.6 of the NRC Enforcement Policy, these issues should be documented in inspection reports (inspection records should not be used) as violations.

➜ **NOTE**: These violations should not be documented in inspection reports as NCVs.

The "NCV" term is reserved for violations that meet the criteria for discretion in accordance with Section VI.A. These violations should be addressed in the summary of findings, report details, and conclusion sections of the inspection report. The report should state, "Discretion is being exercised after consultation with the Office of Enforcement pursuant to Section VII.B._ of the Enforcement Policy and a violation is not being issued." The cover letter to the licensee should include a reference to the applicable section of the Policy, the severity level of the violations, and a clear basis for exercising this discretion. Example cover letter discussions are provided in each of the discretion sections in Chapter 6.

3.12.7 Documenting Multiple Examples of a Violation

As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation or NCV. However, it is recognized that inspector judgement must be used to evaluate each individual case on its own merits to conclude the appropriate manner for dispositioning issues.

Whether or not multiple examples should be cited in a single violation should consider whether different root causes are involved and whether different corrective actions are necessary to prevent recurrence for the different examples. If the corrective action is similar for multiple examples of violations of the same requirement(s) they should normally be cited in a single citation. For these situations, the following guidance is provided:

An Unresolved Item from a previous inspection report period that is subsequently resolved to be a violation may be included with additional examples in a current report period if, in the judgement of the inspector and his/her management, the similarities of the violations reasonably constitute "examples" of the same underlying violation.

Absent the multiple examples, each example must be able to stand alone as a separate Severity Level IV violation, i.e., multiple minor violations must not be aggregated to justify a Severity Level IV violation.

The number of examples cited should be limited to the number necessary to make the case for any corrective actions beyond the specific details of each example such that the scope and depth of needed corrective actions is illustrated. If numerous examples were identified during the inspection, the NOV should cite representative examples of the highest safety/regulatory significance.

The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

3.12.8 Documenting Related Violations (Violation Grouping)

The staff should not view the significance of a group of related programmatic violations as being greater than the individual violations (i.e., aggregation). While these issues may be considered in developing the appropriate enforcement action and agency response (increased inspections, management meetings, etc.,), they **should not** be used to increase significance.

Although violations should not be aggregated for purposes of increasing the significance, in some cases, it may be appropriate to group violations into one problem. The reason for grouping violations into a problem is to appropriately characterize the significance of the event or incident. Grouping the violations informs the licensee and the public that NRC is aware that the violations are closely related and are not separate regulatory breakdowns. Therefore, the staff will need to use judgement in determining whether grouping the violations will convey the appropriate message. When dispositioning violations as a problem, the staff should follow the guidance below:

- The staff should only group violations that are closely related, such as having a cause and affect relationship or directly related to the same event (e.g., failure to perform adequate testing that results in a piece of inoperable equipment, loss of material and failure to report the loss).

- The staff can group violations that have the same or different severity levels. When doing so, the problem should be assigned the severity level of the most significant violation. The staff should not assign a severity level to the problem that is higher than the most significant violation (i.e., should not aggregate lower severity level violations into a problem assigned a higher severity level).

- When determining the civil penalty for the problem, the staff should follow the civil penalty assessment process for each escalated violation and should not assess a civil penalty higher than would be assessed for an individual violation. Do not follow the civil penalty assessment process for the problem as a whole.

Examples:

- Grouping two Severity Level III violations grouped into one problem:

  For the first violation, we may not give identification credit, give corrective action credit, therefore, base Severity Level III civil penalty. For the second violation, give identification

credit, not give correction action credit, therefore, base Severity Level III civil penalty. Therefore, assign the problem a base Severity Level III civil penalty. Note if you would have considered the problem as a whole, you may have given both identification and corrective action credit and issued no civil penalty or said given neither identification nor corrective action credit and issued two times the base civil penalty.

- Grouping a Severity Level II and a Severity Level III violation:

  For Severity Level II violation, not given identification credit, given corrective action credit, therefore, base Severity Level II civil penalty. For Severity Level III violation, not given identification credit, not given corrective action credit, therefore, two times base Severity Level III civil penalty. Therefore, assign the problem a two times base Severity Level III civil penalty.

The cover letter should discuss the significance of each individual violation.

The problem should include all applicable supplements.

➜**NOTE**: These examples are not controlling. As stated before, the staff will need to use judgement in determining whether grouping violations is appropriate.

3.12.9 Documenting Additional Examples of Violations Previously Cited

Cases frequently arise in which additional examples of violations are identified that have already been cited as NOVs or dispositioned as NCVs. In such cases, if corrective actions from the earlier issues have not been completed at the time of the violation and no broad additional corrective actions are warranted (i.e., the examples, if known at the time of the original inspection, would not have been included in the initial citation to establish the scope and depth of the needed corrective actions), the additional examples need not be cited. In these cases, any inspection report description of the additional example(s) should include text similar to the following:

> This violation constitutes an additional example of [violation][NCV] 50-333/98-15-01 and is not being cited individually. No additional response to violation 50-333/98-15-01 is required. Further corrective actions for this additional example are expected to be taken in conjunction with corrective actions for the previously cited violation.

3.13 Proper Handling of Predecisional Enforcement Information

The NRC staff should discuss the identification of apparent violations with licensees or release inspection reports that document apparent violations to licensees to ensure that corrective actions are initiated to protect the public health and safety and to obtain compliance. (Information that may impact an OI matter should be coordinated with OI (see Section 7.5)).

The NRC staff may not discuss or release predecisional enforcement information to licensees or the public regarding matters such as the potential severity level of a violation, the proposed amount of a civil penalty, or the nature or context of an order. The release of predecisional information may unnecessarily interfere with the enforcement process and may inappropriately affect licensees or their employees. The premature release of information, other than premature release by clearly inadvertent actions, is a serious matter and may be considered for referral to the Office of the Inspector General (OIG). It is recognized

that predecisional information may need to be released to achieve a settlement of an enforcement action or to reach agreement on a confirmatory order. The Director, OE, must be consulted before predecisional information is released or if predecisional information has been released. If a licensee requests the status of a particular matter under enforcement review, the Regional Administrator may advise the licensee, for example, that the matter is being referred to headquarters for consideration of escalated enforcement action.

Predecisional documents associated with a proposed enforcement action should be clearly marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval of The Director, OE," until the final enforcement action is issued.

Additional information is included in Management Directive 3.4, “Release of Information to the Public.”

CHAPTER 4
NON-CITED VIOLATIONS & NON-ESCALATED ENFORCEMENT ACTIONS

4.1 Scope of the Chapter

This chapter describes the how Non-Cited Violations (NCVs) and various non-escalated enforcement actions should be prepared and processed. Timeliness goals for issuing these actions are included in the general discussion for each sanction.

4.2 Non-Cited Violations (NCVs)

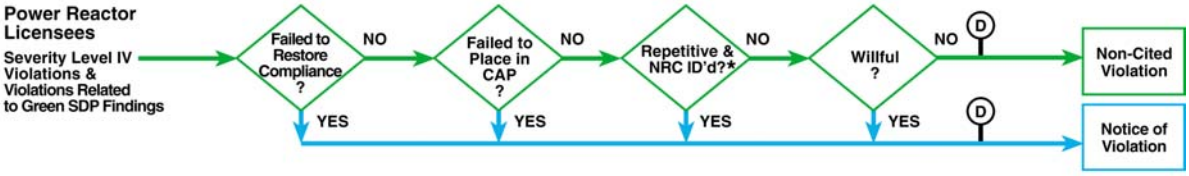
Non-Cited Violations (NCVs) are addressed in Section VI.A of the Enforcement Policy. NCV is the term used to describe a method for dispositioning a Severity Level IV violation or a violation associated with a finding that the Reactor Oversight Process's SDP evaluates as having very low safety significance (i.e., green). These issues are documented as violations in inspection reports (or inspection records for some materials licensees) to establish public records of the violations, but are not cited in Notices of Violation (NOVs) which normally require written responses from licensees. Dispositioning violations in this manner does not eliminate the NRC's emphasis on compliance with requirements nor the importance of maintaining safety. Licensees are still responsible for maintaining safety and compliance and must take steps to address corrective actions for these violations. While licensees are not required to provide written responses to NCVs, this approach allows licensees to dispute violations described as NCVs. The following sections describe the circumstances under which a violation may or may not be dispositioned as an NCV.

4.2.1 NCVs for Power Reactor Licensees

In accordance with Section VI.A.1 of the Enforcement Policy, Severity Level IV violations and violations associated with green SDP findings are normally dispositioned as NCVs. Violations dispositioned as NCVs will be described in inspection reports, although the NRC will close these violations based on their being entered into the licensee's corrective action program. (See Section 3.12.2 for specific guidance on documenting NCVs.) At the time a violation is closed in an inspection report, the licensee may not have completed its corrective actions or begun the process to identify the root cause and develop action to prevent recurrence. Licensee actions will be taken commensurate with the established priorities and processes of the licensee's corrective action program. The NRC inspection program will provide an assessment of the effectiveness of the corrective action program. In addition to documentation in inspection reports, violations will be entered into the Plant Issues Matrix (PIM). Because the NRC will not normally obtain a written response from licensees describing actions taken to restore compliance and prevent recurrence of these violations, this enforcement approach places greater NRC reliance on licensee corrective action programs.

➜**NOTE**: Violations at a decommissioned facility that still has a Part 50 corrective action program and Part 72 violations that occur at a facility with a Part 50 corrective action program should be evaluated under this NCV policy.

The following graphic represents the circumstances that the staff should consider in deciding whether a violation should be dispositioned as an NCV or in an NOV.



Any one of the following circumstances will result in consideration of an NOV requiring a formal written response from a licensee.

a. **The licensee failed to restore compliance within a reasonable time after a violation was identified.**

➜ **NOTE**: This criterion applies only to violations that are continuing at the time of discovery (see further discussion below).

The purpose of this criterion is to emphasize the need to take appropriate action to restore compliance in a reasonable period of time once a licensee becomes aware of a violation and, if compliance cannot be reasonably restored, to take compensatory measures until compliance is restored. Absent an exemption, license amendment, or Notice of Enforcement Discretion (NOED), action must be taken to restore compliance. Until compliance can be restored, compensatory measures, as warranted, must be taken. Restoring compliance is important to prevent an ongoing violation.

For purposes of this criterion, restoring compliance includes those actions taken to stop an ongoing violation from continuing. It does not include actions necessary to address root causes and prevent recurrence. The NRC recognizes that some violations require prompt action to restore compliance and some do not based on whether the underlying requirement is continuous or conditional. Thus, "within a reasonable time" in this criterion refers to the time needed to stop an ongoing violation from continuing (which should be as soon as possible) or the time needed to take compensatory actions for a continuing violation, and if compensatory action is not allowed by the requirement, the time to be in a state where the requirement no longer applies if relief is not provided from the NRC.

For example, if a valve is found in the wrong position, the NRC expects a licensee to take prompt action to either place the valve in the position required by the current mode of operation, take action to be in a state where the requirement no longer applies, or take appropriate compensatory actions. On the other hand, the requirement may not be applicable for the mode or circumstances the licensee is in at the time the violation is identified (as opposed to when it occurred). Reasonableness allows the licensee to delay corrective actions until the requirement is next applicable. For example, if the violation involved an inadequate procedure only used in refueling, action to address the particular procedure and prevent recurrence would not need to be taken until before the next time the procedure would be used; in this case prior to the next refueling.

b. **The licensee did not place the violation into a corrective action program to address recurrence.**

The purpose of this criterion is to emphasize the need to consider actions beyond those necessary to restore compliance, including actions necessary to address root causes and prevent recurrence. Placing a violation into a corrective action program to prevent recurrence is fundamental to the NRC's ability to close out a violation in an inspection report without detailed information regarding the licensee's corrective actions. The licensee would be expected to provide the NRC with a file reference evidencing that the violation had been placed in the corrective action program. This will assist the NRC should it review the particular violation as part of an NRC inspection of the effectiveness of the licensee's corrective action program.

The staff recognizes that there are violations that do not require substantial efforts to prevent recurrence. For example, an isolated implementation error with more than minor safety significance not reflecting inadequate training, procedures, resources, or oversight. In such cases, a corrective action process that includes: restoring compliance; evaluating the need for additional corrective actions to prevent recurrence; and maintaining records for trending so that the licensee can have assurance that the matter is in fact isolated, and that may be inspected at a later time would be adequate to avoid an NOV under this criterion.

c. **The violation is repetitive as a result of inadequate corrective action, and was identified by the NRC.**

➜ **NOTE**: This exception does not apply to violations associated with green SDP findings.

The purposes of this criterion are to emphasize the importance of effective corrective action to prevent recurrence and the importance of licensees identifying recurring issues. Therefore, an NOV would not normally be considered for a licensee-identified repetitive violation.

For purposes of applying this exception, a repetitive violation is:

- A violation that reasonably could have been prevented by the licensee's corrective action for a previous violation or a previous docketed licensee noncompliance finding that occurred within the 2 years prior to the date of the violation.

It should be noted that an original issue may be a previous violation or a previous licensee finding. In other words, an issue can be considered under this exception if a licensee identifies a compliance issue that requires corrective action in a Licensee Event Report (LER). It is not necessary for the original compliance issue to be documented and labeled a violation by the NRC.

In determining whether a violation is repetitive, the test is not just whether the violation recurs. The fact that a violation recurs does not necessarily mean that past corrective action was not reasonable or effective.

A violation is considered repetitive if:

- corrective action for the previous violation or licensee finding had sufficient time to take effect and was deemed inadequate; or

- adequate corrective action for the previous violation or licensee finding wasn't taken in a time frame commensurate with its safety significance.

The standard for evaluating the past corrective actions is the reasonableness of those actions as they pertain to the nature and significance of the originally identified problem. As long as the corrective actions acceptably address the identified causes and no other significant credible causes exist, and the schedule for and actions necessary for implementation of the corrective actions were appropriate, the licensee's past actions should be considered acceptable and the violation should not be considered repetitive. Further, an NOV would not result if, despite the violation's recurrence, the NRC finds the licensee's corrective actions for the previous violation reasonable at the time the first violation was identified. In making a citation under this criterion, the NRC is expected to be able to address why the licensee's actions were unreasonable and why reasonable corrective action would have prevented the second violation.

The previous discussion is especially important when dealing with procedural violations. Given the vast multitude and diversity of procedural requirements, the fact that a previous procedural violation occurred does not necessarily mean that the current procedural violation is repetitive. The scope of the previous corrective action must be considered. For example, the failure to follow a maintenance procedure would not be considered a repetitive procedural violation based on the existence of a failure to follow a radiation protection procedure that occurred 1 year ago, because it is not reasonable to expect that corrective action for the radiation protection procedural violation (e.g., procedure revision, enhanced training) would have prevented the maintenance procedure violation. There must be a sufficient nexus between the current issue and the previous corrective action.

For implementation purposes, the determination of whether or not a violation is repetitive need only be made for those violations **identified by the NRC**. As previously stated, the purpose of this exception is to encourage licensee identification and correction of repetitive issues. Licensee-identified, non-willful repetitive violations would be cited only if the ineffectiveness of the licensee's corrective action program is significant enough to rise to Severity Level III. Before making a decision to issue such a Severity Level III violation, consideration would be given to additional inspection effort, issuance of Demands for Information, management meetings, predecisional enforcement conferences, and outcomes of performance assessments.

In applying this exception, it is important to note that the NRC need not have identified the original violation or licensee finding. In addition, for the purposes of this guidance, a violation should not be considered NRC-identified if it is reasonable to conclude that the licensee would have identified the violation in a timely manner had it not been for the NRC identifying the issue. For example, an NOV should not be considered under this exception if the NRC identifies a self-disclosing event that the licensee likely would have identified in a timely manner. This provision provides for flexibility to address those situations where it is only happenstance that the NRC identifies a violation first and the lack of licensee identification is not due to inadequate performance.

Therefore, for NRC-identified violations, reasonable reviews must be performed to ensure that the current violation is not a repetitive issue before concluding that an NCV is appropriate. The reviews should be two-part.

The expectation for these reviews would first include a review of NRC inspection findings included in the Plant Issues Matrixes (PIMs) and the Reactor Program System (RPS) for previous NCVs and NOVs to determine whether the current violation had previously occurred. In considering previous NRC violations or licensee findings, the staff should only use docketed information so that the licensee will have been put on notice by the NRC of the need to take corrective action for a noncompliance or that the licensee is on record as having identified a noncompliance issue that requires corrective action (e.g., LER). Use of licensee corrective action program records is

appropriate only to the extent that the inspector or regional staff had previously described the issue in an inspection report or it was described in other docketed information. Notwithstanding this provision, the NRC's level of concern about a recurring violation is unrelated to whether it can be cited. In the event a recurring violation is identified and the previous violation was not docketed, then the violation should be dispositioned as an NCV and the documentation should note the NRC's concern about its recurrence and that an NOV will be issued if the violation recurs.

Consistent with existing guidance, original noncompliance issues should be of more than minor significance. In other words, the policy for documenting minor violations and guidance on thresholds of significance in Inspection Manual Chapters 0610 and 0612 has not changed. Inspectors should not document minor violations for the purpose of establishing repetitiveness.

In conclusion, the PIM should generally serve as the reference for determining previous occurrences for the first review, as it should provide notice to the licensee of NRC findings or violations.

If this first review identifies a previous violation, then a second review must be performed to determine if: corrective action for the previous violation had sufficient time to take effect and was deemed inadequate; or adequate corrective action for the previous violation wasn't taken in a time frame commensurate with its safety significance. Responses to previous NOVs, inspection reports, or the licensee's corrective action program should be reviewed to make this determination. It is acceptable to request background information from the licensee to address this review.

d. **The violation was willful. Notwithstanding willfulness, an NCV may still be appropriate if:**

1. The licensee identified the violation and the information concerning the violation, if not required to be reported, was promptly provided to appropriate NRC personnel, such as a resident inspector or regional branch chief (who, in turn, is responsible to get the information to the appropriate regional staff);

2. The violation involved the acts of a low-level individual (and not a licensee official as defined in Section IV.A of the Enforcement Policy);

3. The violation appears to be the isolated action of the employee without management involvement and the violation was not caused by lack of management oversight as evidenced by either a history of isolated willful violations or a lack of adequate audits or supervision of employees; and

4. Significant remedial action commensurate with the circumstances was taken by the licensee such that it demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's organization. While removal of the employee from licensed activities is not necessarily required, substantial disciplinary action is expected.

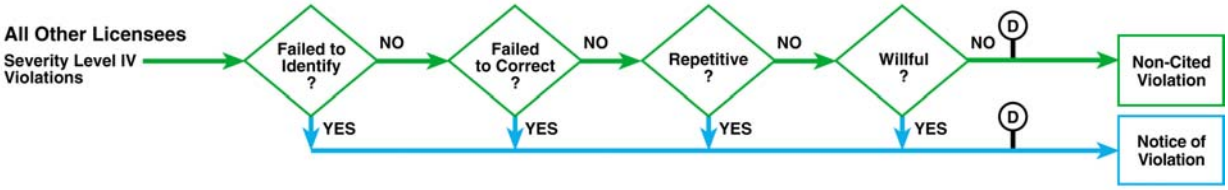
The purpose of this criterion is to emphasize the importance of integrity and candor in carrying out licensed activities, as expressed in Section IV.A.4 of the Enforcement Policy. Use of this criterion refers only to those situations where the significance of the willfulness does not justify an increase to Severity Level III; if it did, escalated enforcement action would be considered.

➜ **The approval of the Director, Office of Enforcement, with consultation with the Deputy Executive Director as warranted, is required for dispositioning willful violations as NCVs.**

4.2.2 NCVs for All Other Licensees

In accordance with Section VI.A.8 of the Enforcement Policy, Severity Level IV violations that are dispositioned as NCVs will be described in inspection reports (or inspection records for some materials licensees) and will include a brief description of the corrective action the licensee has either taken or planned to take. See Section 3.12.2 for specific guidance for documenting NCVs.

The following graphic represents the circumstances that the staff should consider in deciding whether a violation should be dispositioned as an NCV or in an NOV.
Any one of the following circumstances will result in consideration of an NOV requiring a formal written response from a licensee.



a. **The licensee failed to identify the violation;**

Section VI.A.8 of the Enforcement Policy states, "An NOV is warranted when a licensee identifies a violation as a result of an event where the root cause of the event is obvious or the licensee had prior opportunity to identify the problem but failed to take action that would have prevented the event. Disposition as an NCV may be warranted if the licensee demonstrated initiative in identifying the violation's root cause." In application of this provision, consideration should also be given to the Policy discussion associated with civil penalty assessment in Section VI.C.2.b, "Credit for Actions Related to Identification."

Typically, the identifiable event is the result of the underlying violation and not a violation itself. Identification credit should be considered when licensee follow-up of the event demonstrates thoroughness in assessing contributing factors, as well as any obvious, direct cause. The standard for the thoroughness of the licensees' actions is reasonableness based on safety significance. See the additional discussion below.

Cases where identification credit is denied should be limited to superficial investigations when corrective actions or root causes default to "easy fixes" and the inspectors can demonstrate that significant, credible, differing causes existed that were not identified by the licensee. In regard to "easy fixes," there are cases where an event is caused simply by an isolated human error with minimal opportunity for prevention or without contributing causes (e.g., inadequate procedures, labeling errors, lack of resources or supervision, and prior opportunities) - the most obvious cause turns out to be the correct one. Granting of identification credit should be considered for these cases when licensee efforts are thorough enough to rule out the potential for more subtle contributing factors.

In regard to issues identified by the licensee that the NRC is following, the licensee should not be denied credit for identification if it is reasonably pursuing an issue it identified even though NRC may have identified the violation first. This assumes the licensee's plans and intent were such that it is likely the licensee would have identified the violation within a reasonable time.

In sum, credit for identification is warranted for Severity Level IV violations associated with events unless the staff can show credible actions that clearly should of been taken by the licensee in identifying event causes.

➜ **In all non-escalated cases involving events where identification credit is being denied, the Division Director must agree with the denial after consultation with the Regional or NMSS Enforcement Coordinator (as appropriate).**

b. **The licensee did not correct or commit to correct the violation within a reasonable time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;**

In evaluating the scope and comprehensiveness of corrective actions, inspectors and their management should judge whether the licensee's response is commensurate with the significance of the issue. The standard is *reasonableness*. Unless the inspector, in consultation with his or her management, determines that there were significant, credible, differing causes that were not reasonably addressed in the corrective actions, the licensee's actions should be considered adequate. In addition, if the licensee's corrective actions are ongoing and the licensee, after input from the inspector or other NRC staff, agrees that additional actions are necessary and states that additional actions will be taken, the licensee should be given credit for corrective action. However, if the licensee has previously completed its corrective action and, after input from the inspector or other NRC staff, agrees that additional corrective actions are necessary, then credit for corrective action is not appropriate.

➜ **If there is a dispute with the licensee on the reasonableness of its corrective actions, the Division Director must concur on any cited violation.**

The criteria in the Enforcement Policy requires "corrective action committed to [by the licensee] by the end of the inspection." If a licensee identifies an issue that prompts a reactive inspection, or if a licensee identifies an issue while an inspection is open, the licensee's corrective action may not be fully formulated by the end of an inspection. This can create an artificial constraint for assigning an NCV instead of a cited Severity Level IV violation. Judgement is required in these situations to reasonably accommodate the timing of events. Denial of an NCV in favor of a cited Severity Level IV violation should not be based solely on undeveloped corrective actions due to the close proximity to the end of the inspection. If necessary, follow-up discussions via phone with licensees should be made prior to completing the inspection report (or inspection records for those inspections that do not require the issuance of an inspection report) to gain the information needed to make decisions regarding corrective action credit for licensee-identified violations. If the inspection report has to be issued and there has not been a reasonable time for the licensee to develop its corrective actions (but no longer than 30 days from licensee discovery), a potential violation that otherwise meets the criteria for an NCV may be described in the inspection report as an Apparent Violation and still be converted to NCV status once the corrective action becomes known. In sum, NRC is interested in development of adequate corrective actions which reasonably may require more time after the inspection has been completed.

c. **The violation is repetitive as a result of inadequate corrective action;**

Specifically, it was not a violation that could reasonably have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past 2 years of the current inspection, or the period within the last two inspections, whichever is longer. Reviews must be performed to ensure that the current violation is not a repetitive issue before

exercising this discretion. The expectation for these reviews would include a review of NRC inspection findings, such as inspection reports or inspection records for previous NCVs and NOVs.

In considering previous NRC violations or licensee findings, use only docketed information so that the licensee will have been put on notice of the need to take corrective action for a violation. For determining repetitiveness, the use of licensee records, such as program audit records; or inspection records, is appropriate only to the extent that the issue is also described in previous inspection reports, NRC Form 591s, or other docketed information. Generally, inspection reports and NRC Form 591s should serve as the reference for determining repetitiveness, as these documents provide clear notice to the licensee concerning NRC findings or violations. This guidance may result in the inspector not issuing an NOV for a licensee-identified recurring violation because it was not previously described in any docketed document. However, in this case, the violation should be docketed as an NCV so that if the licensee's corrective action fails again, a citation would be warranted at that point.

In determining repetitiveness, the fact that the violation repeats is not the only criteria that should be considered. If a violation recurs, it does not necessarily mean that past corrective action was not reasonable or effective. The key is: Did the licensee develop and implement reasonable corrective actions for the previous violation, commensurate with the safety significance, such that at the time the corrective actions were implemented, there was a reasonable expectation that the root causes of the violation would be corrected?

d. **The violation was willful. Notwithstanding willfulness, an NCV may still be appropriate if it meets the criteria in Section VI.A.1.d of the Enforcement Policy**.

See the guidance included in Section 4.2.1.d. The approval of the Director, Office of Enforcement, with consultation with the Deputy Executive Director as warranted, is required for dispositioning willful violations as NCVs.

4.2.3 Issuing an NCV When Criteria in Section VI.A of the Enforcement Policy are Met for Issuing an NOV

Notwithstanding meeting one of the exceptions in Section VI.A of the Enforcement Policy, there may be situations where a Severity Level IV violation or violation associated with a green SDP finding does not warrant citation in an NOV. These cases should be discussed during the regular weekly enforcement or SDP panel conference calls. In these cases, the Regional Administrator and the Director of OE must approve the NCV prior to issuance. The cover letter transmitting the NCV should clearly state the reason for not citing the issue, notwithstanding that it met one of the defined circumstances identified in Section VI.A of the Enforcement Policy.

4.2.4 NCV Coordination and Review

a. NCVs are normally issued by the region without prior OE approval. Enforcement Coordinators are available and should be consulted on NCVs, as warranted.

b. The regional Division Director should concur on an NCV prior to issuance if: (1) the Branch Chief and Enforcement Coordinator disagree on the disposition of the issue, (2) the staff is informed by the licensee during the exit that it disagrees that the issue is a violation or that the violation warrants Severity Level IV categorization or that the inspection finding warrants green

SDP characterization, or (3) the staff wants to exercise discretion and refrain from issuing an NOV beyond the Policy.

c. The approval of the Director, OE, with consultation with the DEDO as warranted, is required for issuing willful violations as NCVs.

d. The region must schedule an enforcement or SDP panel if it proposes not to issue an NOV when one or more criteria in Section VI.A.1 of the Enforcement Policy are met for issuing an NOV.

4.2.5 NCV Signature Authority

a. Regional Branch Chiefs normally sign and issue inspection reports that include NCVs. The Regional Administrator may redelegate the authority to issue NCVs on NRC Form 591s to qualified inspectors.

b. Program Office Section Chiefs normally sign and issue inspection reports that include NCVs. The Director, NMSS may redelegate the authority to issue NCVs on NRC Form 591s to qualified inspectors.

4.2.6 Licensee Denial of NCV

If the region receives a licensee response that disputes an NCV, and the action did not have an EA number when it was issued, the region should request an EA number from OE and provide sufficient information to document the issue on a Strategy Form. The staff should follow the guidance below, depending on whether the licensee (a) denies the violation, or (b) disagrees with the significance.

a. If the licensee **disagrees that an NCV is a violation**, the region should normally acknowledge receipt of the denial within 30 days from receipt of the licensee's denial if a response cannot be provided in that time period. The acknowledgment letter and the final NRC response should be sent to the same person and address as the NCV.

The region's response to the licensee's denial should normally be completed within 90 days of receipt of the licensee's denial and should address the licensee's points of contention. If the licensee denies the violation based on incorrect information or additional information not previously disclosed, the region should prepare a more detailed response as appropriate. Any errors identified in the NCV must be addressed in the region's response.

Within 80 days from the receipt of the licensee's denial (or 20 days if the region plans on responding in 30 days), the region should submit its prepared response to the licensee to the Deputy Director, OE, (and OEMAIL). The region's submittal to OE should include all documents necessary to support the region's position. OE will review the region's response and should provide comments to the region within 5 days of the date of the region's submittal.

If the NRC maintains that the NCV remains valid, the subject line should read,"RESPONSE TO DISPUTED VIOLATION." If the region concludes that a second, revised NCV should be issued, the subject line should read, "REVISED VIOLATION." If the region concludes that the violation should be withdrawn, the subject line should read, "WITHDRAWAL OF VIOLATION."

b. If the licensee **disagrees with the significance,** the region should follow the same process as described above if the licensee's denial addresses specific NRC guidance (i.e., Manual, Enforcement Policy, or MC 0612) that would support the violation being categorized as minor. If the licensee argues that the violation is minor without providing this type of information, the region should send out a simple acknowledgment letter within 30 days that states that the NRC reviewed the licensee's response, concluded that the licensee did not provide an adequate basis to reclassify the violation, and that the NRC maintains that the violation occurred as stated. Any errors identified in the NCV must be addressed either in a formal response or an acknowledgment letter.

4.3 Non-Escalated Notice of Violation (NOV)

Notices of Violation (NOVs) are addressed in Section VI.B of the Enforcement Policy, and 10 CFR 2.201 sets forth the procedures for issuing NOVs. An NOV is a formal written citation setting forth one or more violations of a legally binding requirement. An NOV including a Severity Level IV violation or an NOV associated with a green SDP finding is considered non-escalated enforcement action and may be sent to the licensee as an attachment to an inspection report or, in the case where inspection records are used to document the noncompliance, as an attachment to a transmittal letter. NRC Form 591 may also be used as an NOV, see Section 4.4 for guidance.

The timeliness goal for issuing routine non-escalated NOVs is the same as for issuing clear inspections (i.e., 30 calendar days after the inspection has been completed, 45 days for integrated reports and major team inspections, see NRC Inspection Manual Chapters 0610 and 0612).

NOVs should be issued for Severity Level IV violations and violations associated with green SDP findings when they meet the applicable criteria in Section VI.A of the Enforcement Policy. See the previous discussion in Section 4.2 to determine whether an NOV is appropriate.

4.3.1 Issuing a Non-Escalated NOV Beyond the Criteria in Section VI.A of the Enforcement Policy

Judgement cannot or should not be totally eliminated from enforcement decisions. There may be cases where the use of judgement results in a more equitable approach than might otherwise be called for by strict application of the Enforcement Policy. Although it should be rare, this section provides guidance for situations when, notwithstanding the outcome of the normal process for dispositioning Severity Level IV violations and violations associated with green SDP findings, the staff chooses to exercise discretion (represented in the flowchart by a "D" in a circle) and issue an NOV beyond the criteria in Section VI.A of the Enforcement Policy.

For reactor cases, the Director of OE, and the EDO must approve the action. The action requires an EA number. OE will coordinate the action with NRR. The region should prepare a 3-day EN to notify the Commission of the staff's intent to issue an NOV, notwithstanding the policy. The Regional Administrator must sign the transmittal letter.

For materials cases, OE must be consulted prior to issuance of the NOV. Consultation by telephone or e-mail is normally sufficient. These actions require EA numbers.

The cover letter transmitting the NOV must clearly state the reason for issuing the NOV, notwithstanding that it was not one of the defined circumstances identified in Section VI.A of the Enforcement Policy.

4.3.2 Preparing a Non-Escalated NOV Action

The responsible office should prepare a non-escalated NOV package, including the following elements as discussed below.

a. Inspection reports should be prepared in accordance with the guidance in the NRC Inspection Manual (Chapter 0610, "Inspection Reports," Chapter 0612, "Power Reactor Inspection Reports," and Chapter 87100, "Licensed Materials Program") and Section 3.7.a of this Manual.

b. NOVs should be prepared by using the applicable standard format (Form 4) in Appendix B and the applicable standard citations in Appendix C. NOVs should be dated the same date as the cover letter transmitting the enforcement action to the licensee. The NOV should include the following elements:

   1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).

   2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement. Each violation, including a violation with multiple examples, contains a single "contrary to" statement.

   3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation. See Section 3.12.7 for additional guidance on multiple examples of a violation.

      The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

   4. The severity level proposed for the violation (i.e., Severity Level IV) and the applicable supplement of the Enforcement Policy under which the violation is categorized or, alternatively

   5. The associated significance of the violation (i.e., green SDP finding).

   6. The licensee response (if the staff concludes that a response is necessary), including: the reason for the violation, or if contested, the basis for disputing the violation; the corrective steps that have been taken and the results achieved; the corrective steps that will be taken to avoid further violations; and the date when full compliance will be achieved, or

   7. A waiver of the licensee response (if the staff concludes that a response is not necessary) if information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already addressed on the docket. This alternative requires the licensee to respond if the description does not accurately describe the licensee's corrective action position.

d. Cover letters that transmit inspection reports and non-escalated NOVs to licensees should be prepared by the region using Form 2 in Appendix B. If an inspection report is not issued, as may be the case for certain material licensees, then all references to the inspection report in Form 2 should be deleted. Cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable. NRR and NMSS should use Form 10, as appropriate for vendor and approved Quality Assurance cases, respectively. The letter should:

1. Clearly state why a citation is being issued in terms of which criteria in Section VI.A of the Enforcement Policy they met. The explanation may be expanded, where warranted, to convey the appropriate message to the licensee in terms of those actions that require additional attention.

2. Provide an explanation of why a citation is being issued if, by the guidance in Enforcement Policy and this Manual, the violation could have been dispositioned as an NCV.

3. Describe the response that is necessary from the licensee (if the region concludes that a response is necessary), including any area that deserves special emphasis, or

4. Include a conclusion that a licensee response is not necessary (if the region concludes that a response is not necessary), including a provision that the licensee must respond if its understanding of the corrective action is different.

5. Address, if applicable, any apparent violations being considered for escalated enforcement action and the scheduling of a predecisional enforcement conference.

4.3.3 Non-Escalated NOV Coordination and Review

Non-escalated NOVs should be coordinated and reviewed according to the following guidelines:

a. Non-escalated NOVs for materials cases are normally issued by the regions or appropriate program office without prior consultation or review and approval by OE (see noted exceptions below).

b. Regional Enforcement Coordinators should be available for consultation on non-escalated NOVs for materials licensees and should concur on non-escalated NOVs involving power reactors.

c. The Regional Division Director must concur on non-escalated NOVs involving power reactors.

d. The Regional Division Director must concur on Severity Level IV NOVs involving materials licensees if there is a dispute with the licensee on the reasonableness of its corrective actions.

e. In all Severity Level IV NOVs for materials licensees involving events where identification credit is being denied, the Division Director must agree with the denial after consultation with the Regional or NMSS Enforcement Coordinator (as appropriate).

f. Non-escalated NOVs that must be coordinated with OE (usually by telephone or e-mail to support issuance of an EA number) prior to issuance include:

1. Licensee-disputed violations, violations of 10 CFR 50.59, violations of 10 CFR Part 55, or violations of 10 CFR 50.65 that **can be resolved** via coordination between the involved offices.

2. Any actions resulting from an Augmented Inspection Team (AIT), Diagnostic Evaluation Team (DET), or Incident Investigation Team (IIT) inspection.

3. Any actions related to currently proposed escalated enforcement actions.

4. Any case in which a Notice of Enforcement Discretion (NOED) is issued, and the root cause that results in the need to request the NOED was a Severity Level IV violation or violation associated with a green SDP finding warranting citation in an NOV.

5. Any actions involving the loss or failure to control or account for licensed material.

g. Non-escalated NOVs that must be coordinated with OE (through an enforcement or SDP panel) prior to issuance include:

1. Any actions based on willful violations or an OI investigation.

2. Any actions involving an individual (other than an individual licensed by 10 CFR Parts 30, 40, & 70).

3. Any non-escalated enforcement action which, by the examples in the Supplements, could be categorized at Severity Level I, II or III or characterized as red, yellow, or white by the SDP.

4. Licensee-disputed violations, violations of 10 CFR 50.59, violations of 10 CFR Part 55, or violations of 10 CFR 50.65 that **cannot be resolved** via coordination between the involved offices.

h. Any actions the regions believe warrant headquarters' review.

i. Any actions that the Director, OE believes warrant headquarters' review prior to issuance, such as violations that were the subject of predecisional enforcement conferences or regulatory conferences where the Director, OE, requests OE review.

j. The approval of the EDO is required for issuing a non-escalated NOV beyond the defined exceptions in Section VI.A (see the discussion in Section 4.3.6 below).

k. The region should send OE all non-escalated NOV packages with EA numbers after it has issued the action.

4.3.4 Non-Escalated NOV Signature Authority

Non-escalated NOVs should be signed and issued according to the following guidelines:

a. The Regional Administrator has the authority for signing all non-escalated NOVs issued in the region. Except as noted in Section 4.3.1, the Regional Administrator may redelegate to Branch Chiefs and above, the authority to sign and issue non-escalated NOVs issued in the region. In addition, the Regional Administrator may redelegate to qualified inspectors, the authority to sign and issue NRC Form 591 (see Section 4.4 for additional guidance on the use of NRC Form 591).

b. The Director, NRR may redelegate to Branch Chiefs and above, the authority to sign and issue non-escalated NOVs involving vendors and non-power reactors.

c. The Director, NMSS may redelegate to Section Chiefs and above, the authority to sign and issue non-escalated NOVs for which NMSS evaluates, directly manages, or conducts inspections. The Director, NMSS may redelegate to qualified inspectors, the authority to sign and issue NRC Form 591 (see Section 4.4 for additional guidance on the use of NRC Form 591).

d. When a predecisional enforcement conference is held and does not result in an escalated action, the non-escalated action will normally be signed by the person conducting the conference.

4.3.5 Licensee Notification, Mailing, & Distribution for Non-Escalated NOVs

Licensees, States, and ADAMS (PARS) are normally sent non-escalated NOVs at the time an inspection report is issued. The mailing and distribution of the inspection report and NOV are controlled by regional procedures. OE receives copies of all non-escalated enforcement actions through the Document Control System. Copies of non-escalated NOVs issued by the program offices should be sent to the appropriate regional office. In addition, for non-escalated NOVs issued to Agreement State licensees, a copy should be sent to the Agreement State and to the appropriate Regional State Agreements Officer(s) of the appropriate region or regions.

4.3.6 Licensee Response to a Non-Escalated NOV

If the staff concludes that a licensee response is necessary, the provisions of 10 CFR 2.201 require that a licensee submit a written response to an NOV within 20 days of the date of the NOV or other specified time frame; however, normally 30 days should be used. If a licensee does not respond to an NOV within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the NOV) and consideration will be given to whether additional enforcement action is warranted.

Licensees may be granted response extensions where good cause is shown. The region may grant extensions of up to 2 weeks without OE approval. OE should be promptly notified of any extensions the region grants. OE approval is required for extensions beyond 2 weeks. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due. The confirmation may either be prepared by the NRC or the licensee. A copy of this followup correspondence is to be sent to OE and the region.

The staff should follow the guidance below, depending on whether the licensee (a) accepts the violation, (b) denies the violation, or (c) disagrees with the significance.

➔**NOTE**: If the region receives a licensee response that denies the violation or disagrees with the significance, and the action did not have an EA number when it was issued, the region should request an EA number from OE and provide sufficient information to document the issue on a Strategy Form.

a. **If the licensee does not dispute that the violation occurred as stated in the NOV**, the regional office is to review the licensee's response for the adequacy of the corrective action and should request additional information from the licensee if necessary. In determining the adequacy of corrective action, the region should consider whether the licensee has properly identified the root causes.

   The licensee's response is to be acknowledged by the region usually within 30 days after its receipt. The acknowledgment letter should be sent to the same person and address to which the NOV was sent, with a copy to ADAMS (PARS) and the docket file (the acknowledgment letter need not be sent to the full distribution).

b. **If the licensee denies the violation**, the region should normally acknowledge receipt of the denial within 30 days from receipt of the licensee's denial if a response cannot be provided in that time period. The acknowledgment letter and the final NRC response should be sent to the same person and address as the NOV.

   The region's response to the licensee's denial should normally be completed within 90 days of receipt of the licensee's denial and should address the licensee's points of contention. If the licensee denies the violation based on incorrect information or additional information not previously disclosed, the region should prepare a more detailed response as appropriate. Any errors identified in the NOV must be addressed in the region's response.

   Within 80 days from the receipt of the licensee's denial (or 20 days if the region plans on responding in 30 days), the region should submit its prepared response to the licensee to the Deputy Director, OE, (and OEMAIL). The region's submittal to OE should include all documents necessary to support the region's position. OE will review the region's response and should provide comments to the region within 5 days of the date of the region's submittal.

   If the NRC maintains that the NOV remains valid, the subject line should read,"RESPONSE TO DISPUTED NOTICE OF VIOLATION." If the region concludes that a second, revised NOV should be issued, the subject line should read, "REVISED NOTICE OF VIOLATION." If the region concludes that the violation should be withdrawn, the subject line should read, "WITHDRAWAL OF NOTICE OF VIOLATION."

c. **If the licensee disagrees with the significance,** the region should follow the same process as described above if the licensee's denial addresses specific NRC guidance (i.e., Manual, Enforcement Policy, or MC 0612) that would support the violation being categorized as minor. If the licensee argues that the violation is minor without providing this type of information, the region should send out a simple acknowledgment letter within 30 days that states that the NRC reviewed the licensee's response, concluded that the licensee did not provide an adequate basis to reclassify the violation, and that the NRC maintains that the violation occurred as stated. Any errors identified in the NOV must be addressed either in a formal response or an acknowledgment letter.

4.4 NRC Form 591

NRC Form 591, "Safety and Compliance Inspection," may be used for certain inspections of materials licensees. Detailed guidance on the use and preparation of NRC Form 591 is included in Inspection Manual Chapter 2800, "Materials Inspection Program." NRC Form 591 is available through ADAMS, as follows:

Region I: ML003716397
Region II: ML003716413
Region III: ML003716425
Region IV: ML003716426

Form 591 summarizes the findings of an inspection related to radiation safety and compliance and includes boxes that when checked can indicate that:

(1) No violations were identified.
(2) Violations are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in NUREG-1600 to exercise discretion, were satisfied.
(3) Certain activities were in violation of NRC requirements.

a. If used to indicate the existence of violations (Box 3), Form 591 serves as the official NOV. As such, it must be posted in accordance with 10 CFR 19.11. Form 591 may be used in lieu of a formal NOV provided:

   1. The violations are non-escalated (i.e., Severity Level IV);
   2. The violations are not willful;
   3. The licensee signs the form acknowledging that corrective actions will be taken within 30 days for the indicated violations; and
   4. The inspector believes that the licensee can complete the corrective actions within 30 days for the indicated violations.

b. If used to indicate the existence of licensee-identified Severity Level IV violations that are not being cited (Box 2), Form 591 serves as a tracking mechanism for Non-Cited Violations (NCVs). Form 591 may be used to cite Severity Level IV violations as NCVs, provided they meet the NCV criteria established in Section VI.A of the Enforcement Policy.

c. minor violations warranting documentation may be documented in inspection records or reports, but are not be cited on Form 591.

4.4.1 Preparing a Form 591

Form 591 is available through ADAMS. Form 591 should include a Nuclear Materials Events Database (NMED) number, if applicable. Inspectors should legibly fill out a Form 591 so that it includes the following elements:

a. Indication, if applicable, that a violation was identified (i.e., Box 3 should be checked).

b. Indication, if applicable, that an NCV was identified (i.e., Box 2 should be checked).

c. A brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met.

d. Reference to the regulation or license condition that was violated.

e. The licensee's signature acknowledging that corrective actions will be taken within 30 days for the indicated violations or NCVs.

f. The inspector's signature.

Violations and NCVs documented on Form 591 should not include a severity level. In addition, avoid making corrections on the form, if at all possible. The following are some examples of properly documented violations:

> "External surfaces of labeled packages were not monitored for contamination from July 7, 1998 to January 4, 1999 (10 CFR 20.1906(b)(1))"
>
> "Physical inventories were not performed at 6-month intervals to account for all sealed sources during the period from January 9, 1998 to December 10, 1998. (License condition 15)"

4.4.2 Form 591 Coordination and Review

Because a Form 591 is considered non-escalated enforcement action, it does not need to be coordinated with OE prior to issuance.

4.4.3 Form 591 Signature Authority

a. Regional Administrators may redelegate their authority to sign and issue Form 591s to qualified inspectors.

b. The Director, NMSS may redelegate his or her authority to sign and issue Form 591s to qualified inspectors.

4.4.4 Licensee Notification, & Mailing for a Form 591

Completed Form 591s are normally provided to licensees at the end of inspections or may be subsequently mailed.

4.5 Notice of Deviation (NOD)

Notices of Deviation are addressed as item (1) in Section VI.E of the Enforcement Policy. An NOD is a written notice to a licensee describing its failure to satisfy a commitment that is not a legally binding requirement. Although an NOD is considered an administrative mechanism, it is processed as a non-escalated enforcement action. An NOD is normally sent to the licensee as an attachment to an inspection report.

The timeliness goal for issuing a routine NOD is the same as for issuing clear inspections (i.e., 21 calendar days after the inspection has been completed, 30 days for team inspections, see NRC Inspection Manual Chapters 0610 and 0612).

4.5.1 Preparing an NOD Action

The regions should prepare an NOD action package, including the following elements as discussed below.

a. Inspection reports should be prepared in accordance with the guidance in the NRC Inspection Manual (Chapter 0610, "Inspection Reports," and Chapter 87100, "Licensed Materials Program") and Section 3.12.3 of this Manual.

b. NODs should be prepared by the region using the applicable standard format shown in Appendix B (Form 8). NODs should be dated the same date as the transmittal letter to the licensee. The NOD should include the following elements:

   1. A concise, clear statement of the applicable commitment.

   2. A brief statement (usually no more than a few sentences) of the circumstances of the deviation, including the date(s) of the deviation and the facts necessary and sufficient to demonstrate that the commitment was not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the commitment. Each deviation, including a deviation with multiple examples, contains a single "contrary to" statement.

   3. As a general rule, multiple examples of the same deviation during the period covered by an inspection should be included in one citation. The "contrary to" paragraph should generally state the deviation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular deviation are numerous, sufficient examples should be cited to convey the scope of the deviation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

   4. A request for the licensee to respond, including the reasons for the deviation, the corrective steps which will be taken to avoid further deviations, and the date when the corrective actions will be completed.

c. Cover letters that transmit inspection reports and NODs should be prepared by the region using Form 2 in Appendix B with appropriate modifications to reflect the NOD as the enforcement action versus an NOV.

4.5.2 NOD Coordination and Review

Because an NOD is considered a non-escalated enforcement action, it normally does not need to be coordinated with OE prior to issuance.

NODs involving the FSAR require the approval of the Director, OE.

Regional Enforcement Coordinators should be available for consultation on NODs.

4.5.3 NOD Signature Authority

The Regional Administrator may redelegate to Section Chiefs and above, the authority to issue non-escalated enforcement actions, including NODs.

4.5.4 Licensee Notification, Mailing, & Distribution for NODs

Licensees are normally sent NODs at the time an inspection report is issued. NODs are made available to the Public in accordance with agency procedures. The mailing and distribution of the inspection report and NOD are controlled by regional procedures.

4.6 Notice of Nonconformance (NON)

Notices of Nonconformance are addressed as item (2) in Section VI.E of the Enforcement Policy. An NON is a written notice to a vendor or certificate holder describing its failure to meet commitments related to NRC activities. These commitments are normally contained in contract requirements and are not directly imposed on the vendor or certificate holder by the NRC. NOVs should be used for certificate holders who fail to meet requirements directly imposed on them by the NRC and for vendors who violate 10 CFR Part 21 requirements or other requirements directly imposed on them by the NRC. Although an NON is considered an administrative mechanism, it is processed as a non-escalated enforcement action. An NON is normally sent to the vendor or certificate holder as an attachment to an inspection report.

The timeliness goal for issuing a routine NON is the same as for issuing clear inspections (i.e., 21 calendar days after the inspection has been completed, 30 days for team inspections, see NRC Inspection Manual Chapters 0610 and 0612).

4.6.1 Preparing an NON Action

The staff in NRR for vendor cases, or in NMSS for shipping package transportation cases, should prepare the NON action package, including the following elements as discussed below.

a. Inspection reports should be prepared in accordance with the guidance in the NRC Inspection Manual (Chapter 0610, "Inspection Reports," and Chapter 87100, "Licensed Materials Program") and Section 3.12.3 of this Manual.

b. NONs should be prepared by the appropriate branch using the standard format in Appendix B (Form 11). NONs are dated the same date as the cover letter transmitting the action to the vendor or certificate holder. The NON should include the following elements:

    1. A concise, clear statement of the applicable requirement or requirements, appropriately referenced, paraphrased, or quoted.

    2. A brief statement (usually no more than a few sentences) of the circumstances of the nonconformance, including the dates of the nonconformance (if possible to determine) and the facts necessary to demonstrate that one or more of the requirements were not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement. Each nonconformance, including a nonconformance with multiple examples, contains a single "contrary to" statement.

    3. As a general rule, multiple examples of the same nonconformance during the period covered by an inspection should be included in one citation. The "contrary to" paragraph should

generally state the nonconformance and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular nonconformance are numerous, sufficient examples should be cited to convey the scope of the nonconformance and to provide a basis for assessing the effectiveness of the corrective actions. Normally three to five examples should be adequate.

4. A request for the vendor or certificate holder to respond, including a description of the steps taken or planned to correct the nonconformances, the steps taken or planned to prevent recurrence, and the date when the corrective actions were or will be completed.

c. Cover letters that transmit inspection reports and NONs should be prepared by the appropriate branch using Form 9 in Appendix B.

4.6.2 NON Coordination and Review

Because an NON is considered a non-escalated enforcement action, it does not need to be coordinated with OE prior to issuance.

4.6.3 NON Signature Authority

NONs should be signed and issued according to the following guidelines:

a. The Director, NRR may redelegate to Branch Chiefs and above, the authority to issue non-escalated enforcement actions involving vendors.

b. The Director, NMSS may redelegate to Branch Chiefs and above, the authority to issue non-escalated enforcement actions.

4.6.4 Notification, Mailing, & Distribution of NONs

Vendors or certificate holders are normally sent NONs at the time an inspection report is issued. NONs are made available to the Public in accordance with agency procedures.

4.7 Confirmatory Action Letter (CAL)

Confirmatory Action Letters are addressed as item (3) in Section VI.E of the Enforcement Policy. CALs are letters issued to licensees or vendors to emphasize and confirm a licensee's or vendor's agreement to take certain actions in response to specific issues. The NRC expects licensees and vendors to adhere to any obligations and commitments addressed in a CAL. CALs are normally used for emergent situations where the staff believes that it is not necessary or appropriate to develop a legally binding requirement, in light of the agreed-upon commitment. CALs are flexible and valuable tools available to the staff to resolve licensee issues in a timely and efficient manner.

For example, a CAL may be issued when a materials licensee is violating a particular license condition, but the license condition prescribes neither the action nor the timeliness for restoring compliance as would be prescribed by a reactor licensee's technical specification action statement. A CAL would be useful in this type of situation to confirm compensatory actions which, if implemented, would ensure safety such that an immediate suspension of licensed activities might not be necessary. The use of a CAL in this situation is generally reserved for materials licensees. A Notice of Enforcement Discretion (NOED) would be the appropriate tool for reactor licensees and gaseous diffusion plants if the issue is

addressed by a license or certificate condition. (See Section 6.4 for additional guidance on the use of NOEDs.)

a. CALs may be issued to confirm the following types of actions (note that this is not an exhaustive list):

- In-house or independent comprehensive program audit of licensed activities.
- Correction of training deficiencies such as radiological safety, licensed operator, etc.
- Procedural improvements.
- Equipment maintenance.
- Equipment operation and safety verification.
- Voluntary, temporary suspension of licensed activities.
- Licensee's agreement to NRC approval prior to resumption of licensed activities.
- Root cause failure analyses.
- Improved control and security of licensed material.
- Transfer of licensed material.
- Future submittal of license amendment request.
- Commitment to honor an AIT or IIT quarantine request.
- Specific actions in response to an unsatisfactory operator requalification program.
- Actions to be taken to regain compliance with Commission requirements, including compensatory actions.

b. CALs should only be issued when there is a sound technical and/or regulatory basis for the desired actions discussed in the CAL. Specifically, CALs must meet the threshold defined in the Enforcement Policy (i.e., "to remove significant concerns about health and safety, safeguards, or the environment"). In other words, the issues addressed in a CAL should be at a level of significance such that if the licensee did not agree to meet the commitments in a CAL, the staff would likely proceed to issue an order.

c. Even though a CAL by definition confirms an agreement by the licensee to take some described action, it may, at times, require some negotiation with the licensee prior to issuance. The licensee must, however, agree to take the action. However, once a CAL is agreed upon, the licensee is expected to take the documented actions and meet the conditions of the CAL.

d. On occasion, licensees elect to submit letters to the NRC addressing actions that they intend to take in reaction to safety issues. While the staff may, depending on the significance of the issues involved, elect to issue a brief CAL accepting the licensee's letter and commitments, this practice should not be routine. CALs should be limited to those cases where the issues involved clearly meet the threshold for issuing a CAL (see the discussion in paragraph b). If a CAL is issued in this case, the first three elements in Section 4.7.2 may, as appropriate, merely reference the licensee's letter.

e. CALs are not normally used to remove an individual from, or restrict his or her ability to perform, licensed activities. Such action normally requires an order, not just to ensure enforceability, but because individual rights are affected and the opportunity for a hearing must be given both to the licensee and the affected individual. However, a CAL may be used for a situation in which an individual, under existing license conditions or regulations, lacks authorization to be involved in the licensed activity, and the CAL is merely being used to confirm that the licensee will adhere to existing provisions (i.e., in such a situation the CAL would not affect the individual's rights, because the person did not meet specific qualifications). In such cases, CALs require coordination with OE and review by OGC.

f. The issuance of an order, in lieu of a CAL, should be considered whenever there is a need to ensure that a legally binding requirement is in place. Orders must be coordinated between the regional office, the appropriate program office, OGC, and OE. Orders should be issued instead of CALs in the following situations:

- When it is apparent that the licensee will not agree to take certain actions that the staff believes are necessary to protect public health and safety;
- When there is an integrity issue.
- When there is some likelihood that a licensee may not comply with a commitment; or
- When the staff has concluded that the CAL will not achieve the desired outcome.

g. If it has been decided that an order is warranted to address a specific issue, a CAL is a suitable instrument to confirm initial, agreed upon, short-term actions covering the interval period prior to the actual issuance of the order. Use of a CAL in this manner is desirable in that the CAL is an effective regulatory tool to provide timely confirmation of actions the licensee has agreed to take. It also documents the matter for the NRC, the licensee, and the public.

4.7.1 Noncompliance With CALs

Other than the reporting provisions pursuant to Section 182 of the Atomic Energy Act[1], CALs do not establish legally binding requirements. However, failure to meet a commitment in a CAL could be addressed through an NOD. In addition, an order or a Demand For Information could be issued where the licensee's performance, as demonstrated by the failure to meet CAL commitments, does not provide reasonable assurance that the NRC can rely on the licensee to meet the NRC's requirements and protect public health and safety. In accordance with the provisions of the Enforcement Policy, commitments in a CAL may be made NRC requirements through the issuance of an order.

Issuance of a CAL does not preclude the NRC from taking enforcement action for violations of regulatory requirements that may have prompted the issuance of the CAL. Such enforcement action is intended to emphasize safe operation in compliance with regulatory requirements, and to clarify that the CAL process is not a routine substitute for compliance. However, the NRC would not normally take additional enforcement action for those violations that continue after a CAL has been issued where compensatory actions have been accepted by the NRC and taken by the licensee in accordance with its commitments.

[1] Pursuant to Section 182 of the Act and the NRC's implementing regulations, CALs may require a licensee to notify the NRC if its understanding of its commitments differs from what is stated in the CAL, if it cannot meet the corrective actions schedule, and when corrective actions are completed. Failure to provide such required notification may be treated like any other violation of a requirement.

4.7.2 Preparing a CAL

CALs should be prepared using the standard format in Appendix B (Form 24). CALs should include the following elements:

a. A brief discussion of the specific issues with which the NRC has concern, including how and when they were identified.

b. A brief statement summarizing NRC/licensee communication on the agreed-upon actions. This statement should include when the communication took place, the names and positions of the principal individuals involved in the communication, and whether the communication took place in a telephone conversation or a face-to-face meeting. Face-to-face meetings should also include the location of the meeting (i.e., regional office, licensee's facility).

c. A clear description of the agreed-upon actions and where warranted and appropriate, the date(s) when actions will be completed.

d. A statement that requires the licensee to provide written notification to the NRC if its understanding of the relevant issues and commitments differ from what is stated in the CAL.

e. A statement that requires the licensee to provide written notification to the NRC if for any reason it cannot complete the actions within the specified schedule. It should also require that the licensee inform the NRC of the modified schedule.

f. A statement that requires the licensee to provide written notification to the NRC if it intends to change, deviate from, or not complete any of the documented commitments, prior to the change or deviation.

g. A statement that requires the licensee to provide the NRC with written confirmation of completed actions.

h. A statement that issuance of the CAL does not preclude issuance of an order formalizing the commitments in the CAL or requiring other actions nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of the CAL.

i. A statement that failure to meet the commitments in a CAL may result in an order if the licensee’s performance, as demonstrated by the failure to meet CAL commitments, does not provide reasonable assurance that the NRC can rely on the licensee to meet the NRC’s requirements and protect public health and safety.

j. A statement that the letter and any licensee response will be made available to the Public.

k. A statement of citation to the regulation implementing Section 182 of the Act and authorizing the required responses to the CAL by the licensee.

4.7.3 CAL Coordination and Review

CALs should be coordinated and reviewed according to the following guidelines:

a. CALs issued by the region must be coordinated with the appropriate program office by telephone prior to issuance. Unless NMSS requests, CALs issued to materials licensees do not require NMSS concurrence. CALs issued to reactor licensees must be concurred on by the Director, NRR.

b. Regional Enforcement Coordinators should be consulted before issuing regional CALs. CALs issued by the program offices should coordinated with the applicable program office enforcement coordinator before the CAL is issued.

c. CALs issued by NRR or NMSS must be coordinated with the appropriate region. This coordination will help to provide consistency between the regions and program offices in response to similar issues and provide program oversight and assistance.

d. Except for CALs issued under 4.7.e or unless OE requests, CALs do not need to be coordinated with or concurred in by OE.

e. CALs issued under 4.7.e should be reviewed by OGC prior to issuance.

4.7.4 CAL Signature Authority

CALs should be signed and issued according to the following guidelines:

a. The Regional Administrator should sign all CALs issued by the region. Delegation of signature authority should not be below the Division Director or acting Division Director level.

b. The Director, NRR and the Director, NMSS should sign all CALs issued by NRR or NMSS respectively. Delegation of signature authority should not be below the Division Director or acting Division Director level.

4.7.5 Licensee Notification, Mailing, & Distribution for CALs

CALs should be sent to the licensee by either Certified Mail (Return Receipt Requested) or Express Mail. Upon issuance, CALs should be distributed to OE, the appropriate Deputy EDO, the appropriate program office (NRR or NMSS), and the appropriate region. CAL's should also be sent to the appropriate regional public affairs officer, the Regional State Liaison Officer, the State, and made available to the Public. In addition, a copy of the CAL for a material licensee should be sent to the Regional State Agreements Officer.

The staff should be sensitive to describing agreed upon licensee corrective actions that involve safeguards matters to prevent inadvertent release of safeguards information.

4.7.6 CAL Tracking Responsibilities

The issuing office (i.e., region, NRR, or NMSS) is responsible for tracking the CALs it has issued, including how many CALs have been issued, to whom and why they were issued (i.e., a brief description of the issues), and when all corrective actions were or will be completed. The region will assign CAL tracking numbers based on the region number, the year of issuance, and the sequential CAL number in that region for that year (e.g., 2-00-008). NRR and NMSS will assign CAL tracking numbers similarly (e.g., NRR-00-006, NMSS-00-003). Addendums to CALs should retain the same CAL number followed by an alphabetical reference based on the corresponding addendum for that CAL (e.g., 2-00-008A, NRR-00-006B). The issuing office should maintain a list summarizing this information suitable for auditing actions associated with CALs.

4.7.7 Closing Out CALs

It is expected that the issuing office (i.e., region, NRR or NMSS) will issue documentation formally closing out the CAL. This correspondence should be sent to the same person/address as the CAL. Verbal notification, in advance of written correspondence, may be sufficient to permit plant restart or resumption of affected licensee activities.

Because CALs are tailored to address a variety of issues, CALs may be closed in a number of ways. For example, a CAL closure may or may not require follow-up inspection to verify completion of the specified licensee actions. Whether the staff believes that an inspection is necessary to close a CAL will be determined on a case-by-case basis and will depend on the circumstances of the case.

4.7.8 Press Releases for CALs

Press releases are not routinely issued to address the issuance of a CAL. If a region believes that a press release is appropriate, it should be coordinated with Public Affairs.

CHAPTER 5
ESCALATED ENFORCEMENT ACTIONS

5.1 Scope of the Chapter

This chapter describes predecisonal enforcement conferences and regulatory conferences; how to determine whether a civil penalty should be proposed for an escalated enforcement action; and how to process escalated actions, including Notices of Violation with and without civil penalties, and orders. Timeliness goals for issuing escalated enforcement actions are included in the general discussion for each sanction. This chapter also describes processing and administrative tracking methods for Demands for Information and Letters of Reprimand.

5.2 Predecisional Enforcement Conferences and Regulatory Conferences

Predecisional enforcement conferences are addressed in Section V of the Enforcement Policy. A predecisional enforcement conference is normally an open meeting between the NRC and a licensee, vendor, or other person when the NRC has learned of apparent violations for which escalated enforcement action appears warranted.

Regulatory conferences are normally open meetings between the NRC and reactor licensees to discuss issues that the SDP assessment determines to be potentially risk significant (white, yellow, or red)--whether or not violations are involved. Because the significance assessment from the SDP determines whether or not escalated enforcement action will be issued (i.e., a Notice of Violation associated with a white, yellow, or red SDP finding), a subsequent predecisional enforcement conference is not normally necessary. Although these regulatory conferences are similar to predecisional enforcement conferences in many respects, specific guidance for regulatory conferences is included in NRC Inspection Manual Chapter 0609.

➜**NOTE**: Meeting notices for regulatory conferences with enforcement implications should be sent to "OEMAIL" and the OE Web site Coordinator "OEWEB" to ensure that these conferences are posted on the **Enforcement** Web site.

Predecisional enforcement conferences and regulatory conferences are normally categorized as Category 1 meetings in accordance with the Commission's Public Meeting Policy. The policy statement as well as additional guidance on conducting public meetings is included on the **Communications and Public Meetings** Web site, (http://www.internal.nrc.gov/NRC/SES/comm.html).

See Section 7.3.1 for guidance on conducting conferences with individuals.

The decision to hold a predecisional enforcement conference does not mean that the agency has concluded that a violation has occurred or that enforcement action will be taken.

The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, such as:

- a common understanding of the facts, root causes, and missed opportunities to identify the violation sooner,
- a common understanding of corrective actions, or

- a common understanding of the significance of the issues and the need for lasting and effective corrective action.

Predecisional enforcement conferences are not meetings to negotiate sanctions.

5.2.1 Applicability

Predecisional enforcement conferences are applicable as follows:

a. Predecisional enforcement conferences will normally be held when the NRC needs additional information prior to making an enforcement decision involving a potential escalated action, i.e., Severity Level I, II, and III violations, civil penalties, and orders. NOTE: Issuing a "choice letter" may be appropriate where a licensee appears to understand the significance of the violation and the need for corrective action at the inspection exit, but that the inspector may not be aware of all of the corrective actions subsequent to the inspection exit. Issuing a choice letter may provide the emphasis to the licensee to develop and implement comprehensive corrective actions to avoid the potential for a civil penalty.

b. Predecisional enforcement conferences will normally be held when the NRC needs additional information prior to making an enforcement decision involving a significant vendor case, such as those involving recurring nonconformances.

c. Predecisional enforcement conferences will normally be held before issuing an order based on a violation of the Deliberate Misconduct rule.

d. Predecisional enforcement conferences will normally be held before issuing a civil penalty to an unlicensed individual.

e. The NRC may take immediate enforcement action (prior to a conference) if necessary to protect the public health and safety. Conferences may be subsequently held in these cases.

f. A licensee, vendor, or other person may seek to waive their opportunity to participate in a conference. The region should notify OE if a licensee seeks to waive a conference. In this case, a DFI may be warranted to get the information that the NRC needs.

g. The region should consult with OE for those cases involving potential escalated enforcement action where it proposes not to conduct a conference if there has been an escalated enforcement action within the last 2 years or 2 inspections, or if the violation is categorized at Severity Level I or II or is willful.

h. If the NRC concludes that a conference is not necessary, the region may either: (1) issue the inspection report including the apparent violations and providing the licensee a choice of requesting a conference or providing a response to the apparent violations ("choice letter"), or (2) make a telephone call to the licensee informing them that the NRC does not see the need for a conference and does not see the need for a civil penalty ("choice call"). See Section 3.11.3 for additional guidance on these options.

i. Notwithstanding the NRC's conclusion that a conference is not necessary, a conference will normally be held if the licensee requests it.

5.2.2 Scheduling and Announcing Predecisional Enforcement Conferences

(See Section 7.3.1 for additional guidance on predecisional enforcement conferences involving individuals.)

Once the region determines that a predecisional enforcement conference should be conducted, it should notify OE of its intent. (See Section 7.6 for guidance on cases that have been referred to the Department of Justice (DOJ). These cases require coordination with DOJ and approval of the Director, OE, prior to scheduling a conference.) OE will assign an EA number to the case. Predecisional enforcement conferences should generally be held within 5 weeks after completion of an inspection. If a conference is scheduled subsequent to a licensee's response to a "choice letter," the conference should generally be held within 4 weeks of receipt of the licensee's response.

➜**NOTE**: See the **Public Meeting Checklist** http://www.internal.nrc.gov/NRC/SES/checklist.html for additional guidance on scheduling and announcing public meetings.

a. After receiving an EA number, the region should inform the licensee (as soon as possible) of the intent to hold a predecisional enforcement conference and whether the conference will be open or closed to public observation (see Section 5.2.3.3). The region should also inform the licensee of the purpose of the conference and the information that the licensee is encouraged to present at the conference. This will help direct the licensee's focus and ensure that the licensee understands what is expected at the conference. This communication is especially important for material licensees because of their infrequent contact with the NRC. If time permits, a written outline or agenda of specific issues should be provided. The region should also inform the licensee that any information provided during the conference, including handouts or preliminary evaluations, will be made available to the Public, unless it meets the provisions of 10 CFR 2.790 (a)(4) or (6).

   The region should coordinate with the licensee a date to hold the conference, with a goal of giving the licensee at least 2 weeks to prepare. Licensees should have adequate time to perform necessary reviews or investigations, develop corrective action plans, and prepare presentations. While licensees are expected to begin their presentation based on the inspection exit meeting, the specific findings or issues of concern may not be fully understood until the licensee has received the written report. Therefore, unless prior approval is given by the Director, OE, or unless the licensee waives receipt of the inspection report, the licensee should normally be given the inspection report at least 2 weeks in advance. (Form 1-I in Appendix B should be used for this purpose.) Inspection reports should be sent to OE and the appropriate program office the same time the region sends it to the licensee.

   In addition to the inspection report, the licensee should normally be sent a factual summary for cases involving OI reports. The factual summary provides notice to the conference participants of the factual basis for the staff's preliminary conclusion that NRC regulatory violations occurred. The summary should provide sufficient factual detail to fully apprize conference participants of the operative facts involved in the apparent violation. It is not intended to provide a full discussion of the evidence gathered in the course of the NRC's investigation. The summary should not normally include the names of individuals involved in the potential enforcement matter, rather titles or other generic description should be utilized. Other personal or proprietary information should not be included. While the length of the summary in each case depends on the facts, it should not ordinarily exceed two single-space pages. (An example of

such a summary is provided in Appendix D.) In most cases the factual summary will provide the same information that is contained in the OI report synopsis; therefore, the synopsis need not normally be enclosed. (See the guidance in Section 7.5.4.5 for additional information on release of OI reports and exhibits.) Additional information is included in Management Directive 3.4, "Release of Information to the Public," and Management Directive 8.8, "Management of Allegations."

Additional time may be needed to prepare for conferences involving complex issues. The timeliness of the process is also dependent on effective exit meetings. The licensee should be put on notice if, after the exit meeting, the agency concludes that different issues should be the focus of the conference. This should also be considered in scheduling the conference.

b. After the conference date and time have been set, the region should promptly notify OE, the appropriate program office, OI (if applicable) and the appropriate State liaison officers (unless the conference is closed). The region should highlight any novel or complex cases for the attention of the Director, OE.

c. The region should prepare a meeting notice in accordance with regional procedures and include information (as applicable) in the **Public Meeting Checklist** Web site http://www.internal.nrc.gov/NRC/SES/meeting.html. Meeting notices should also include specific enforcement-related information. Appendix D includes a checklist that consolidates the required information for conferences.

✔ The meeting notice should include the EA number.

✔ The meeting notice should clearly identify the meeting as a "predecisional enforcement conference."

✔ The purpose statement should provide sufficient detail to inform the public about the general issues, including the activity area, or equipment involved.

✔ The notice should refer to the issues as "apparent violations" or "potential noncompliances," to reflect the predecisional nature. If the case involves potential willfulness, the notice should refer to the issues generally as "apparent willful violations," instead of "apparent deliberate violations."

The following examples demonstrate inadequate and adequate purpose statements.

NO The purpose of the meeting is to discuss the procedural violation identified in NRC Inspection Report No. 50-277/02-06.

YES The purpose of the predecisional enforcement conference is to discuss the apparent procedural violation involving the motor driven emergency feedwater pump.

NO The purpose of the predecisional enforcement conference is to discuss the deliberate transfer of licensed byproduct material without a specific license.

YES The purpose of the predecisional enforcement conference is to discuss the apparent willful violation involving the transfer of licensed byproduct material (EXIT signs containing tritium) without a specific license.

✔ The notice should indicate whether the conference is open or closed to public observation.

If the conference is open, include the following statement:

> This is a Category 1 Meeting: The public is invited to observe this meeting and will have one or more opportunities to communicate with the NRC after the business portion, but before the meeting is adjourned.

If the conference is closed, include one of the following statements:

> This conference is closed to public observation because it involves the findings of an NRC Office of Investigations report that has not been publically disclosed.
>
> This conference is closed to public observation because it involves safeguards information, Privacy Act information, or information which could be considered proprietary.
>
> This conference is closed to public observation because it involves potential wrongdoing by an individual.
>
> This conference is closed to public observation because it involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference.
>
> This conference is closed to public observation because it involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing the exposed individual's name.
>
> This conference is closed to public observation because it will be conducted at a relatively small licensee's facility (or will be conducted by telephone).

✔ The notice should include the **inspection report number and the ADAMS accession number**. This is very important in meeting the intent of the Commission's policy on public meetings on providing background information. Creating an ADAMS package including the meeting notice, agenda, and other related documents is normally not necessary, as the inspection report and transmittal letter typically provide sufficient information. However, if a separate agenda is created, a WordPerfect file should be sent to "OEWEB" for posting on the **Enforcement** Web site.

d. The region should submit meeting notices for all predecisional enforcement conferences (open or closed) at least 10 calendar days in advance of the meeting to the Public Meeting Notice System Coordinator (e-mail "PMNS"). The region should also send a copy of the meeting notice (including the EA number) to "OEMAIL" and the OE Web site Coordinator ("OEWEB") at the same time to support posting the conference on the **Enforcement** Web site.

➜**NOTE**: **Meeting notices for regulatory conferences with enforcement implications** should be sent to "OEMAIL" and the OE Web site Coordinator ("OEWEB") to ensure that these conferences are posted on the **Enforcement** Web site. These meeting notices should include a statement that the meeting will also address whether enforcement action is warranted.

e. The region should notify OPA of all predecisional enforcement conferences. OPA will determine whether to issue a press release announcing the conference. All press releases should be brief and include language that clearly indicates that the decision to hold a predecisional

enforcement conference does not mean that the agency has concluded that a violation has occurred or that enforcement action will be taken and that apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action. The press release should include an explicit description of the nature of the conference as a predecisional opportunity for the licensee to present any additional material information before the NRC arrives at a decision.

5.2.3 Attendance at Predecisional Enforcement Conferences

This section provides specific guidance concerning attendance at predecisional enforcement conferences, including: NRC personnel (Section 5.2.3.1), licensee personnel (Section 5.2.3.2), media and members of the public (Section 5.2.3.3), and State government personnel (Section 5.2.3.4).

5.2.3.1 NRC Attendance at Predecisional Enforcement Conferences

NRC personnel should attend conferences according to the following guidelines:

a. The Regional Administrator should determine regional staff attendance at conferences. The region should be sensitive to the potential impact on a conference when the number of NRC attendees is significantly greater than the number of licensee attendees. <u>There should be a reason for each NRC person's attendance</u>

b. The region should discuss with the cognizant OE Enforcement Specialist or the Director, OE whether the issues warrant OE attendance at the conference. This will improve communication and minimize potential disagreements or inconsistencies in the enforcement actions. OE staff should attend all significant conferences, either in person or by video or telephone. (OE should generally not participate by telephone if safeguards information will be discussed; see Section 5.2.4.)

   If the Regional Administrator believes that telephone or video participation would make a particular conference less effective, OE should be notified at least 1 week in advance so that travel arrangements can be made. If OE plans to attend the conference in person or by video or telephone, the region shall send OE, along with the inspection report, any additional relevant information prior to the conference.

c. The NRR, NMSS, or NSIR Enforcement Coordinator should attend conferences as deemed appropriate by the program office, or as requested by the region.

d. Additional program office designees (NRR/NMSS/NSIR technical or projects staff) may attend conferences as deemed appropriate by the program office, or as requested.

e. Regional Counsel should attend conferences, unless their schedule does not permit, and in particular, should attend those conferences involving complex or novel issues or those involving a complex or significant OI investigation. OGC should be requested to attend conferences involving legal issues.

f. OI should be invited to attend those conferences that involve a complex or significant OI investigation, or those that could potentially result in an OI referral for investigation.

5.2.3.2 Licensee Attendance at Predecisional Enforcement Conferences

Licensee personnel should attend conferences according to the following guidelines:

a. The region should request that licensee attendance include senior level managers and individuals prepared to address the circumstances of the apparent violations and the corrective actions, e.g. Radiation Safety Officer. The licensee senior representative at a conference should be empowered to bind the licensee to commit to corrective actions on its behalf.

b. When an individual's significant personal error contributed to the violation, consideration should be given to that person's attendance at the licensee's conference. It may be beneficial for NRC management to hear first-hand the individual's explanation for the actions taken, to get a more complete understanding of the violation circumstances.

c. When a significant enforcement action against an individual is contemplated, the opportunity should normally be provided for a specific conference with the individual. Additional considerations apply to who should attend individual conferences (see Section 7.3.1).

5.2.3.3 Public Attendance at Predecisional Enforcement Conferences

As stated in the Enforcement Policy, predecisional enforcement conferences are meetings between the NRC and the licensee and are normally held in the regional offices and open to public observation. Open predecisional enforcement conferences are classified as Category 1 meetings in accordance with the Commission's Public Meeting Policy. However, conferences will not normally be open to the public if the enforcement action being contemplated:

a. Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

b. Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

c. Is based on the findings of an NRC Office of Investigations (OI) report that has not been publicly disclosed; or

d. Involves safeguards information, Privacy Act information, or information which could be considered proprietary;

In addition, conferences will not normally be open to the public if:

e. The conference involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing the exposed individual's name; or

f. The conference will be conducted at a relatively small licensee's facility.

Notwithstanding meeting any of these criteria, a conference may still be open if the conference involves issues related to an ongoing adjudicatory proceeding with one or more interveners or

where the evidentiary basis for the conference is a matter of public record, such as an adjudicatory decision by DOL. In addition, notwithstanding the above normal criteria for opening or closing conferences, with the approval of the EDO, conferences may either be open or closed to the public after balancing the benefit of the public observation against the potential impact on the agency's decision-making process in a particular case.

The Regional Administrator has the discretion to determine whether the public should be allowed to observe a video conference on a case-by-case basis.

The public attending an open conference may observe but not participate in the conference. Members of the public may tape record (including videotape) an open conference if that activity is not disruptive. It is noted that the purpose of conducting conferences in the open is not to maximize public attendance, but rather to provide the public with opportunities to be informed of NRC activities while balancing the need for the NRC staff to exercise its regulatory and safety responsibilities without undue administrative burden. Following the conference, the staff is to be available for a brief period to entertain questions and comments from members of the public concerning matters discussed at the conference.

5.2.3.4 State Government Attendance at Predecisional Enforcement Conferences

Since most predecisional enforcement conferences are open to the public, state government personnel will be able to attend. Nonetheless, if the particular conference is closed, the Commission's "Policy on Cooperation with States at Commercial Nuclear Power Plants and Other Nuclear Production or Utilization Facilities," dated February 15, 1989, permits State representatives to attend predecisional enforcement conferences if information relevant to an enforcement action is obtained by a State representative during an inspection under a State/NRC inspection agreement.

When other circumstances warrant, the Director, OE may authorize the Regional Administrator to permit State personnel to attend a closed predecisional enforcement conference. Examples of situations were permission would be granted include if the State representative could provide helpful information or insight (e.g., the enforcement action involves a matter in which the State may also have a related regulatory interest, as with naturally occurring radioactive material) or where the enforcement action involves a general license under 10 CFR Part 150 and an Agreement State has issued a specific license.

If attendance by State personnel has been deemed appropriate, the following guidelines should be met for closed conferences:

a. State attendance should be from the appropriate State office (i.e., a person from the State office of operational or radiation protection safety and not from the State rate-setting office).

b. The State attendee should be informed that participation during the predecisional enforcement conference is not allowed unless the State attendee was a participant in the inspection under discussion, and then the State attendee may only make statements related to the areas inspected.

c. If actual safeguards information is to be discussed, State personnel may be excluded unless they have the necessary clearance.

d. The State attendee must agree not to disclose the pre-decisional enforcement conference details with the media or the public.

The non-disclosure arrangement between the state and NRC should be written down in a Memorandum of Understanding (MOU) or, in its absence, a protocol agreement. This MOU or protocol agreement should be signed by the Regional Administrator, or his designee, and the State attendee or State liaison officer.

A sample protocol agreement follows:

> (State) will conform to NRC practices regarding information disclosure. (State) will abide by NRC protocol not to disclose publicly inspection findings prior to official release of NRC inspection results. To preclude the premature public release of sensitive information (i.e., concerning matters under investigation and security (safeguards) information), NRC and (State) will protect sensitive information to the extent permitted by the Federal Freedom of Information Act, 10 CFR 2.790, and other applicable authority. (State) will consult with NRC before releasing sensitive information to ensure that its release is not premature or would not affect an ongoing investigation or other NRC action. NRC will inform (State) of the release of sensitive information as appropriate. Additionally, neither NRC nor (State) will release proprietary data until a release is approved by the person(s) having proprietary rights therein or until release is approved by appropriate NRC management.

Although State personnel may be permitted to be present at predecisional enforcement conferences, only NRC personnel may attend enforcement caucus meetings following the conference, unless the Director, OE, has given prior approval for someone other than NRC employees to be present at an enforcement caucus meeting. If a person is allowed to attend a caucus, they should sign a non-disclosure arrangement.

5.2.4 Conducting Predecisional Enforcement Conferences

Predecisional enforcement conferences should be conducted according to the following guidelines:

a. Conferences are normally conducted in the regional offices. There may be special circumstances where the agency determines that it would be beneficial to the enforcement process to conduct the conference at the licensee's facility or where it would be more practical for the agency to conduct the conference by telephone or video. In these cases, the region should consult with OE prior to scheduling the conference. It is up to the Regional Administrator’s discretion to allow a particular conference to be conducted by telephone or video conference.

b. Members of the public will be allowed access to the NRC regional offices to attend open conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" will be permitted, and that disruptive persons may be removed.

c. The Regional Administrator should determine the appropriate member of regional management to serve as the presiding official at the conference. The presiding official should not normally be below a Deputy Division Director. However, the Regional Administrator may determine that it is appropriate for a Branch Chief to serve as the presiding official for certain conferences involving materials licensees.

d. For those conferences in which safeguards information is to be discussed at the conference, NRC staff should not participate by telephone, for security reasons. If such participation is necessary, it should be done in accordance with Management Directive 12.4, "NRC Telecommunications System Security Program," and 12.6, "NRC Sensitive and Unclassified Information Security Program." If security issues (not directly related to safeguards information) are the subject of the conference, NRC staff should not participate by telephone unless a compelling reason exists and safeguards information will clearly not be discussed.

e. Although some conferences may warrant transcription (see Section 5.2.5), conferences are not conducted under oath. However, if warranted, the staff should be clear that whether or not a statement is under oath, a false statement on a material matter may be subject to civil and criminal prosecution.

f. The presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should (1) announce the meeting as an open or closed predecisional enforcement conference, (2) discuss the purpose of the conference, (3) inform the licensee and public attendees that the decision to hold the conference does not mean that the agency has determined that violations have occurred or that enforcement action will be taken, (4) inform the public attendees (for open conferences) that the conference is a meeting between the NRC and the licensee and that the meeting is open for public observation but not participation, and (5) briefly explain the enforcement process. When NRC staff is participating by video or telephone on a case involving security, the presiding official should also announce that safeguards information should not be discussed during the conference, for security reasons. If the conference is open, the region should ensure that it has copies available of the Enforcement Policy, inspection report, and slides to be discussed.

g. The region should briefly discuss the apparent violations and explain the agency's basis for concern. The level of detail to be discussed is related to the complexity and significance of the issues. Most of the detailed information will have been included in the inspection report. The discussion should include the root causes of the apparent violations and the corrective actions planned or taken. Corrective actions considered by the NRC to be inadequate (or only marginally acceptable) should be emphasized. It is helpful to have a slide of the apparent violations, especially in complex cases, to guide the discussion.

   Although the region should address the apparent safety significance of the issues, it should not specifically discuss severity level categorizations, civil penalty amounts, or the nature or content of any orders. If the region chooses to use slides or handouts for any part of its presentation, they should contain the following note: **"The apparent violations discussed in this predecisional enforcement conference are subject to further review and are subject to change prior to any resulting enforcement action."**

h. The licensee should be encouraged to present its understanding of the facts and circumstances surrounding the apparent violations and whether it agrees with the NRC's understanding of the facts, the root cause(s), the safety significance, and the immediate and long-term corrective actions taken or planned. The licensee should also be encouraged to present other information relevant to the agency's enforcement decision, such as the licensee's perspective on the severity of the issue, the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed (e.g., missed opportunities to identify the violation sooner), and any other factors that may warrant enforcement discretion.

   The licensee should understand that the conference is a means of providing to the NRC information it believes the agency should consider in determining the appropriate enforcement

action. The conference is not a meeting to negotiate sanctions with the staff, nor should it be used as a forum for protracted debate. Once the pertinent facts have been established, the presiding official must recognize differences of opinion and keep the conference productive. The conference should normally not last longer than 3 hours.

i. The region should normally take a short break prior to the conclusion of the conference to meet with the staff to ensure that the staff has no outstanding questions.

j. The region should provide closing remarks and the presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should remind the licensee and public attendees that the apparent violations discussed are subject to further review and are subject to change prior to any resulting enforcement action and that the statements of views or expressions of opinion made by NRC employees at the predecisional enforcement conference, or the lack thereof, are not final conclusions.

k. After the business portion of the meeting, the presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should announce that the staff is available to address comments or questions from the public. Although licensees are not obligated, they may respond to questions if they choose to do so.

5.2.5 Transcribing Predecisional Enforcement Conferences

Under certain circumstances, the NRC may choose to transcribe a predecisional enforcement conference. Absent coordination with the Director, OE, conferences should be transcribed for cases involving a licensed operator, a licensee employee who may have committed a willful violation, a significant case in which a record is warranted, any other case involving an OI report, or a case involving discrimination. OE should be consulted if the region believes that other conferences should be transcribed.

Transcribed conferences should normally be closed meetings between the NRC and the licensee. As such, licensees will not be allowed to transcribe or record a conference. Transcripts should not be released until after any associated enforcement action has been issued without the approval of the Director, OE. If the licensee or any individual at the conference is subsequently provided a copy of the transcript, whether by the staff's offer or the individual's request, the individual should be informed that a copy will also be made available to the Public (subject to removal of privacy information, proprietary information, etc.). Transcripts for open conferences may be made available to the Public sooner.

Although transcribed conferences are not conducted under oath, the staff should be clear that whether or not a statement is under oath, a false statement on a material matter may be subject to civil and criminal prosecution.

5.2.6 Predecisional Enforcement Conference Summary

After the conference has been held, the region should prepare a Predecisional Enforcement Conference Summary as shown in Appendix D. The Predecisional Enforcement Conference Summary documents the proceedings and serves as a vehicle for making the licensee's handouts and the NRC's outline or agenda available to the Public. In most cases, the licensee's presentation handouts (and the NRC's handouts, if used) will provide sufficient information to summarize the

conference proceedings. The summary should include the following information (if not already addressed in the licensee's handouts):

1. A brief description of the licensee's position (i.e., if the licensee agrees with the findings in the inspection report, or if the licensee takes issue with the apparent violation(s)).

2. A brief description of significant additions or corrections to the factual information in the inspection report.

3. A brief description of any significant additional information that affects the significance of each violation.

4. A brief description of the short-term and long-term corrective actions the licensee has implemented or has committed to implement. (This description should be sufficient for the staff to judge the corrective action as part of the civil penalty assessment process.)

The summary should be as brief as possible. The summary should not include predecisional, safeguards, or proprietary information.

The region should include the summary as part of the background material submitted with proposed escalated enforcement actions. The Predecisional Enforcement Conference Summary should be sent to the licensee either before or when the enforcement action is issued.

5.3 Enforcement and SDP Caucuses

Enforcement caucuses are meetings that are held subsequent to a predecisional enforcement conference or following receipt of a licensee's response to a "choice letter," to discuss whether new information or perspectives were obtained warranting reconsideration of the enforcement approach for the case and whether, for "choice letter" responses, a conference should be conducted.

SDP/enforcement caucuses are meetings that are held subsequent to a regulatory conference or following receipt of a licensee's response to a "choice letter," to discuss whether new information or perspectives were obtained warranting reconsideration of the significance determination for the case and whether, for "choice letter" responses, a conference should be conducted. Because the outcome of the SDP provides an input into the enforcement process, a secondary purpose for such meetings is to discuss and reach agreement on an enforcement approach for any violations that might be associated with the inspection findings. Although these caucuses are similar to enforcement caucuses in many respects, specific guidance for SDP/enforcement caucuses is included in Inspection Manual Chapter 0609.

5.3.1 Participating in Enforcement Caucuses

Participation in enforcement caucuses should be in accordance with the following guidelines:

a. **Region**: The region should schedule a caucus as soon after a conference or receipt of a licensee's response to a "choice letter" as possible. The region should notify OE, and the applicable program office Enforcement Coordinator(s). The region should also invite the Assistant General Counsel for Materials Litigation and Enforcement and the applicable OI investigator and Regional Field Office Director for caucuses involving willfulness.

It is expected that the region will be represented by a person at the Division Director level or higher. It is important to recognize that the regional caucus participants provide a recommendation to the Regional Administrator and that their position does not represent the final region position. (See Section 5.3.2.g for additional guidance on enforcement strategy disagreements.)

c. **OE**: Enforcement Specialists should attend all caucuses. If OE management did not participate in the caucus, it will provide its position to the region within 1 day of the meeting. A final decision on the enforcement action is not to be made until the Director or Deputy Director, OE agrees with the enforcement strategy.

d. **Program Office**: The program offices should be invited to participate in caucuses (attendance is not necessarily mandatory). The NRR, NMSS, and NSIR Enforcement Coordinators are responsible for arranging for participation by the appropriate and necessary program office staff and for ensuring that the staff has necessary materials in advance of the meeting (e.g., conference handouts).

   In evaluating the appropriateness of the proposed enforcement strategy, program office participants should focus on whether the violations are technically accurate and factual and whether the enforcement strategy is consistent with the program office's policy, guidance, position, or past practice. If program office participants disagree with the enforcement strategy discussed during the caucus, they are responsible for elevating their concerns to program office management (the Associate Director for Inspection and Programs for NRR cases, the applicable Division Director for NMSS cases, and the Director, Division of Nuclear Security, NSIR). (See Section 5.3.2.g for additional guidance on enforcement strategy disagreements.)

e. **OGC/OI**: OGC (Assistant General Counsel for Materials Litigation and Enforcement) should be invited to caucuses involving willfulness and other cases with potential issues of legal significance. OI (applicable investigator and Regional Field Office Director) should be invited if there are questions as to OI findings.

5.3.2 Enforcement Caucus Outcome

Subsequent to an enforcement caucus involving OE participation, OE will amend (as warranted) its understanding of the enforcement strategy that was agreed upon during the enforcement caucus by completing the lower portion of the Strategy Form. OE will send the form to the region and provide it to the program office (through their Enforcement Coordinator). The form also serves as the basis to brief the Regional Administrator, the Director, OE (if he or she did not participate in the caucus), the Associate Director for Inspection and Programs in NRR , the applicable Division Director in NMSS, or the Director, Division of Nuclear Security, NSIR, if warranted, and to subsequently develop the enforcement action and the enforcement action transmittal letter.

Depending on the information gathered during the conference or provided in the licensee's response to the "choice letter," and the discussions in the caucus, the staff will determine one of several outcomes. The staff will also determine the level of headquarters review that is necessary for the case.

a. **If the staff concludes that no violation occurred**, for enforcement caucuses that involved OE, OE will document the disposition of the issue by completing the Strategy Form. OE will send the form to the region and make it available to the program office and OGC. The region should

inform the licensee that the NRC does not intend to issue enforcement action. The region may use the Predecisional Enforcement Conference Summary to clarify why a citation was not issued.

b. **If the staff concludes that non-escalated enforcement action should be proposed**, OE will document the disposition of the issue by completing the Strategy Form. OE will send the Strategy Form to the region, the program offices, and OGC. The regions may generally issue the non-escalated enforcement action based on region/OE/program office agreement on the Strategy Form. In special cases, OE may request that the actual enforcement action be submitted for review and approval prior to issuing a non-escalated NOV that was the subject of a predecisional enforcement conference. The region should include an explanation in the cover letter to the licensee of why non-escalated action was appropriate in the particular case. The final action should be signed by someone at least at the level of the presiding official at the predecisional enforcement conference and should be sent to OE to close out the EA number.

c. **If the staff concludes that escalated enforcement action should be proposed**, OE will document the disposition of the issue by completing the Strategy Form. OE will send the form to the region and make it available to the program office and OGC. The region should prepare the appropriate escalated enforcement action.

d. **If additional facts are disclosed or developed** (at or after the conference) that could lead to additional violations, special efforts should be taken to substantiate these violations before they are included in the proposed enforcement action. In addition, it may be appropriate to contact the cognizant licensee official, by at least a telephone conference call, to (1) discuss the apparent violation before it is formalized and (2) provide any additional information that may be relevant. New EA numbers should be assigned to any additional Severity Level I, II, III violations or problems that are proposed with the action. Strategy Forms should be prepared and updated, as appropriate.

e. **If the staff concludes that a conference should be conducted**, or if the licensee requests a conference, the region should arrange for a conference with the licensee as soon as possible. A conference may be necessary if the staff concludes that the documented corrective action is not sufficiently prompt and comprehensive such that a civil penalty may be warranted. The Strategy Form should be updated to reflect the information.

f. **If the staff concludes that an additional caucus or discussion is necessary**, the same principal caucus participants should attend if practicable. The other participants, to the extent that they might have information relevant to the issues to be discussed, should also attend if practicable. However, all of the participants need not be present to conduct a subsequent caucus or discussion. The Enforcement Specialist should bring the previous Strategy Form(s) to subsequent caucuses for the case. It is not always necessary to hold a new caucus to change a past agreement recorded on a Strategy Form. OE management can agree to change an agreement as a result of telephone calls or meetings outside the caucus process. After a subsequent caucus or substantiative discussion, the Strategy Form will be updated noting the outcome of the meeting, including a brief explanation of the reason for any change in enforcement strategy and distributed so that the region, program office, and OGC are aware of the change and can comment, if desired. Following receipt of the revised Strategy Form, it is the responsibility of the principal participants to verify that the revised strategy is acceptable to the office or region. The principal participants are responsible for discussing, as warranted, changes to previously agreed upon strategy with the prior caucus participants from their office or region who may not have been involved in the subsequent caucus or discussion. The regional principal participants

should discuss, as warranted, the issues with OI. Disagreements with the revised strategy should be handled as discussed below.

g. **If, after being briefed on the caucus outcome, the Regional Administrator, the Associate Director for Inspection and Programs for NRR cases, the applicable Division Director for NMSS cases, or the Director, Division of Nuclear Security for NSIR cases disagree on enforcement strategy issues** such as significance, SDP characterization, severity level, civil penalty assessment, or enforcement discretion, they should contact the Director, OE as soon as possible, and normally no later than 24 hours after receiving OE's summary of the enforcement strategy documented on the Strategy Form. In the case of a regional disagreement, the Regional Administrator and Director, OE should confer and either resolve their differences or promptly escalate the matter to the DEDO. (Depending on the nature of the regional disagreement, OE may arrange for program office participation.) In the case of a program office disagreement, the Associate Director for Inspection and Programs for NRR cases, the applicable Division Director for NMSS cases, or the Director, Division of Nuclear Security for NSIR cases, should confer with the Director, OE, and the Regional Administrator to resolve their differences or the Director, OE will promptly escalate the matter to the DEDO. Based on the outcome of these discussions, if warranted, OE will revise the summary of the agreed upon enforcement strategy on the Strategy Form, send it to the region, and make it available to the program office and OGC.

h. Depending on the circumstances of the case, OE will decide whether agreement on the Strategy Form is sufficient or whether the actual enforcement action package needs to be submitted to headquarters for review and approval prior to issuance.

   In addition, as stated above, if the Director, OE cannot resolve an enforcement strategy issue with the Regional Administrator, the Director, OE may request that the complete case (including the transmittal letter to the licensee) be submitted to headquarters for review and approval prior to issuance.

5.4 Civil Penalty Process: Determining Whether a Civil Penalty Should Be Proposed

Civil penalties are normally assessed for Severity Level I and II violations and knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act. Civil penalties are considered for Severity Level III violations.

Civil penalties are also considered for violations associated with white, yellow, or red inspection findings evaluated through the Reactor Oversight Process's SDP that involved actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, failure to make the required notifications that impact the ability of Federal, State and local agencies to respond to an actual emergency preparedness event (site area or general emergency), transportation event, or a substantial release of radioactive material.

To the extent that the SDP can provide an assessment of the significance of the underlying violation or issue, it should be used as a first step in resolving the violation. This will ensure a consistent approach for significance determinations. The staff should consider the SDP output in conjunction with the guiding principles for assessing significance and the guidance included in the Supplements of the Enforcement Policy to determine the appropriate severity level.

➜ **NOTE**: Civil penalties **are not** proposed for violations associated with low to moderate, or greater safety significant findings absent actual consequences.

The next phase of the enforcement process (civil penalty process) involves determining whether a civil penalty should be proposed for the violation.

Step 1: Determining the base civil penalty appropriate for the significance of the violation and the class of licensee (Section 5.4.1).

Step 2: Completing the civil penalty assessment process, which considers:

- whether (for a non-willful Severity Level III issue) the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past 2 years or past 2 inspections, whichever is longer;
- whether the licensee should be given credit for actions related to identification;
- whether the licensee's corrective actions are prompt and comprehensive; and
- whether, in view of all the circumstances, the matter in question requires the exercise of discretion (Section 5.4.2).

Step 3: Comparing the amount of the civil penalty resulting from the civil penalty process described above with the amount allowed by statute, to ensure that the civil penalty amount actually issued is within the statutory maximum (Section 5.4.3).

Step 4: Depending on the outcome of the civil penalty process, the staff will conclude whether an escalated NOV should be issued with or without a civil penalty (Section 5.4.4).

5.4.1 Base Civil Penalty

The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons. Violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device are treated separately, regardless of the use or the type of licensee. The first step in the civil penalty process is to determine the base civil penalty for the violation.

Tables 1A and 1B in the Enforcement Policy show the base civil penalties for various reactor, fuel cycle, and materials programs, and for the loss, abandonment or improper transfer or disposal of a sealed source or device. The structure of these tables generally takes into account both the gravity of the violation and the licensee's ability to pay. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. (Civil penalties issued to individuals are determined on a case-by-case basis.)

5.4.1.1 Ability to Pay and Size of Operation

Although Tables 1A and 1B in the Enforcement Policy are structured to take into account the gravity of violations and the licensee's ability to pay, there may be circumstances that warrant an adjustment to the base civil penalty or consideration of payment of a civil penalty over time.

a. It may be appropriate to increase the size of the base penalty on the basis of the amount of nuclear materials inventoried, the potential hazards associated with them, and the size and

nature of the licensee operation and program. Increasing the penalty requires OE approval and may require Commission consultation.

b. It is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts a licensee out of business (orders, rather than civil penalties, should be used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts take into account a licensee's ability to pay. If payment of a civil penalty could impair the licensee's ability to safely conduct licensed activity, the staff should consider whether the licensee should be allowed to maintain its license, given its questionable financial stability.

   If a licensee can demonstrate financial hardship, the NRC will normally consider payments over time, including interest, rather than reducing the amount of the civil penalty. If, after consultation with OE, payments over time or reduction of the penalty appears appropriate, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees. The licensee should be requested to provide the NRC with written evidence to demonstrate that payment of the civil penalty would substantially affect its ability to remain in business or would substantially affect its ability to safely conduct licensed activities. Further, the licensee must support its position with documentation for the past 3 years (such as profit and loss statements showing income and expenses including such items as gross sales and salaries, balance statements showing assets and liabilities, auditor's reports, and tax returns or other evidence). The Licensee must also provide a statement from at least one financial institution that it could not obtain a loan. Further, a DFI should be included to ask the licensee to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

   If the licensee's submittal does not support its claim, the responsible office should impose the civil penalty and inform the licensee that NRC evaluation of the submitted evidence does not reflect the licensee's claim.

   If the licensee's submittal supports its claim, the civil penalty should be imposed over a time-frame that is consistent with NRC evaluation of the licensee's evidence and should provide the licensee the basis for such conclusion. The regional office should prepare a Promissory Note in Payment of the Civil Penalty (Note) using the standard format in Appendix B (Form 12). OE will get the payment schedule for insertion from the Office of the Controller and subsequently issue it to the licensee. After the licensee signs and returns the Note to the NRC, the Director, OE, counter-signs the Note and OE forwards a copy to the licensee.

5.4.1.2 Small Business Regulatory Enforcement Fairness Act (SBREFA)

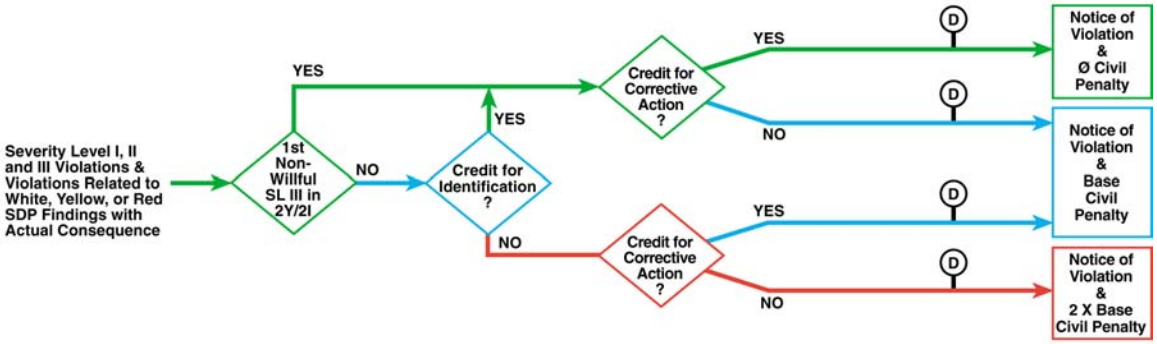
The NRC is subject to the Small Business Regulatory Enforcement Fairness Act (SBREFA). Among the requirements of the SBREFA, the NRC must consider the Act in taking civil penalty actions against small entities. The NRC's Enforcement Policy has been analyzed and is believed to be in compliance with this requirement as the civil penalty structure takes into account the size of the licensee by virtue of the nature of the operation, the significance of the violations, and consideration of factors such as identification, corrective action, licensee history, and willfulness or other particularly poor performance. The Act also addresses financial hardship, which is covered by Section 5.4.1.1.b. Nonetheless, in reaching decisions concerning enforcement

actions, the staff should keep the intent of the Act in mind. There may be cases in which, after considering the normal adjustment factors and the size of a qualified small entity to whom a civil penalty may be issued, the staff believes that the penalty should be reduced or eliminated. In those cases, it is appropriate to propose such a modification based on the intent of the Act. This would be applied as an exercise of discretion and the appropriate Enforcement Action Tracking System (EATS) keyword should be entered.

5.4.2 Civil Penalty Assessment Process

The civil penalty assessment process is addressed in Section VI.C.2 of the Enforcement Policy. In an effort to (1) emphasize the importance of adherence to requirements and (2) reinforce prompt self-identification of problems and root causes and prompt and comprehensive correction of violations, the NRC reviews each proposed civil penalty on its own merits and, after considering all relevant circumstances, may adjust the base civil penalties shown in Table 1A and 1B for Severity Level I, II, and III violations as described below.

The flow chart presented below is a graphic representation of the civil penalty assessment process.



The civil penalty assessment process considers these decisional points:

1. Is this the first non-willful Severity Level III enforcement action (regardless of the activity area) that the licensee has had during the past 2 years or past 2 inspections (whichever is longer)?

2. Should the licensee be given credit for actions related to identification? (Only consider if the answer to question 1 is no.)

3. Are the licensee's corrective actions prompt and comprehensive?

4. In view of all the circumstances, does the matter in question require the exercise of discretion? (For example, Severity Level I and II violations should normally result in a civil penalty.)

Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or twice the base civil penalty.

The next five sections provide detailed guidance on the decisional points.

5.4.2.1 Initial Escalated Action

When the NRC determines that a non-willful Severity Level III violation or problem has occurred, and the licensee has not had <u>any</u> previous Severity Level I, II, or III escalated actions (regardless of the activity area) for this site during the past 2 years or 2 inspections, whichever is longer, the NRC will consider whether the licensee's corrective action for the present violation or problem is reasonably prompt and comprehensive (see discussion under Section 5.4.2.4, below).

➜ **NOTE**: This includes new licensees who have not been in existence during the past 2 years or for 2 inspections (provided that they have not had previous escalated actions). However, in these cases, the staff should consider whether the apparent significant violation in question calls for the exercise of discretion to impose a civil penalty or take even more stringent action to address the apparent poor performance by a new licensee.

➜ **NOTE**: This criterion should also be considered for license transfers and when a licensee moves, including situations where the license is terminated and a new license is obtained. This is appropriate if the facility personnel, procedures, and equipment stay the same after a license

transfer or move, thereby making past enforcement history a valid issue. However, if significant changes have been made in the above areas, consideration of enforcement history may be inappropriate.

➜ **NOTE**: This criterion considers past escalated actions with severity levels--it does not include past escalated actions associated with the SDP.

➜ **NOTE**: This criterion considers past NRC escalated enforcement history--it does not include previous escalated enforcement actions in an Agreement State. Considering previous escalated actions in an Agreement State is not appropriate because of variations in enforcement programs in the different Agreement States. However, if an Agreement State licensee violates a requirement while working in NRC jurisdiction under reciprocity and the staff is aware of previous escalated action in an Agreement State and the violation is directly repetitive or the enforcement history is particularly poor, the staff *may* consider an adjustment to the civil penalty assessment process by exercising enforcement discretion under Section VII.A.1.d of the Enforcement Policy.

Using 2 years as the basis for assessment is expected to cover most situations, but considering a slightly longer or shorter period might be warranted based on the circumstances of a particular case. The starting point of this period should be considered the date when the licensee was put on notice of the need to take corrective action. For a licensee-identified violation or an event, this would be when the licensee is aware that a problem or violation exists requiring corrective action. For an NRC-identified violation, the starting point would be when the NRC puts the licensee on notice, which is typically at the inspection exit meeting, or as part of post-inspection communication.

If the corrective action is judged to be prompt and comprehensive, an NOV normally should be issued with no associated civil penalty. If the corrective action is judged to be less than prompt and comprehensive, the NOV normally should be issued with a base civil penalty.

5.4.2.2 Credit for Actions Related to Identification

If a Severity Level I or II violation or a willful Severity Level III violation has occurred--or if, during the past 2 years or 2 inspections, whichever is longer, the licensee has been issued at least one other escalated action--the civil penalty assessment should normally consider the factor of identification in addition to corrective action (see discussion under Section 5.4.2.4, below). The civil penalty assessment should also normally consider the factor of identification in addition to corrective action in those cases where a licensee has not been in existence during the past 2 years or for 2 inspections. As to identification, the NRC should consider whether the licensee should be given credit for actions related to identification.

In each case, the decision should be focused on identification of the problem requiring corrective action. In other words, although giving credit for *Identification* and *Corrective Action* should be separate decisions, the concept of *Identification* presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed. The decision on *Identification* requires considering all the circumstances of identification including:

- Whether the problem requiring corrective action was NRC-identified, licensee-identified, or revealed through an event;[1]

- Whether prior opportunities existed to identify the problem requiring corrective action, and if so, the age and number of those opportunities;

- Whether the problem was revealed as the result of a licensee self-monitoring effort, such as conducting an audit, a test, a surveillance, a design review, or troubleshooting;

- For a problem revealed through an event, the ease of discovery, and the degree of licensee initiative in identifying the root cause of the problem and any associated violations;

- For NRC-identified issues, whether the licensee would likely have identified the issue in the same time-period if the NRC had not been involved;

- For NRC-identified issues, whether the licensee should have identified the issue (and taken action) earlier; and

- For cases in which the NRC identifies the overall problem requiring corrective action (e.g., a programmatic issue), the degree of licensee initiative or lack of initiative in identifying the problem or problems requiring corrective action.

- Although some cases may consider all of the above factors, the importance of each factor will vary based on the type of case as discussed in the following general guidance:

a. **Licensee-Identified**: When a problem requiring corrective action is licensee-identified (i.e., identified before the problem has resulted in an event), the NRC should normally give the licensee credit for actions related to identification, regardless of whether prior opportunities existed to identify the problem.

b. **Identified Through an Event**: When a problem requiring corrective action is identified through an event, the decision on whether to give the licensee credit for actions related to identification normally should consider the ease of discovery, whether the event occurred as the result of a licensee self-monitoring effort (i.e., whether the licensee was "looking for the problem"), the degree of licensee initiative in identifying the problem or problems requiring corrective action, and whether prior opportunities existed to identify the problem.

   Any of these considerations may be overriding if particularly noteworthy or particularly egregious. For example, if the event occurred as the result of conducting a surveillance or similar self-monitoring effort (i.e., the licensee was looking for the problem), the licensee should normally be given credit for identification. As a second instance, even if the problem

[1] An "event," as used here, means (1) an event characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, or (2) a radiological impact on personnel or the environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above NRC limits, or a loss of radioactive material. For example, an equipment failure discovered through a spill of liquid, a loud noise, the failure to have a system respond properly, or an annunciator alarm would be considered an event; a system discovered to be inoperable through a document review would not. Similarly, if a licensee discovered, through quarterly dosimetry readings, that employees had been inadequately monitored for radiation, the issue would normally be considered licensee-identified; however, if the same dosimetry readings disclosed an overexposure, the issue would be considered an event.

was easily discovered (e.g., revealed by a large spill of liquid), the NRC may choose to give credit because noteworthy licensee effort was exerted in ferreting out the root cause and associated violations, or simply because no prior opportunities (e.g., procedural cautions, post-maintenance testing, quality control failures, readily observable parameter trends, or repeated or locked-in annunciator warnings) existed to identify the problem.

c. **NRC-Identified**: When a problem requiring corrective action is NRC-identified, the decision on whether to give the licensee credit for actions related to *Identification* should normally be based on an additional question: should the licensee have reasonably identified the problem (and taken action) earlier?

   In most cases, this reasoning may be based simply on the ease of the NRC inspector's discovery (e.g., conducting a walkdown, observing in the control room, performing a confirmatory NRC radiation survey, hearing a cavitating pump, or finding a valve obviously out of position). In some cases, the licensee's missed opportunities to identify the problem might include a similar previous violation, NRC or industry notices, internal audits, or readily observable trends.

   If the NRC identifies the violation but concludes that, under the circumstances, the licensee's actions related to *Identification* were not unreasonable, the matter would be treated as licensee-identified for purposes of assessing the civil penalty. In such cases, the question of *Identification* credit shifts to whether the licensee should be penalized for NRC's identification of the problem.

d. **Mixed Identification**: For "mixed" identification situations (i.e., where multiple violations exist, some NRC-identified, some licensee-identified, or where the NRC prompted the licensee to take action that resulted in the identification of the violation), the NRC's evaluation should normally determine whether the licensee could reasonably have been expected to identify the violation in the NRC's absence. This determination should consider, among other things, the timing of the NRC's discovery, the information available to the licensee that caused the NRC concern, the specificity of the NRC's concern, the scope of the licensee's efforts, the level of licensee resources given to the investigation, and whether the NRC's path of analysis had been dismissed or was being pursued in parallel by the licensee.

   In some cases, the licensee may have addressed the isolated symptoms of each violation (and may have identified the violations), but failed to recognize the common root cause and taken the necessary comprehensive action. Where this is true, the decision on whether to give licensee credit for actions related to *Identification* should focus on identification of *the problem requiring corrective action* (e.g., the programmatic breakdown). As such, depending on the chronology of the various violations, the earliest of the individual violations might be considered missed opportunities for the licensee to have identified the larger problem.

e. **Missed Opportunities to Identify:** Missed opportunities include prior notifications or missed opportunities to identify or prevent violations such as (1) through normal surveillances, audits, or quality assurance (QA) activities; (2) through prior notice i.e., specific NRC or industry notification; or (3) through other reasonable indication of a potential problem or violation, such as observations of employees and contractors, and failure to take effective corrective steps. It may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, consideration will be given to, among other things, the opportunities available to discover the violation, the ease of discovery, the similarity between the violation and the notification, the period of time between when the violation occurred and when the notification was issued, the action taken (or planned) by the licensee in response to the notification, and the level of management review that the notification received (or should have received).

   The evaluation of missed opportunities should normally depend on whether the information available to the licensee should reasonably have caused action that would have prevented the violation. Missed opportunities is normally not applied where the licensee appropriately reviewed the opportunity for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

   In some situations the missed opportunity is a violation in itself. In these cases, unless the missed opportunity is a Severity Level III violation in itself, the missed opportunity violation may be grouped with the other violations into a single Severity Level III "problem." However, if the missed opportunity is the *only* violation, then it should not normally be counted twice (i.e., both as the violation and as a missed opportunity--"double counting") unless the number of opportunities missed was particularly significant.

   The timing of the missed opportunity should also be considered. While a rigid time-frame is unnecessary, a 2-year period should generally be considered for consistency in implementation, as the period reflecting relatively current performance.

When the NRC determines that the licensee should receive credit for actions related to *Identification*, the civil penalty assessment should normally result in either no civil penalty or a base civil penalty, based on whether *Corrective Action* is judged to be reasonably prompt and comprehensive. When the licensee is *not* given credit for actions related to *Identification*, the civil penalty assessment should normally result in a Notice of Violation with either a base civil penalty or a base civil penalty escalated by 100%, depending on the quality of *Corrective Action*, because the licensee's performance is clearly not acceptable.

5.4.2.3 Examples of Applying the *Identification* Factor

Generally, if the licensee identifies a problem before an event occurs or before the NRC identifies it, the licensee should normally get credit for the identification (even if missed opportunities existed, including the failure of past corrective action for similar violations). However, if the violation is identified as the result of an event associated with normal operations, in contrast to an event associated with an assessment activity such as a surveillance test, any missed opportunities should be considered. If the NRC identifies the violation, it is appropriate to consider whether the licensee should have identified the violation. The actual application of the factor will be a function of the circumstances of the case, the issues associated with

identification, and the regulatory message warranted by the facts of the case. Identification also presumes recognizing that some corrective action is required.

The following examples are intended to provide general guidance on how the identification factor is to be applied. Recognizing that application of this factor will require applying judgment to the particular set of facts and circumstances in each case, the following guidance should not be viewed as controlling or exhaustive.

a. **Situations In Which the Licensee Should Be Given Credit**:

1. Violations involving the failure to install required parts on a pump, where the failure results in high vibration readings before the pump fails.

2. Violations identified as a result of surveillances or tests, when a parameter check is required by the procedure and limits or ranges do not meet regulatory requirements.

3. Discovery of a valve or controller in the wrong position while performing a step in a surveillance procedure.

4. Discovery of inoperable equipment during surveillance testing performed to determine the operability of that equipment. If as a result of the surveillance testing, an event occurs because of other equipment (i.e., equipment not being tested) failing, missed opportunities should be considered when evaluating identification for the failure of the "other" equipment.

5. Violations identified during a surveillance test where an evolution or process that is being tested does not proceed as expected. For example: (1) a liquid spill due to a mispositioned valve; (2) safety-related equipment failing to start because of failure to include the position of a controller in a surveillance procedure; or (3) unanticipated equipment starts or work proceeds on an energized circuit because of a previous failure to tagout equipment.

6. Disclosure of a fitness-for-duty violation during routine testing.

7. Identification of a violation as a result of the licensee followup of safety concerns raised by an employee of the licensee.

8. Violations identified in audit findings, deficiency reports, or contractor reviews, in which the condition adverse to quality was not corrected in a timely manner, but was later disclosed by a licensee review before an event occurred.

9. Violations identified by a contractor doing audits provided action was taken to correct the matter. For example, the licensee would *not* get credit for its contractor identifying a violation if the licensee took no action to address the violation and NRC later identified the violation.

10. Violations identified as the result of procedurally required checks of a medical treatment plan before treatment occurs, or as the result of daily checks of radiography equipment before the equipment is used.

11. Cases in which, in response to an event, a licensee investigation identifies violations that were not involved in or did not contribute to the event.

12. Cases in which the licensee initiates a review of data anomalies or unusual circumstances not involving an event and, as a result, identifies violations. For example: (1) deliberate contamination of clothing discovered due to a licensee-initiated health physics review of a plant condition; (2) falsified information on an employee application discovered due to follow-up of discrepancies by the licensee; (3) discovery of a design deficiency due to special or complex evaluations of unusual equipment interactions; or (4) discovery of a fitness-for-duty violation during testing, where observation of an employee resulted in licensee initiation of the testing.

13. Violations identified as the result of a licensee's review of generic communications, reports from other sites, reports generated by outside groups, reports generated by industry groups, reports contracted by the licensee, NRC Information Notices, generic letters, or follow-up from general discussions with an NRC inspector as a result of his or her knowledge gained from other plants or NRC activities.

14. The identification of failures to follow procedures or deficient procedures by a licensee employee, where the failure would not have been disclosed by subsequent procedural checks prior to an event occurring.

15. If the NRC finds a violation prior to the licensee's identification of it, but the licensee was aggressively pursuing the same issue as the result of an NRC Information Notice and likely would have found it within a reasonable time, the licensee should get credit for its identification activities.

b. **Situations In Which Missed Opportunities Should Be Considered Before Giving the Licensee Credit for Identification**:

1. Violations identified as the result of an event that was readily obvious by human observation or mechanical instrumentation such as a reactor trip, or leak, spills, or annunciator alarms.

2. As the result of a reactor trip, the licensee identifies deficient procedures that led to a failure to reset instrument controls.

3. As the result of a dropped fuel assembly, the licensee identifies the failure to confirm that a fuel assembly grappling device had closed.

4. As the result of a lost or damaged gauge, the licensee identifies a failure to maintain constant control over a gauge containing byproduct material.

5. Discovery of an overexposure documented in a dosimetry report.

6. Licensee identifying the improper shipment or packaging of radioactive material found by the receiving company.

7. Licensee identifying the loss of control of material after being informed by a member of the public that material has been found in the environment.

8. Receipt of records from the Federal Bureau of Investigations indicating that a person who has been granted unescorted access had a criminal history of which the licensee was not aware, although the information was available in the licensee's records.

9. As a result of an event or NRC questions, the licensee identifies violations that it should have found earlier if it had been responsive to previous audits findings, deficiency reports or contractor reviews, where conditions adverse to quality were not corrected in a timely manner.

10. Violations that caused or contributed to an event, identified as part of a follow-up to the event.

11. Violations identified as part of determining the root causes for a radiation injury to a patient.

12. Cases in which the inappropriate location of sources results in a misadministration being disclosed when the source is removed.

13. Cases in which an overexposure is identified after reading personal dosimetry or data documented in dosimetry reports following an event where, due to the event, the potential for an overexposure exists.

14. Cases in which an event occurs as a result of an evolution or process during operations that do not proceed as expected and violations are subsequently identified. For example, (1) a liquid spill due to a mispositioned valve; (2) indications in the control room that safety-related equipment fails to start because of failure to include the position of a controller in an operations procedure; or (3) unanticipated equipment starts or work proceeds on an energized circuit because of the failure to tagout equipment.

c. **NRC-Identified Situations**:

1. Cases in which a licensee does not appear to have been pursuing a matter on its own but, due to concerns raised by the NRC, identifies (1) violations related to equipment failures when the NRC has questioned operability of the equipment; or (2) violations of reporting requirements found when the NRC requested information on the event.

2. Violations related to an event would be considered NRC-identified if the violation is subsequently discovered by the NRC during event follow-up, where the licensee has failed to initiate reviews or investigations that would have reasonably identified the violation. For example, a misadministration may have occurred that the licensee attributes to a failure to follow procedure, and does not pursue the matter further. If the NRC finds that an underlying root cause violation exists (e.g., a training violation), but the licensee has not pursued it, that violation would not be considered licensee-identified.

5.4.2.4 Credit for Prompt and Comprehensive Corrective Action

The purpose of the *Corrective Action* factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.

Regardless of other circumstances (e.g., past enforcement history, identification), the licensee's corrective actions should always be evaluated as part of the civil penalty assessment process. As a reflection of the importance given to this factor, an NRC judgment that the licensee's corrective

action has not been prompt and comprehensive will always result in issuing at least a base civil penalty.

In assessing this factor, consideration will be given to the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the adequacy of the licensee's root cause analysis for the violation, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). Even in cases when the NRC, at the time of the predecisional enforcement conference, identifies additional peripheral or minor corrective action still to be taken, the licensee may be given credit in this area, as long as the licensee's actions addressed the underlying root cause and are considered sufficient to prevent recurrence of the violation and similar violations.

Normally, the judgment of the adequacy of corrective actions will hinge on whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action. This will normally be judged at the time of the predecisional enforcement conference (e.g., by outlining substantive additional areas where corrective action is needed). Earlier informal discussions between the licensee and NRC inspectors or management may result in improved corrective action, but should not normally be a basis to deny credit for *Corrective Action*. For cases in which the licensee does not get credit for actions related to *Identification* because the NRC identified the problem, the assessment of the licensee's corrective action should begin from the time when the NRC put the licensee on notice of the problem. Notwithstanding eventual good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, corrective action would not be considered prompt and comprehensive.

Corrective action for violations involving discrimination should normally only be considered comprehensive if the licensee takes prompt, comprehensive corrective action that (1) addresses the broader environment for raising safety concerns in the workplace, and (2) provides a personal remedy for the particular discrimination at issue. See Section 7.7.10 for additional guidance on this issue.

In response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee

a. Makes a prompt decision on operability; and either

b. 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

c. 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.

5.4.2.5 Exercise of Civil Penalty Discretion

The civil penalty assessment process described above is intended to be a normative standard for most Severity Level III issues. Departures from this process by the exercise of discretion (for either escalation or mitigation of the enforcement action) normally requires the approval of the Director, OE, the DEDO and/or consultation with the EDO or the Commission (as specified in the Enforcement Policy), and should be in keeping with the guidance included in Section 5.4.2.1

(new licensees), Section 5.4.4.2 (SBREFA), and Chapter 6. However, in no instance will a civil penalty for any one violation exceed $120,000 per day.

5.4.3 Assigning Final Civil Penalty Amounts

The statutory maximum civil penalty amount, as established in the 1980 revision to the AEA, is $100,000 per violation, per day; but that amount has been adjusted by the Debt Collection Improvement Act of 1996 to be $120,000. To calculate the statutory maximum for a given Severity Level I, II, or III problem, each associated violation should be assigned the $120,000 value, multiplied by the number of days the violation existed, and then added to the civil penalty amounts for the other violations. In other words, the statutory maximum for a given Severity Level I, II, or III problem is the cumulative result of the number of associated violations and the number of days that each violation existed.

The civil penalty assessment process described above, including the exercise of discretion, should be used to arrive at a civil penalty amount that appropriately conveys the desired regulatory message. This amount should then be compared with the amount allowed by statute, to ensure that the civil penalty amount actually issued is within the statutory maximum.[2] If the desired civil penalty amount is within the statutory maximum, then the civil penalty should be issued at the desired amount. If the desired civil penalty amount exceeds the statutory maximum, then the amount actually issued should be at the statutory maximum. For cases in which the civil penalty issued is less than the desired amount, based on the statutory maximum, the NRC's correspondence to the licensee should clarify the basis for the final civil penalty amount by indicating that the civil penalty amount would have been higher but was limited by statute to the amount proposed.

5.4.4 Civil Penalty Assessment Process Outcome

Depending on the outcome of the civil penalty assessment process, the staff will conclude that an escalated NOV should be issued without a civil penalty or that an escalated NOV should be issued with a civil penalty. Section 5.5 includes guidance for preparation of an escalated NOV without a civil penalty and Section 5.6 includes guidance for preparation of a Notice of Violation and Proposed Imposition of Civil Penalty (civil penalty).

5.5 Escalated Notice of Violation (NOV) (Without Civil Penalty)

Notices of Violation are addressed in Section VI.B of the Enforcement Policy, and 10 CFR 2.201 sets forth the procedures for issuing NOVs. An NOV is a formal written citation setting forth one or more violations of a legally binding requirement. An NOV including Severity Level I, II, or III violations is considered escalated enforcement action.

➜ **NOTE**: **An NOV including violations associated with white, yellow, or red SDP findings is also considered an escalated enforcement action.**

Civil penalties are normally proposed for violations at Severity Level I, II, and are considered for violations at Severity Level III. However, the staff may fully mitigate a civil penalty through the civil

[2] Note that, for a Severity Level III problem for a power reactor licensee, with a base civil penalty of $60,000, the maximum civil penalty normally proposed (base +100%, or $120,000) would always be within the statutory maximum, even if a single Severity Level III violation had occurred lasting only 1 day.

penalty assessment process or by exercising discretion as discussed in Section VII.D of the Enforcement Policy. Absent actual consequences, civil penalties are not proposed for violations associated with white, yellow, or red findings SDP findings.

Escalated NOVs are normally issued subsequent to conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report.

Escalated NOVs are included in the Significant Enforcement Actions collection on the **Enforcement** Web site.

Agency Enforcement Action Output Measures:

a. **Cases that do not include an OI investigation**:

1. 100% completed within 180 calendar days.
2. 100% will average 120 calendar days.

b. **Cases that include an OI investigation**:

1. 100% completed within 360 days of NRC processing time.
2. 100% will average 180 days of NRC processing time.

Applicability: Cases with a start date prior to October 1, 2001, but closed after that date will, on a case-by-case basis, be exempted from the new measure.

Start Date: The measuring period starts on the latest of the following dates: (1) inspection exit date, (2) the date the results of an agency investigation are forwarded to the staff, (3) the date that the Department of Justice (DOJ) says NRC may proceed, for cases referred to the DOJ, or (4) the date of the Department of Labor decision that is the basis for the action. The inspection exit date will be defined by the region or office performing the inspection and may be the date of a telephone re-exit. For investigation cases, the start date will typically not be the a re-exit date. However, on rare occasions, when significant additional inspection effort is needed after issuance of the investigation results are forwarded to the staff, the re-exit date will be used as the start date.

Processing Time: NRC processing time is defined as that time from the date the case is opened to the issuance of an enforcement action or other appropriate disposition less: (1) anytime the NRC could not act due to the case residing with DOL, DOJ, other government entity or where the licensee requests a lengthy deferment, and (2) anytime the NRC could not act due to processing FOIA requests.

Enforcement Action Timeliness Goals:

Timeliness goals for processing escalated NOVs are based on the agency's enforcement action output measures.

a. **Cases that do not include an OI investigation**:

1. Cases issued after OE consultation (usually via a panel or caucus) should be issued within 120 calendar days from the start date.

2. Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 90 calendar days from the start date.

b. **Cases that include an OI investigation**:

1. Cases issued after OE consultation (usually via a panel or caucus) should be issued within 180 days of NRC processing time.

2. Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 150 days of NRC processing time.

5.5.1 Preparing an Escalated NOV (Without Civil Penalty) Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare an escalated NOV package, including the following elements as discussed below:

a. Escalated NOVs without civil penalties should be prepared by using the applicable standard format (Form 4) in Appendix B and the applicable standard citations in Appendix C. Escalated NOVs should be dated the same date as the cover letter transmitting the enforcement action to the licensee. The escalated NOV should include the following elements:

1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).

2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement. Each violation, including a violation with multiple examples, contains a single "contrary to" statement.

3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation. See Section 3.12.7 for additional guidance on multiple examples of a violation.

   The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

4. The severity level proposed for the violation and the applicable supplement of the Enforcement Policy under which the violation is categorized or, alternatively

5. The associated significance of the violation (i.e., white, yellow, or red SDP finding).

6. The EA number should be included for each violation or problem when there is more than one escalated issue in the action.

7. The licensee response (if the region concludes that a response is necessary), including: the reason for the violation, or if contested, the basis for disputing the violation; the corrective steps that have been taken and the results achieved; the corrective steps that will be taken to avoid further violations; and the date when full compliance will be achieved, or

8. A waiver of the licensee response (if the region concludes that a response is not necessary) based on information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already addressed on the docket. This alternative requires the licensee to respond if the description does not accurately describe the licensee's corrective action position.

b. Cover letters that transmit escalated NOVs without civil penalties to licensees should be prepared by the region using Form 3-I (NOV without SDP) or Form 3-II (NOV with SDP) in Appendix B. The staff should refer to Inspection Manual Chapters 0612 and 0609 for guidance related to the overall structure of the cover letter and content of introductory paragraphs for NOVs associated with SDP findings. Transmittal letters with and without SDP findings should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:

1. A summary of (1) the purpose of the inspection, (2) if and how the issue was reported, e.g., 50.72, LER etc., and (3) when the inspection report(s) related to this action were issued.

2. A discussion of whether a conference was conducted, a “choice letter” was issued, or a “choice call” was made, as applicable

3. A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation. For NOVs without SDP findings, the discussion should be sufficiently detailed to permit licensee management (and others who may review the action) to understand the safety significance of the violations. For NOVs with SDP findings, a statement that the NOV is considered escalated action in accordance with the Enforcement Policy because it is associated with a white, yellow, or red SDP finding.

4. For NOVs without SDP findings, a concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC’s ability to perform its regulatory function, or it was willful and how it relates to severity level categorization.

5. For NOVs without SDP findings, a statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable routine decisional points in the civil penalty assessment process, i.e., (1) whether the licensee has had any escalated actions during the past 2 years or 2 inspections (include specific reference to any prior escalated action within 2 years or 2 previous inspections), (2) whether credit was given for identification (address only if the answer to (1) is no, and (3) whether credit was given for corrective action (include a brief description of corrective actions). It should also include an

additional explanation if discretion was exercised, including a reference to the particular section of the Enforcement Policy.

6. For NOVs without SDP findings, a statement associated with not proposing a civil penalty, i.e., to encourage prompt (identification, if applicable) and comprehensive correction of violations, (and to recognize the absence of previous escalated enforcement action, if applicable). This section should also indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission.

7. A description of the response that is necessary from the licensee (if the region concludes that a response is necessary), including any area that deserves special emphasis, or

   A conclusion that a licensee response is not necessary (if the region concludes that a response is not necessary), including a provision that the licensee respond if its understanding of the corrective action is different.

8. A statement that the NRC will determine, based on the licensee's NOV response, corrective actions, and results of future inspections, whether further enforcement action is necessary.

9. A statement that the letter and the licensee's response will be made available to the Public.

c. Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

5.5.2 Escalated NOV (Without Civil Penalty) Coordination and Review

All escalated NOVs must be coordinated with OE and headquarters prior to issuance. For the purposes of this Manual, “coordination” means either that:

- the action needs to be submitted to headquarters for actual enforcement action package review, or
- the enforcement strategy for the action needs to be agreed upon (usually via a panel or caucus).

If a proposed enforcement action is required to be submitted to headquarters for formal review and approval prior to issuance, it should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the NRR, NMSS, or NSIR Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. These documents and supporting background materials should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

a. All escalated NOVs with Severity Level I and II violations and all NOVs associated with white, yellow, or red SDP findings must be submitted to headquarters for actual enforcement action package review and approval prior to issuance.

b. Escalated NOVs with Severity Level III violations should be submitted to headquarters for actual enforcement action package review and approval prior to issuance if they involve an exercise of discretion, require DEDO approval or Commission consultation, or if OE specifically requests (usually after a panel or caucus).

   1. Unless OE requests, OGC will not normally provide comments for an escalated action issued without a civil penalty or order. OGC review and concurrence (or statement of no legal objection) is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).

   2. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE and "OEMAIL" within 5 working days**. (Comments are normally provided through the program office Enforcement Coordinators.)

   3. OE will consider timely program office comments and OGC comments, if proposed, and revise the enforcement action, as appropriate. The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

   4. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
   5. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.

   6. OE will either approve the action (for Severity Level II materials actions), or if appropriate, forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

c. Escalated NOVs with Severity Level III violations 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 a panel or caucus, or after additional discussions following a licensee's response to an inspection report where no conference has been conducted, OE will amend (as warranted) the Strategy Form to reflect the enforcement strategy that was agreed upon during the discussions and send it to the region and program office. The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary). 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. 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.

2. Regional Counsel review and statement of no legal objection is required prior to issuance by the region. If Regional Counsel is not available to review the case and there will be a significant delay due to the Regional Counsel's unavailability, then the region should submit the action to headquarters for OE review.

3. The region should send OE the complete escalated enforcement package after it has issued the action.

5.5.3 Escalated NOV (Associated with White, Yellow, or Red SDP Findings) Enforcement Notification

Enforcement Notification for NOVs associated with white, yellow, or red SDP findings should be provided according to the following guidelines:

a. The staff notifies the Commission of its intent to issue an escalated NOV associated with a white, yellow, or red SDP finding by issuing an Enforcement Notification (EN). ENs include a brief description of the SDP finding and assigned color and a brief discussion of the violation that was cited.

b. OE prepares and issues ENs using the standard format in Appendix B (Form 26-III). OE assigns the EN a sequential number.

c. Three working days after the EN is sent to the Commission, the action may be signed and issued.

d. ENs should not be put in ADAMS (PARS) or otherwise publicly disclosed until after (1) the Commission has exercised its review of the enforcement action and (2) the enforcement action has been received by the licensee.

e. Delays in issuing enforcement actions after issuance of ENs requires the notification and approval of OE.

f. If an enforcement action will not be issued by the date specified in the EN, OE will notify the Office of Congressional Affairs and the region will notify OPA of the issuing delay to prevent a premature release of information.

g. If the information in the EN has already been disclosed, OE will coordinate with the region and OPA to determine the appropriate date to issue the enforcement action. OE will notify the EDO in these cases.

5.5.4 Escalated NOV (Without Civil Penalty) Signature Authority

Escalated NOVs without civil penalties should be signed and issued according to the following guidelines:

a. The Regional Administrator normally signs and issues NOVs with Severity Level I, II, and III violations and NOVs associated with white, yellow, or red SDP findings, after appropriate coordination with OE (and the DEDO, if applicable).

b. The Regional Administrator may redelegate the authority to sign and issue NOVs with Severity Level III violations and NOVs associated with white or yellow SDP findings to the Deputy Regional Administrator, after appropriate coordination with OE (and the DEDO, if applicable).

c. The Director, NRR, normally signs and issues escalated NOVs involving vendors and non-power reactors, after appropriate coordination with OE (and the DEDO, if applicable).

d. The Director, NRR, may redelegate to Associate Directors and above, the authority to sign and issue NOVs for Severity Level I and II violations involving vendors, after appropriate coordination with OE (and the DEDO, if applicable) and may redelegate to Division Directors and above, the authority to sign and issue NOVs with Severity Level III violations involving vendors after appropriate coordination with OE (and the DEDO, if applicable).

e. The Director, NRR, may redelegate to the Deputy Director, the authority to sign and issue NOVs for Severity Level I and II violations involving non-power reactors, after appropriate coordination with OE (and the DEDO, if applicable) and may redelegate to the Division Director and above, the authority to sign and issue NOVs with Severity Level III violations involving non-power reactors after appropriate coordination with OE (and the DEDO, if applicable).

f. The Director, NMSS, normally signs and issues NOVs with Severity Level I, II, or III violations involving areas that they inspect, after appropriate coordination with OE (and the DEDO, if applicable).

g. The Director, NMSS, may redelegate to the Deputy Director, the authority to sign and issue NOVs with Severity Level III violations, after appropriate coordination with OE (and the DEDO, if applicable).

5.5.5 Licensee Notification, Mailing, & Distribution of Escalated NOVs (Without Civil Penalties)

Escalated NOVs are normally mailed to licensees and States by regular mail. NRC distribution should be made according to the distribution lists in Appendix D and regional procedures. Copies of escalated NOVs issued by the program offices should be sent to OE as well as to the appropriate regional office.

➜ NOTE: Escalated NOVs should NOT be made publically available in ADAMS until confirmation that the licensee has received a copy of the enforcement action (i.e., e-mail, facsimile, courier).

➜ NOTE: Escalated NOVs should be e-mailed to "OEWEB" when they are put in ADAMS to ensure that they are posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of the enforcement action."

For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees. The Board of Trustees frequently has oversight responsibility for the legal title, management of funds, and direction of policy for the medical licensee. This distribution effort will (1) ensure that escalated enforcement actions and their potential implications are raised to the highest level of authority, (2) deter future violations, and (3) promote the health and safety of the public, including employees' health and safety.

In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the **Enforcement** Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. **In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available.**

5.5.6 Press Releases for Escalated NOVs (Without Civil Penalties)

Press releases are normally issued for escalated NOVs associated with white, yellow, or red SDP findings.

Regional enforcement personnel will inform the regional Public Affairs Officer (RPAO) at least 72 hours prior to issuance of an action. The RPAO will provide a draft press release to the regional staff for concurrence. OE may also review press releases in the more significant cases. After the enforcement action has been signed, the RPAO will receive verification that the licensee has been notified of the action and has received a copy of the enforcement action. The press release is generally issued (via ADAMS and the Web) 24 hours **after the licensee receives a copy of the enforcement action**. If the licensee issues its own press release during the intervening period, the RPAO may immediately issue a press release. Press releases on the Web typically provide a specific link to the enforcement action on the **Enforcement** Web site. If the enforcement action has not posted when the press release is issued, the press release should state that the action will be posted on the **Enforcement** Web page http://www.nrc.gov/what-we-do/regulatory/enforcement.html.

Although press releases are not normally issued for escalated NOVs proposed without a civil penalty under the traditional enforcement process, there are two situations in which a press release should be issued.

Press releases should be issued for escalated NOVs proposed without a penalty, where, but for the 5-year statute of limitations, a civil penalty would have been proposed.

Press releases should also be issued for escalated NOVs proposed without a penalty, where, but for the limitation of proposing a civil penalty against a vendor (i.e., could not establish that the violation was a knowing and conscious failure to notify the NRC in accordance with 10 CFR Part 21), a civil penalty would have been proposed.

In these situations, press releases should put the safety significance into context by discussing the severity level categorization and by addressing whether the violation reflects an actual or a potential consequence, or whether it impacted the NRC's ability to perform its regulatory function, or whether it was willful. In addition, if the licensee reported the violation or identified it, the press release should so state. The regional Enforcement Coordinator should review such press releases.

OPA may also choose to issue press releases for other enforcement actions that they view as newsworthy. These press releases should be coordinated with OE.

The press release is generally issued (via ADAMS and the Web) 24 hours **after the licensee receives a copy of the enforcement action**. Press releases on the Web typically provide a link to the enforcement action on the **Enforcement** Web site.

5.5.7 Licensee Response to Escalated NOV (Without Civil Penalty)

If the region concludes that a licensee response is necessary, the provisions of 10 CFR 2.201 require that a licensee submit a written response to an NOV within 20 days of the date of the NOV or other specified time frame; however, normally 30 days should be used. If a licensee does not respond to an escalated NOV within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE, at least within 45 days, and consideration will be given to whether additional enforcement action is warranted.

Licensees may be granted response extensions where good cause is shown. The region may grant extensions of up to 2 weeks without OE approval. OE should be promptly notified of any extensions the region grants. OE approval is required for extensions beyond 2 weeks. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due. The confirmation may either be prepared by the NRC or the licensee. A copy of this followup correspondence is to be sent to OE and the region.

As discussed further below, licensees' responses to escalated NOVs may either (a) accept the violation or (b) contest the staff's facts and conclusions regarding the escalated NOV.

a. **If the licensee does not dispute that the violation occurred as stated in the NOV**, the regional office is to review the licensee's response for the adequacy of the corrective action and should request additional information from the licensee if necessary. In determining the adequacy of corrective action, the region should consider whether the licensee has properly identified the root causes.

   The licensee's response is to be acknowledged by the region usually within 30 days after its receipt. The acknowledgment letter should be sent to the same person and address as the escalated NOV.

b. **If the licensee denies the violation**, the region should normally respond to the licensee within 30 days. The response, which should be sent to the same person and address as the escalated NOV, should address the licensee's points of contention and the acceptability of its corrective action. If the licensee denies the violation based on additional information not previously disclosed, the region should prepare a more detailed response as appropriate. Licensee denials include disputes involving NRC requirements, facts of the case, application of the Enforcement Policy, and severity levels. Any errors identified in the enforcement action must be addressed in the region's response.

   ➜ **NOTE**: If the licensee disputes the SDP characterization of the inspection finding, the region should notify OE. While the dispute may not change the violation, it may affect how the violation should be dispositioned. In other words, if a licensee successfully argues that a white SDP finding should be green, the associated violation would likely be dispositioned as an NCV, instead of being considered escalated action. In this case, the subject line in the response to the licensee should include, "WITHDRAWAL OF ESCALATED ENFORCEMENT ACTION." OE should be notified in these cases and will take responsibility for removing any action from the **Enforcement** Web site.

   Within 21 days of the date of the licensee's denial, the region should prepare a response to the licensee and submit it (via facsimile) to the Deputy Director, OE, for concurrence.

   For all disputed violations in which it is decided that a second, revised NOV should be issued, or that the NOV should be withdrawn, the region should ensure that the response to the licensee clearly reflects, in both the subject line of the cover letter and the revised NOV, that a violation

is being revised or withdrawn (i.e., REVISED NOTICE OF VIOLATION, or WITHDRAWAL OF NOTICE OF VIOLATION).

5.6 Notice of Violation and Proposed Imposition of Civil Penalty (Civil Penalty)

Civil penalties are addressed in Section VI.C of the Enforcement Policy, and 10 CFR 2.205 sets forth the procedures for issuing civil penalties. Section 234 of the Atomic Energy Act (AEA) of 1954, as amended, authorizes the NRC to impose civil penalties not to exceed $100,000 per violation per day; but that amount has been adjusted by the Debt Collection Improvement Act of 1996 to be $120,000.

Civil penalties are normally proposed for Severity Level I and II violations, are normally considered for Severity Level III violations, and may be proposed for knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act.

Civil penalties are also considered for violations associated with white, yellow, or red SDP findings that involve actual consequences.

Civil penalty actions are normally issued subsequent to conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report.

a. Civil penalties are designed to create a deterrent that will prevent future violations, both for the individual licensee and for other, similar licensees. The purpose of the action is not retributive, but remedial; that is, it should encourage licensees to take effective and lasting corrective actions to avoid future problems by being in compliance. In issuing civil penalties, the following guidelines should be considered:

    1. Separate civil penalties should normally be assessed for separate violations with different root causes.

    2. A single civil penalty should normally be assessed for violations that can be grouped into one problem when they are closely related, such as cause and affect type violations. For example, it would be appropriate to view the failure to perform adequate testing that results in a piece of inoperable equipment as one problem, warranting consideration of one civil penalty. Cited violations should include both requirement paragraphs with one “contrary to” paragraph that addresses the cause and notes the resulting consequence.

    3. Notwithstanding a common root cause, separate civil penalties may be assessed for several violations that occurred over time, provided that each violation is addressed in its own citation (i.e., “contrary to” paragraph).

    4. Civil penalties may be issued to individual directors or responsible officers of a non-licensee vendor organization who knowingly and consciously fail to notify the NRC in accordance with 10 CFR Part 21. Section 206 of the Energy Reorganization Act (ERA) authorizes the NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

5. Section 234 of the AEA gives the NRC the authority to impose civil penalties on "any person," including licensee employees. However (see the Enforcement Policy, Section VIII, Footnote 10), except as noted in paragraph 3 above, the NRC will not normally impose a civil penalty against an individual.

6. Civil penalties should deter future violations not only for the involved licensee but also for other licensees conducting similar activities. Thus, it may be appropriate to issue a civil penalty (for a particularly significant violation) to a licensee who is terminating licensed activities, to deter future violations by other licensees.

Agency Enforcement Action Output Measures:

a. **Cases that do not include an OI investigation**:

1. 100% completed within 180 calendar days.
2. 100% will average 120 calendar days.

b. **Cases that include an OI investigation**:

1. 100% completed within 360 days of NRC processing time.
2. 100% will average 180 days of NRC processing time.

Applicability: Cases with a start date prior to October 1, 2001, but closed after that date will, on a case-by-case basis, be exempted from the new measure.

Start Date: The measuring period starts on the latest of the following dates: (1) inspection exit date, (2) the date the results of an agency investigation are forwarded to the staff, (3) the date that the Department of Justice (DOJ) says NRC may proceed, for cases referred to the DOJ, or (4) the date of the Department of Labor decision that is the basis for the action. The inspection exit date will be defined by the region or office performing the inspection and may be the date of a telephone re-exit. For investigation cases, the start date will typically not be the a re-exit date. However, on rare occasions, when significant additional inspection effort is needed after issuance of the investigation results are forwarded to the staff, the re-exit date will be used as the start date.

Processing Time: NRC processing time is defined as that time from the date the case is opened to the issuance of an enforcement action or other appropriate disposition less: (1) anytime the NRC could not act due to the case residing with DOL, DOJ, other government entity or where the licensee requests a lengthy deferment, and (2) anytime the NRC could not act due to processing FOIA requests.

Enforcement Action Timeliness Goals:

Timeliness goals for processing escalated NOVs are based on the agency's enforcement action output measures.

a. **Cases that do not include an OI investigation**:

1. Cases issued after OE consultation (usually via a panel or caucus) should be issued within 120 calendar days from the start date.

2. Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 90 calendar days from the start date.

b. **Cases that include an OI investigation**:

1. Cases issued after OE consultation (usually via a panel or caucus) should be issued within 180 days of NRC processing time.

2. Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 150 days of NRC processing time.

5.6.1 Preparing a Civil Penalty Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare the civil penalty package, including the following elements as discussed below:

a. NOVs with civil penalties should be prepared by using the applicable standard format (Form 6 or 7) in Appendix B and the applicable standard citations in Appendix C. The NOV should be dated the same date as the cover letter transmitting the enforcement action. The NOV should include the following elements:

1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).

2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph). To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement. Each violation, including a violation with multiple examples, contains a single "contrary to" statement.

3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation. See Section 3.12.7 for additional guidance on multiple examples.
The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc. When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.

4. The severity level proposed for the violation or the severity level of the problem when several violations have been grouped.

5. The applicable supplement of the Enforcement Policy under which the violation is categorized.

6. The amount of the civil penalty proposed.

7. The EA number should be included for each violation or problem when there is more than one escalated issue in the action.

8. The required licensee response, including; admission or denial of the alleged violation; the reason for the violation if admitted, and if denied, the reasons why; the corrective steps that have been taken and the results achieved; the corrective steps that will be taken to avoid further violations; and the date when full compliance will be achieved.

9. Instructions to the licensee for payment of the civil penalty or for protesting the civil penalty.

b. Cover letters that transmit escalated NOVs with civil penalties to licensees should be prepared by the region using Form 5 in Appendix B. The letter should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:

1. A summary of (1) the purpose of the inspection, (2) if and how the issue was reported, e.g., 50.72, LER etc., and (3) when the inspection report(s) related to this action were issued.

2. A discussion of whether a conference was conducted, a “choice letter” was issued, or a “choice call” was made, as applicable.

3. A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation. The summary should not be as detailed as the discussion in the inspection report. However, it should be sufficiently detailed to permit licensee management and others who may review the action to understand the safety significance of the violations.

3. A concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC’s ability to perform its regulatory function, or it was willful and how it relates to severity level categorization.

4. A statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable decisional points in the civil penalty assessment process, i.e., (1) whether the licensee has had any escalated actions for the site during the past 2 years or 2 inspections (include specific reference to any prior escalated action), (2) whether credit was given for identification (address only if the answer to (1) is no), and (3) whether credit was given for corrective action (include a brief description of corrective actions). It should also include an additional explanation if discretion was exercised, including a reference to the particular section of the Enforcement Policy.

5. A conclusion of why a civil penalty is being proposed. First, it should state the regulatory emphasis of the case, e.g., the importance of "system operability," "procedural compliance," "attention to detail," "accurate and complete information," "control of licensed material,"

compliance with technical specifications," "compliance with dose limits," etc. Second, it should address the licensee's shortcomings based on the civil penalty assessment process that resulted in the civil penalty. In other words, it should emphasize the importance of prompt identification and comprehensive correction of violations if the licensee did not get credit for these factors. Similarly, it should recognize previous escalated enforcement actions, if applicable. This section should also indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission. It may also be appropriate to indicate additional concerns the NRC may have. However, care should be exercised to keep the correspondence focused on the overall regulatory concern.

6. A discussion of any violations included in the enforcement action that were not assessed a civil penalty.

7. A description of the response that is necessary from the licensee. The response paragraph should be expanded if a particular response is desired.

8. A statement that the NRC will determine, based on the licensee's NOV/civil penalty response, corrective actions, and results of future inspections, whether further enforcement action is necessary.

9. A statement that the letter and the licensee's response will be made available to the Public.

c. Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

5.6.2 Civil Penalty Coordination and Review

All civil penalty actions must be coordinated with OE and headquarters prior to issuance. For the purposes of this Manual, “coordination” means either that:

- the action needs to be submitted to headquarters for actual enforcement action package review, or
- the enforcement strategy for the action needs to be agreed upon (usually via a panel or caucus).

If a proposed enforcement action is required to be submitted to headquarters for formal review and approval prior to issuance, it should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the NRR, NMSS, or Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. These documents and supporting background materials should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

a. All civil penalty actions including Severity Level I and II violations are sent to headquarters for formal review and approval prior to issuance.

b. Civil penalty actions with Severity Level III violations should be submitted to headquarters for actual enforcement action package review and approval prior to issuance if they involve an exercise of discretion, require DEDO approval or Commission consultation, or if OE specifically requests (usually after a panel or caucus).

   1. **OGC will review the proposed enforcement package and provide comments to OE within 5 working days of receipt of the package.** OGC advises that acceptance of these comments does not necessarily constitute legal concurrence (or statement of no legal objection). OGC review and concurrence (or statement of no legal objection) is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).

   2. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days**. (Comments are normally provided through the program office Enforcement Coordinators.)

   3. OE will consider timely OGC and program office comments and revise the enforcement action, as appropriate. The OE Enforcement Specialist will notify the NRR, NMSS, or NSIR Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

   4. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

   5. **The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.**

   6. As appropriate, OE will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

c. Civil penalty actions with Severity Level III violations 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 a panel or caucus, or after additional discussions following a licensee's response to an inspection report where no conference has been conducted, OE will amend (as warranted) the Strategy Form to reflect the enforcement strategy that was agreed upon during the discussions and send it to the region and program office. The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary). 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. 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.

2. Regional Counsel review and statement of no legal objection is required prior to issuance by the region. If Regional Counsel is not available to review the case and there will be a significant delay due to the Regional Counsel's unavailability, then the region should submit the action to headquarters for OE review.

3. The region should send OE the complete escalated enforcement package after it has issued the action.

5.6.3 Civil Penalty Enforcement Notification

Enforcement notification for civil penalties should be provided according to the following guidelines:

a. The staff notifies the Commission of its intent to issue a civil penalty action by issuing an Enforcement Notification (EN). ENs include a brief description of the violation or problem and include the assigned severity level. ENs also include a brief discussion of the outcome of civil penalty assessment process (e.g., "Notwithstanding the licensee's prompt and comprehensive correction of the violation, a base civil penalty of $55,000 was issued because the licensee had an escalated enforcement action within the last 2 years and because the NRC identified the violation).

b. OE prepares and issues ENs using the standard format in Appendix B (Form 26) for civil penalty actions that are submitted to headquarters for review and approval prior to issuance. OE assigns the EN a sequential number.

c. The region prepares and issues ENs using the standard format in Appendix B (Form 26) for civil penalty actions that are not submitted to headquarters for formal review and approval prior to issuance. The region is to contact OE for an EN number. The region should notify OE of civil penalty actions to be issued to licensees located in the greater Washington, DC area so that OE can personally notify the EDO, due to the potential for local media attention.

d. Three working days after the EN is sent to the Commission, the action may be signed and issued.

e. ENs should not be put in ADAMS (PARS) or otherwise publicly disclosed until after (1) the Commission has exercised its review of the enforcement action and (2) the enforcement action has been received by the licensee.

f. Delays in issuing enforcement actions after issuance of ENs requires the notification and approval of OE.

g. If an enforcement action will not be issued by the date specified in the EN, OE will notify the Office of Congressional Affairs and the region will notify OPA of the issuing delay to prevent a premature release of information.

h. If the information in the EN has already been disclosed, OE will coordinate with the region and OPA to determine the appropriate date to issue the enforcement action. OE will notify the EDO in these cases.

i. For cases involving staff disagreement with the conclusions of an OI report, the Commission should be provided a Special Enforcement Notification (SEN) 5 days in advance, and the EN should describe the disagreement between the staff's and OI's investigative conclusions.

5.6.4 Civil Penalty Signature Authority

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

a. The DEDO may choose to sign any civil penalty action. For cases that involve multiple actions (e.g., a single overall occurrence that results in an order, and a civil penalty), each of the actions should be signed by the same individual.

b. The Regional Administrator normally signs and issues all civil penalty actions, after appropriate coordination with OE (and the DEDO and the Commission, if applicable).

c. The Director, NRR may redelegate to Associate Directors and above, the authority to issue civil penalty actions for violations involving vendors, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable).

d. The Director, NRR may redelegate to the Deputy Director, the authority to issue civil penalty actions for violations involving non-power reactors, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable).

e. The Director, NMSS, normally signs and issues civil penalty actions involving areas that NMSS inspects, after review and approval by the Director, OE (and the DEDO and the Commission, if applicable))

5.6.5 Licensee Notification, Mailing, & Distribution of Civil Penalties

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

a. In most cases, the region will notify the licensee by telephone of an enforcement action involving a civil monetary penalty. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification. In all cases, the licensee will be notified of the proposed civil penalty before the information is made public.

b. Licensees are to be provided a written copy of escalated enforcement actions as expeditiously as possible. Electronic transmission of escalated enforcement actions should be used to provide a written copy to licensees having facsimile equipment. Alternatively, licensees in close geographic proximity to regional offices may choose to have a written copy picked up by courier from the regional office. In addition, escalated enforcement packages are to be mailed by either Certified Mail (Return Receipt Requested) or Express Mail. If facsimile equipment is not available, escalated enforcement packages are to be mailed by Express Mail.

c. The office in which the package is signed is responsible for its distribution. Distribution lists for NRC addressees are in Appendix D. In addition, a copy should be sent to the appropriate State. (The region's State Liaison Officer will normally handle this for program office cases, provided the Enforcement Specialist notifies the Regional Enforcement Coordinator.)

   ➜ NOTE: Escalated NOVs should NOT be made publically available in ADAMS until confirmation that the licensee has received a copy of the enforcement action (i.e., e-mail, facsimile, courier).

➜ NOTE: A copy of the action should be e-mailed to "OEWEB" to ensure that the action is posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of the enforcement action."

d. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees. See Section 8.6.6 for distribution on cases involving VA medical facilities or radiographers.

e. In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. **In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available.**

5.6.6 Press Releases for Civil Penalties

Press releases are generally issued for proposed civil penalty actions.

Regional enforcement personnel will inform the regional Public Affairs Officer (RPAO) at least 72 hours prior to issuance of an action with a proposed civil penalty. The RPAO will provide a draft press release to the regional staff for concurrence. OE may also review press releases in the more significant cases. After the enforcement action has been signed, the RPAO will receive verification that the licensee has been notified of the action and has received a copy of the enforcement action. The press release is generally issued (via ADAMS and the Web) 24 hours **after the licensee receives a copy of the enforcement action**. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site. If the licensee issues its own press release during the intervening period, the RPAO may immediately issue a press release.

➜**NOTE**: As a matter of convenience and efficiency, press releases for program office civil penalty actions may be coordinated through the applicable RPAO or headquarters OPA staff. Because of the infrequency of these program office actions, the OE Enforcement Specialist should make sure that a press release is drafted.

For particularly significant cases, OPA prepares a draft press release and has it reviewed by OE. Staff review should focus on the technical content of the release to ensure that it accurately reflects the content of the cover letter and the action being taken. The press release should adhere closely to the language of the enforcement action and should not state the issues in a manner other than how they are stated in the enforcement action.

Press releases should normally include information regarding:

- the significance of the violation in terms of whether the issue reflects an actual or potential consequence, or a regulatory concern. The agency's categorization of the severity level should also be given. If the matter has little or no potential safety consequence, but there is a regulatory concern, the nature of that concern should be identified, e.g., the repetitive nature of the violation, willfulness reflecting disregard for compliance with requirements.

- if the violations were identified through an NRC inspection.

- if the licensee reported the violation, and also if mitigation was granted on that basis.

- if credit is given for corrective actions (e.g., corrective actions have been initiated and appear acceptable); or, if the plant will remain shut down until completion of corrective actions. There is no need to include in an NRC press release that a licensee contests the violations or contends enforcement action is unnecessary.

- a brief statement of the basis for escalating or mitigating the civil penalty to present a balanced account to the public.

5.6.7 Licensee Response to Civil Penalty

The provisions of 10 CFR 2.201 require that a licensee submit a written response addressing the violations included within a civil penalty action within 20 days of the date of the civil penalty action or other specified time frame; however, normally 30 days should be used. If a licensee does not respond to a civil penalty action within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE within 45 days and consideration will be given to whether the case should be referred to the Attorney General or whether an order imposing the civil penalty should be issued or whether some other enforcement action is warranted.

Licensees may be granted response extensions where good cause is shown. The region may grant extensions of up to 2 weeks without OE approval. OE should be promptly notified of any extensions the region grants. OE approval is required for extensions beyond 2 weeks. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due. The confirmation may either be prepared by the NRC or the licensee. A copy of this followup correspondence is to be sent to OE and the region.

Within 2 weeks, responses should be reviewed for completeness of information. If the response is missing information necessary to evaluate the licensee's action, OE should be promptly notified, and the region, after coordination with OE, should take action to obtain the necessary information without waiting for action under "b" or "c" below.

As discussed further below, licensees may: (a) admit the violation and pay the civil penalty; (b) deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and pay the civil penalty; or (c) deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and not pay the civil penalty.

a. If the licensee **admits that the violation occurred** as stated in the NOV **and pays the civil penalty,** the regional office is to review the licensee's corrective action. The region should notify OE, usually within 2 weeks of receiving the licensee's response, of the acceptability of the licensee's response.
   Once OE has been notified by the region of the acceptability of the licensee's response, OE will send the licensee a letter acknowledging payment of the civil penalty and stating that the corrective actions described in the licensee's response will be examined during future inspections. This acknowledgment should be sent to the licensee within 1 week of the region's notification.

   If the region requires additional information from the licensee, the region should notify OE and OE will send a letter acknowledging payment of the civil penalty and directing the licensee to provide the required information to the region. In either case, after OE sends an acknowledgment letter, OE will normally close out the associated EA number, thereby formally closing the case.

b. If the licensee **denies the violation,** contests the staff's facts or conclusions, or requests mitigation of the civil penalty, **but pays the civil penalty**, the region is to review the licensee's points of contention. If the licensee presents additional information not previously disclosed, then careful consideration should be given to the appropriateness of the original proposed action. In addition, the region is to prepare an evaluation of the licensee's response and submit it to OE for possible inclusion in the acknowledgment letter sent by the Director, OE.

   If the licensee's response does not contain new information, then the region is to prepare and submit to OE a brief response addressing only those issues that are significant and appropriate along with an assessment of the licensee's corrective action. OE will coordinate with the region and issue the NRC's response letter. Even if the licensee's response does not present new information, an error identified in the enforcement action must be corrected. Licensee responses that contest enforcement actions but pay civil penalties should usually be acknowledged within 45 days.

   If the licensee has paid a monetary penalty and then, based on the above review of the licensee's response, it appears that the penalty was **clearly** paid in error, the overpayment is to be returned to the licensee. OE will arrange to have a check issued from the Controller's Office. After it is determined that the Treasury has issued a check, OE will send a letter to the licensee explaining the modification to the civil penalty.

c. If the licensee **denies the violation,** contests the staff's facts or conclusions, or requests mitigation of the civil penalty, **and does not pay the civil penalty,** the regional office should review the licensee's response; decide whether the civil penalty should be imposed, partially mitigated, or withdrawn; and prepare a written evaluation of the licensee's response. The evaluation should be submitted to OE within 45 days and address the licensee's points of contention and should include a restatement of each disputed violation, a summary of the licensee's position concerning each disputed violation, the NRC's evaluation of the licensee's position, and the NRC's conclusion.

   If the region recommends that the civil penalty should be imposed, an Order Imposing Civil Monetary Penalty should be prepared in accordance with the guidance in Section 5.7 with the staff's evaluation included as an appendix to the order. If the region recommends that the civil penalty should be partially mitigated, an Order Imposing Civil Monetary Penalty should be prepared to reflect partial mitigation with the staff's evaluation included as an appendix to the order. If the region recommends that the civil penalty should be withdrawn, the region should prepare a cover letter, for OE issuance, to the licensee with the staff's evaluation as an appendix to the letter.

5.7 Order Imposing Civil Monetary Penalty (Imposition)

Orders are addressed in Section VI.D of the Enforcement Policy, and 10 CFR 2.205 sets forth the procedures for issuing orders imposing civil penalty. The NRC issues an Order Imposing Civil Monetary Penalty when a licensee refuses to pay a civil penalty unless a basis exists for withdrawal of the proposed penalty.

Draft Impositions, with the accompanying evaluation of the licensee's response and draft transmittal letter to the licensee, are submitted to OE within approximately 45 days of receipt of the licensee's response.

5.7.1 Preparing an Imposition Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare the imposition package, including the following elements as discussed below:

a. An Order Imposing Civil Monetary Penalty should be prepared by using the applicable standard format (Form 14) in Appendix B. The Order Imposing Civil Monetary Penalty should be sent to the same person and address as the original proposed enforcement action. The order should include the following sections:

   1. The first section identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

   2. The second section briefly describes the violation(s), when the Notice of Violation and Proposed Imposition of Civil Penalty was issued, and when responses were received from the licensee.

   3. The third section is the statement of the decision to impose the civil penalty.

   4. The fourth section is the statement that orders payment of the civil penalty.

   5. The fifth section states the licensee's opportunity to request a hearing.

b. A cover letter transmitting the order to the licensee should be prepared using the applicable format (Form 13) in Appendix B. The letter should reference previous relevant correspondence between the licensee and the NRC, very briefly take into account any licensee rebuttal or reasons for mitigation or remission, impose the civil penalty, and state that the letter and its enclosures will be made available to the Public. The letter may be more detailed if it is determined that an appendix will not be included (such as in certain discrimination cases).

c. An Appendix may or may not be included as part of the package. Certain cases (such as discrimination) may not require an appendix. OE will coordinate with OGC, the region, and the program office to determine whether an appendix should be included. If applicable, appendices should be prepared using the applicable format (Form 15) in Appendix B. The Appendix should include a restatement of each disputed violation, a summary of the licensee's response, an NRC evaluation of the response, and a conclusion. The appendix should discuss only violations that have been assessed a civil penalty. If the licensee has contested any violations that were not assessed a civil penalty, those violations should be discussed in a separate document as an additional enclosure to the cover letter (see Appendix B, Form 16). In preparing the Appendix it is important to understand that it puts the involved licensee, as well as other licensees, on notice regarding the NRC position. This permits other licensees to be aware of NRC concerns. In addition, it may improve the NRC's litigative position by demonstrating careful consideration of the licensee's arguments.

d. The licensee's response to the proposed civil penalty action should be included in the enforcement package as background material if it has not already been provided in a panel.

5.7.2 Imposition Coordination and Review

All Orders Imposing Civil Monetary Penalties are sent to headquarters for review and approval prior to issuance.

The imposition package should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the NRR, NMSS, or NSIR Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. The imposition package and supporting background materials, including the licensee's response to the proposed civil penalty, should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases. Impositions should be given priority treatment by both the region and headquarters offices.

a. OGC review and concurrence (or statement of no legal objection) is required on all Orders Imposing Civil Monetary Penalties. **OGC will review the proposed order and provide comments to OE within 5 working days of receipt of the package.**

b. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days**. (Comments are normally provided through the program office Enforcement Coordinators.)

c. OE will consider OGC and program office comments and revise the enforcement action, as appropriate. The OE Enforcement Specialist will notify the NRR, NMSS, or NSIR Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

d. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

e. **The region should review the revised order and, if possible, provide concurrence on headquarter's changes by the next day.**

f. OE will obtain a statement of no legal objection or concurrence from OGC and issue the action, if delegated to OE or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

5.7.3 Imposition Enforcement Notification

Enforcement notification is provided for Orders Imposing Civil Monetary Penalties according to the following guidelines:

a. The staff notifies the Commission of its intent to issue an Order Imposing Civil Monetary Penalty by issuing an Enforcement Notification (EN). These ENs reference the initial EN for the proposed action and include the same brief description of the violation or problem as in the initial EN. These ENs also reference the licensee's response and include one of three conclusions: (1) that the civil penalty should be imposed, (2) that the civil penalty should be mitigated, or (3) that the civil penalty should be withdrawn.

b. OE prepares and issues these ENs using the standard format in Appendix B (Form 27). These ENs retain the same EN number as the proposed action followed by the letter A.

c. ENs for impositions are provided to the Commission on the same day the action is signed and issued.

d. Delays in issuing enforcement actions after issuance of ENs requires the notification and approval of OE.

e. If an enforcement action will not be issued by the date specified in the EN, OE will notify the Office of Congressional Affairs and the region will notify OPA of the issuing delay to prevent a premature release of information.

f. If the information in the EN has already been disclosed, OE will coordinate with the region and OPA to determine the appropriate date to issue the enforcement action. OE will notify the EDO in these cases.

5.7.4 Imposition Signature Authority

Orders Imposing Civil Penalties should be signed and issued according to the following guidelines:

a. The DEDR signs all impositions for 10 CFR Part 50 and 55 licensees.

b. The DEDMRS signs impositions including Severity Level I violations for 10 CFR Part 30, 40, 70, and 76 licensees.

c. The Director, OE, signs impositions including violations up to and at Severity Level II for 10 CFR Part 30, 40, 70, and 76 licensees.

5.7.5 Licensee Notification, Mailing, & Distribution of Impositions

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

a. In most cases, the region will notify the licensee by telephone of an Order Imposing Civil Monetary Penalty. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification. **In all cases, the licensee will be notified of the order before the information is made public.**

b. Licensees are to be provided a copy of the order as expeditiously as possible. Electronic transmission should be used to provide a copy to licensees having facsimile equipment. Orders should be mailed by Express Mail.

c. OE is responsible for distribution of the order. NRC distribution lists are in Appendix D. A copy should also be sent to the appropriate State.

   ➜ NOTE: A copy of the action should be e-mailed to "OEWEB" to ensure that the action is posted to the Enforcement Web site in a timely manner.

d. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

e. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. **In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.**

f. All Orders Imposing Civil Monetary Penalties are published in the *Federal Register*. OE is responsible for this action.

5.7.6 Press Releases for Impositions

Press releases are normally only issued for impositions where the amount of the civil penalty has been changed from the original civil penalty action. Even when the civil penalty has been changed, the Regional Administrator may decide that a press release is not warranted (i.e., if only a minor adjustment was made to the civil penalty). In these cases, the Regional Administrator should notify OE and OE will discuss the issue with Public Affairs.

Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when an imposition is about to be issued. For impositions involving a press release, the RPAO will provide the draft press release to the regional staff for concurrence. OE may also review press releases in particularly significant cases. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy. The press release is generally issued (via ADAMS and the Web) 24 hours **after the licensee receives a copy of the enforcement action**. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site. If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.

Press releases for impositions should indicate whether the originally proposed civil penalty is being imposed partially or in full.

5.7.7 Licensee Response to Imposition

The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame; however, normally 30 days should be used. A licensee may either (1) pay the civil penalty or (2) request a hearing. If a licensee does not respond to the order within the allotted time, the region should contact OE and the case will be referred to the Attorney General for collection.

If a licensee requests a hearing, OE will provide the request to OGC to forward to the Office of the Secretary of the Commission.

Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing. A licensee's request for an extension must be made in writing to the Director, OE, and include a statement of good cause for the extension.

5.8 Order Modifying, Suspending, or Revoking License

➜**NOTE**: The guidance included in this section is intended to primarily address orders based on compliance issues, i.e., orders that are issued based on the failure to comply with existing regulatory requirements. The program offices may issue safety orders that impose additional requirements beyond the existing regulations (e.g., 2002 security orders). In addition to program office guidance for these safety orders, the staff should follow the guidance included in Section 5.8.4 on the issuance of Regulatory Notifications (RNs), Sections 5.8.6 and 5.8.9 on Web site posting, and 3.10.1 on the issuance of EA numbers.

Orders are addressed in Section VI.D of the Enforcement Policy, and 10 CFR 2.202 sets forth the procedures for issuing orders. An order is a written NRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such action as may be proper. Orders may also be issued in lieu of, or in addition to civil penalties, as appropriate for Severity Level I, II, or III violations. Unless a separate response is warranted, an NOV need not be issued where an order is based on violations described in the order. The violations described in the order need not be categorized by severity level.

The NRC may also issue orders to unlicensed persons, including vendors and contractors (and employees), when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities. (See Section 7.3 for guidance on actions against individuals.)

a. **License Modification Orders** are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.

b. **Suspension Orders** may be used: to remove a threat to the public health and safety, common defense and security, or the environment; to stop facility construction; when the licensee has not responded adequately to other enforcement action; when the licensee interferes with the conduct of an inspection or investigation; or for any other reason for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

c. **Revocation Orders** may be used: when a licensee is unable or unwilling to comply with NRC requirements; when a licensee refuses to correct a violation; when a licensee does not respond to an NOV where a response was required; when a licensee refuses to pay an applicable fee under the Commission's regulations; or for any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

d. **Cease and Desist Orders** may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.

Orders should be prepared within time-frames that are consistent with the safety and regulatory significance of the situations.

5.8.1 Immediately Effective Orders

Orders may be effective after a licensee or individual has had an opportunity to request a hearing. In such cases, the order becomes effective on the day following the deadline for requesting a hearing, if the licensee does not request a hearing. If the licensee requests a hearing, the order becomes effective as determined in the hearing process. Orders can, however, be made immediately effective without prior opportunity for a hearing whenever the NRC determines that the public health and safety interest so requires, or when the order is responding to a violation involving willfulness. These orders must specify the basis for their immediate effectiveness. The discussion should support the finding that the Commission no longer has reasonable assurance that activities will be conducted without undue risk to the public's health and safety. Immediately effective orders should be expedited. Immediately effective orders should also be supported by a draft affidavit prepared by a person who can testify as to why the public health, safety, or interest requires an immediately effective order in this case. (See Section 5.8.2.c for additional guidance.) All orders are published in the *Federal Register*. OE is responsible for this action.

If an immediately effective order is needed to eliminate an immediate hazard arising from a violation that also warrants a civil penalty, the order should be expedited, and the civil penalty issued promptly thereafter.

5.8.2 Preparing an Order Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare the civil penalty package, including the following elements as discussed below:

a. The order should be prepared using the applicable standard format in Appendix B. Depending on the type of order, the order will include any of the following sections:

1. A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

2. A section that describes the relevant events, facts, violations, technical aspects or legal reasons that substantiate issuing the order.

3. A section that provides the justification for issuing the order.

4. For a confirmatory order, a section that confirms, by the order, a licensee's commitments to take certain actions.

5. A section that orders modification, suspension, or revocation of the license.

6. A section that states the licensee's obligation to respond to the order.

7. A section that states the opportunity for a licensee or any other person adversely affected by the order to request a hearing.

b. A cover letter transmitting the order to the licensee should be prepared using the applicable format (Form 17) in Appendix B, customized to reflect the specific order. The letter should briefly state the basis for the order and describe any actions required or prohibited based on the order. The letter should also state that failure to comply with the provisions of the order may result in civil and criminal sanctions and that the letter and its enclosures will be made available to the Public. A contact should be provided, normally the Director, OE.

c. For immediately effective orders, the originating office should provide, with the draft package, a draft affidavit to support the order's immediate effectiveness. Since 10 CFR 2.202(c)(2)(i) requires the staff to respond to a motion to set aside immediate effectiveness within 5 days of receipt of the motion, the originating office must be prepared to make the knowledgeable personnel available to put the affidavit in final form. The affidavit should be prepared using the applicable standard format in Appendix B (Form 18).

5.8.3 Order Coordination and Review

All orders are sent to headquarters for review and approval prior to issuance.

The order package should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the applicable program office Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. The order package and supporting background materials should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases. Orders should be given priority treatment by both the region and headquarters offices.

a. OGC review and concurrence (or statement of no legal objection) is required on all orders. **OGC will review the proposed order and provide comments to OE within 5 working days of receipt of the package.** (Immediately effective orders should be expedited.)

b. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days**. (Comments are normally provided through the program office Enforcement Coordinators.)

c. OE will consider OGC and program office comments and revise the enforcement action, as appropriate. The OE Enforcement Specialist will notify applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

d. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

e. The region should review the revised order and, if possible, provide concurrence on headquarters' changes by the next day.

f. OE will obtain a statement of no legal objection or concurrence from OGC and issue the order if delegated or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

g. For Confirmatory Orders, the consent of the recipient of the order is required. OE will forward the draft order to the recipient with the text of the ordering portion of the proposed order and a cover letter requesting that the appropriate person sign and return the letter agreeing to the issuance of the order and the fact that the consent waives the right to request a hearing on the order. The text of the order itself will recite this consent. (See Form 23.)

5.8.4 Enforcement Notification and Regulatory Notification for Orders

a. Enforcement Notification should be made for orders according to the following guidelines:

1. The staff notifies the Commission of its intent to issue an order by issuing an Enforcement Notification (EN). The EN should briefly state the basis for the order and describe any actions required or prohibited based on the order.

2. OE prepares and issues ENs using the standard format in Appendix B (Form 26).

3. Same-day ENs are issued for immediately effective orders. Three day ENs are issued for non-immediately effective orders.

4. ENs should not be distributed ADAMS (PARS) or otherwise publicly disclosed until after (1) the Commission has exercised its review of the enforcement action and (2) the enforcement action has been received by the licensee.

5. Delays in issuing enforcement actions after issuance of ENs requires notification and the approval of OE.

6. If an enforcement action will not be issued by the date specified in the EN, OE will notify the Office of Congressional Affairs and the region will notify OPA of the issuing delay to prevent a premature release of information.

7. If the information in the EN has already been disclosed, OE will coordinate with the region and OPA to determine the appropriate date to issue the enforcement action. OE will notify the EDO in these cases.

b. Regulatory Notification should be made for program office safety orders according to the following guidelines:

1. The staff notifies the Commission of its intent to issue a program office order imposing additional regulatory requirements by issuing a Regulatory Notification (RN). The RN should briefly state the basis for the order and describe any actions required or prohibited based on the order.

2. OE prepares and issues RNs using the standard format in Appendix B (Form 27-II).

3. Same-day RNs are issued for immediately effective orders. Three day RNs are issued for non-immediately effective orders.

4. RNs should not be distributed ADAMS (PARS) or otherwise publicly disclosed until after (1) the Commission has exercised its review of the order and (2) the order has been received by the licensee.

5. Delays in issuing orders after issuance of RNs requires notification and the approval of OE.

6. If a program office safety order will not be issued by the date specified in the RN, OE will notify the Office of Congressional Affairs and the region will notify OPA of the issuing delay to prevent a premature release of information.

7. If the information in the RN has already been disclosed, OE will coordinate with the region, program office, and OPA to determine the appropriate date to issue the order. OE will notify the EDO in these cases.

5.8.5 Order Signature Authority

Orders should be signed and issued according to the following guidelines:

a. The Director, OE, normally signs the following orders:

   1. For Part 30, 40, 70, and 76 licensees:

      (a) Confirmatory Orders, and

      (b) Orders Imposing Civil Monetary Penalties for violations up to and including Severity Level II;

   2. For Part 50 licensees: Confirmatory Orders; and

   3. For Individual actions under Parts 30, 40, 50, 70, and 76: Confirmatory Orders.

b. The DEDO signs all other orders.

5.8.6 Licensee Notification, Mailing, & Distribution of Orders

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

a. In most cases, the region will notify the licensee by telephone of the issuance of an order. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification. In all cases, the licensee will be notified of the order before the information is made public.

b. Licensees are to be provided a written copy of the order as expeditiously as possible. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment. Orders should be mailed by Express Mail.

c. OE is responsible for distribution of the order. Distribution lists for NRC addressees are in Appendix D. Orders involving individuals where they are restricted from licensed activities in general, should be sent to the Office of State Programs for distribution to all Agreement States.

   ➜ NOTE: A copy of the action should be e-mailed to "OEWEB" to ensure that the action is posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of this action," so that the Web staff will know that it can be posted.

d. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

e. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. **In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.**

f. All orders are published in the *Federal Register*. OE is responsible for this action.

5.8.7 Press Releases for Orders

Press releases are generally issued for all orders other than impositions (see Section 5.7.6).

Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when these actions are about to be issued. The RPAO will provide a press release to the regional staff for concurrence. OE may also review press releases in some particularly significant cases. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy. The press release is generally issued (via ADAMS and the Web) 24 hours **after the licensee receives a copy of the enforcement action**. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site. If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.

5.8.8 Licensee Responses to Orders

The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame. The licensee may (1) consent to the order, (2) admit or deny each allegation and provide a basis as to why the order should not have been issued, and/or (3) request a hearing. If a licensee does not request a hearing by the deadline provided, the order becomes effective at that time (for orders not immediately effective at the time of issuance). Questions concerning the effectiveness and scope of a given order should be referred to OE. If the licensee has requested a hearing and subsequently calls the NRC to discuss the case, the call should be referred to OE. OE will ensure that the assigned OGC hearings attorney is present in any discussions.

If a licensee requests a hearing, OE will provide a copy to OGC to forward to the Office of the Secretary of the Commission.

Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing. A licensee's request for an extension must be made in writing to the Director, OE, and include a statement of good cause for the extension.

5.8.9 Relaxation of Orders

➜**NOTE**: If the Director of NRR or NMSS relax a program office security order, a copy of the correspondence to the licensee should be sent to “OEWEB” to ensure prompt posting in the security order document collection.

An order provides that the Regional Administrator may relax or terminate conditions of the order. The purpose of this provision is to avoid the need to issue another order should the order need to be relaxed. The Regional Administrator is named to ensure that the licensee works directly with the region concerning the order. Nevertheless, the same offices that were involved in issuing the order are to be involved before relaxing or terminating a provision of the order. Therefore, if the region finds it appropriate to relax or terminate an order, OE should be contacted and OE will obtain the views (as appropriate) of NRR, NMSS, NSIR, OGC, and the DEDO. In some orders, the Director, OE, is the designated official who can relax the order. Similarly, OE will obtain the views of the appropriate offices. In some cases, it is decided to withdraw an order. Use of the term "withdraw" is

appropriate when dropping all or part of an order. The term "rescind" should be used when it is concluded that because of a basic mistake of law or fact, the action should not have been issued at all.

5.9 Demand for Information (DFI)

Demands for Information are addressed in paragraph (5) of Section VI.E of the Enforcement Policy, and 10 CFR 2.204 sets forth the procedures for issuing DFIs. A DFI is a formal request made to a licensee or applicant to obtain information to determine whether the license should be granted, or if issued, whether it should be modified, suspended, or revoked, or other enforcement action taken. Demands for Information may also be issued to unlicensed persons, including vendors and contractors (and employees), for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued. (See Section 7.3.3 for guidance on issuance of a DFI to an individual and Section 7.3.4 for guidance on issuance of a DFI to a licensee to obtain additional information regarding the competence or integrity of a particular licensee employee.) A DFI may also be included within another escalated action, such as an order or proposed imposition of civil penalty.

A DFI is a significant action. It should be used only when it is likely that an inadequate response will result in an order or other enforcement action.

5.9.1 Preparing a DFI Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare the DFI package, including the following elements as discussed below:

a. The DFI should be prepared using the applicable standard format (Form 25) in Appendix B. The Demand should include the following sections:

    1. A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

    2. A section that describes the relevant events, facts, alleged violations, potentially hazardous conditions, technical aspects or legal reasons that provide the substantive basis for issuing the DFI.

    3. A section that requires specific information from the licensee by a certain date (determined on a case-by-case basis) to determine whether the license should be modified, suspended, or revoked.

b. A cover letter transmitting the DFI to the licensee should be prepared using the applicable format (Form 17) in Appendix B, customized to reflect the DFI as the applicable enforcement action. The letter should briefly state the basis for the DFI, describe the information requested, state that the failure to comply with the DFI provisions may result in enforcement action, and note whether the DFI will be made available to the Public.

c. As noted above, a DFI may also be incorporated into another action. In such cases, the DFI is normally included, in an abbreviated format, as part of the transmittal letter for the accompanying action, using language similar to the following:

> In addition, pursuant to Sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 50.54(f), in order for the Commission to determine whether your license should be modified or other actions taken, you are required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, an explanation as to:
>
> > (1) why the NRC can have confidence that [request information specific to the circumstances of the case] . . .
>
> Copies of the response to this Demand for Information should be sent to the Associate General Counsel for Hearings, Enforcement & Administration at the same address, and the Regional Administrator, NRC Region [specify region and regional address] . . .

5.9.2 DFI Coordination and Review

All DFIs are assigned EA numbers and are sent to headquarters for review and approval prior to issuance.

The DFI package should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the applicable program office Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. The order package and supporting background materials should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases. Orders should be given priority treatment by both the region and headquarters offices.

a. **If requested, OGC will review the proposed DFI and provide comments to OE within 5 working days of receipt of the package.**

b. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or**

Deputy Director, OE within 5 working days. (Comments are normally provided through the program office Enforcement Coordinators.)

c. OE will consider timely OGC and program office comments and revise the DFI, as appropriate. The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action. The OE Enforcement Specialist will notify the program office Project Manager when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

d. OE will forward the revised DFI to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

e. The region should review the revised DFI and, if possible, provide concurrence on headquarters' changes by the next day.

f. OE will attempt to resolve any differences among the region, the program office, and OGC.

5.9.3 DFI Signature Authority

The Director, OE, normally signs DFIs issued to Part 30, 40, 50, 55, 70, and 76 licensees and to individuals.

5.9.4 Licensee Notification, Mailing, & Distribution of DFIs

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

a. In most cases, the region will notify the licensee by telephone of the issuance of a DFI. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.

b. Licensees are to be provided a written copy of the Demand as expeditiously as possible. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment. Demands should be mailed by Express Mail.

c. OE is responsible for distribution of the Demand. Distribution lists for NRC addressees are in Appendix D. (See Section 7.3.7 for guidance on distribution to the PDR for DFIs involving individuals.)

5.9.5 Licensee Response to DFI

The provisions of 10 CFR 2.204 require that a licensee submit a written response to a DFI under oath or affirmation within 20 days of the date of the DFI or other specified time frame (determined on a case-by-case basis). (The provisions of 10 CFR 2.204 provide that an individual to whom the Commission has issued a DFI may submit a written response to a DFI under oath or affirmation within 20 days of the date of the DFI or other specified time frame; see Section 7.3 for guidance on enforcement actions involving individuals.)

If a licensee does not respond to a DFI within the required time, the NRC will consider issuing an order to modify, suspend, or revoke the licensee or consider taking such other action as necessary to compel a response.

After reviewing the licensee's response to the DFI, the NRC determines whether further action is necessary to ensure compliance with regulatory requirements.

5.10 Letter of Reprimand (LOR)

Letters of Reprimand are addressed in paragraph (4) of Section VI.E of the Enforcement Policy. An LOR is a letter addressed to an individual (licensed or unlicensed) subject to Commission jurisdiction identifying a significant deficiency in his or her performance of licensed activities. An LOR may be issued to an individual for a violation when the NRC determines that formal enforcement action against the individual is not warranted. The letter should serve as a vehicle for notifying the individual that his or her actions are unacceptable and that if uncorrected or continued, they could lead to formal NRC enforcement action. An LOR may be issued in conjunction with an enforcement action against the licensee.

➜**NOTE**: If the staff decides that action should not be taken against an individual (for what ever reason) the staff should normally prepare a close-out letter using Form 45 in Appendix B.

5.10.1 Preparing a LOR Action

➜ **NOTE**: To avoid the release of predecisional information, all documents included in escalated enforcement packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21."

The responsible office should prepare the LOR package, including the following elements as discussed below:

a. The LOR should be prepared using the applicable standard format for the specific case (Form 38 or 39). Note that the letter is not labeled as a "Letter of Reprimand" in the subject line. The LOR should, depending on the recipient and nature of the letter, include the following elements, as applicable:

    1. Docket and license numbers.

    2. A description of relevant events, facts, or circumstances that substantiate issuing the LOR. This description should reference relevant inspection reports, OI reports, previous correspondence, or predecisional enforcement conferences.

    3. A discussion of enforcement action, if any, that was taken against the facility licensee. If an enforcement action was issued to the facility, a copy should be enclosed.

4. A reminder of an NRC licensed Reactor Operator's responsibilities. For example:

   "You are reminded that you hold a license from the United States government that confers upon you the special trust and confidence of the American people in the safe operation of nuclear facilities and places you in the position where your performance is expected to be above reproach. This includes, as an NRC Reactor Operator license holder, your responsibility to remain alert and attentive at all times to ensure protection of the public health and safety. Your actions (condition) on _(date)_ did not meet those standards."

5. A discussion of how an NRC licensed Reactor Operator failed to meet their responsibilities.

6. Notification of the NRC's authority to take action against individuals. For example:

   "You should be aware that the NRC's regulations allow enforcement actions to be issued directly to unlicensed persons who through their deliberate misconduct, cause a licensee to be in violation of NRC requirements. Similarly, an order may be issued to such an individual preventing him or her from engaging in licensed activities at all NRC licensed facilities."

7. A statement that the Deliberate Misconduct Rule is included as an enclosure to the letter.

8. The basis for not issuing formal enforcement action against the individual.

9. A statement notifying the individual that his or her actions are unacceptable and that if uncorrected or continued, could lead to formal NRC enforcement action.

10. A statement that the individual is not required to respond to the letter. However, if the individual wants to respond, the response should be made to the originating office within 30 days of the date of the letter.

11. If the recipient is licensed, a statement that the letter (and any enclosures), with the individual's home address deleted will be placed in the docket file for the license.

5.10.2 LOR Coordination and Review

All LORs are assigned EA numbers (during review and approval) and are sent to headquarters for review and approval prior to issuance.

The LOR package should be electronically mailed to OE ("OEMAIL"), the OE Enforcement Specialist, the Assistant General Counsel for Materials Litigation and Enforcement, and the applicable program office Enforcement Coordinator. Draft Commission papers should also be electronically mailed, if applicable. The order package and supporting background materials should be mailed (1-day-overnight delivery) to the same addressees.

All documents, including staff comments on escalated enforcement packages, should be marked, "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (ADAMS (PARS)).

Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases. LORs should be given priority treatment by both the region and headquarters offices.

a. Unless OE requests, OGC will not normally provide comments for LORs.

b. The applicable program office should review 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 and risk characterizations has been properly evaluated from an overall agency perspective. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days**. (The program office Enforcement Coordinators normally provide comments.)

c. OE will consider timely program office comments (if applicable) and revise the LOR, as appropriate. The OE Enforcement Specialist will notify the program office Project Manager when substantive program office comments are not going to be incorporated into the final proposed enforcement action.

d. OE will forward the revised LOR to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.

e. **The region should review the revised LOR and, if possible, provide concurrence on headquarters' changes by the next day.**

f. OE will approve issuance of the action or, if warranted, will consult with the DEDO, as appropriate.

g. OE will assign the action an IA number when it is ready to be issued.

5.10.3 LOR Signature Authority

The Regional Administrator (or designee) normally signs and issues LORs, after review and approval by the Director, OE.

5.10.4 Notification, Mailing, & Distribution of LORs

The region is responsible for mailing and distributing LORs. LORs should be mailed by either Certified Mail (Return Receipt Requested) or Express Mail. OE should be on distribution for all LORs. In addition, the licensee should be shown on the "cc" on the LOR.

LORs are not posted on the **Enforcement** Web site of significant actions. Because some LORs may be issued in conjunction with escalated enforcement actions, the following guidance should be followed to avoid posting LORs on the Web. First, the escalated enforcement action cover letter to the licensee should indicate that an LOR is being, or has been, issued in separate correspondence. Second, the LOR should not be shown as an enclosure to the action to the licensee.

The region must ensure that the copies of LORs that are made available to the Public do not include individuals' home addresses.

5.11 Settlement of Enforcement Proceedings and Actions

10 CFR 2.203 sets forth procedures for settlement of a proceeding to modify, suspend, or revoke a license or for other action and compromise of a civil penalty.

For those cases where a hearing has been requested, the staff (normally OGC has the lead) is responsible for preparing a settlement agreement. The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and a hearings attorney for the NRC. The stipulation or compromise is subject to approval by the designated presiding officer, or if none has been designated, by the Chief Administrative Law Judge. If approved, the ASLBP will issue a decision or order settling and discontinuing the proceeding that will include the terms of the settlement or compromise.

For those cases that do not involve a hearing, the staff (normally OE) is responsible for preparing a settlement agreement. (See the sample standard format (Form 40) in Appendix B.) The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and the Director, OE for the NRC. The settlement is subject to approval by the Director, OE after consultation, as warranted, with the DEDO. If approved, the staff (normally OE) will prepare an order settling, modifying, or discontinuing the enforcement action that will include the terms of the settlement or compromise. (See the sample standard format (Form 41) in Appendix B.

CHAPTER 6
EXERCISE OF DISCRETION

6.1 Scope of Chapter

This chapter provides guidance to the staff in those cases where, notwithstanding the normal guidance in the Enforcement Policy, the agency chooses to exercise discretion and either escalate or mitigate enforcement sanctions to ensure that the resulting enforcement action (or lack thereof) appropriately reflects all relevant circumstances of the case and the level of NRC concern. A reference list of issues that may warrant enforcement discretion is included in Appendix D.

6.2 Escalation of Sanctions

Escalation of NRC sanctions is addressed in Section VII.A of the Enforcement Policy. The NRC considers violations categorized at Severity Level I, II, or III to be of significant regulatory concern. The NRC also considers violations associated with findings that the Reactor Oversight Process's Significance Determination Process evaluates as having low to moderate, or greater safety significance (i.e., white, yellow, or red) to be of significant regulatory concern. If the application of the normal guidance in the Enforcement Policy does not result in an appropriate sanction, the NRC may apply its full enforcement authority where the action is warranted. NRC action may include (1) escalating civil penalties; (2) issuing appropriate orders; and (3) assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of $120,000 per violation, per day.

Exercise of escalation discretion requires prior approval by the Director, OE and the DEDO and consultation with the EDO and Commission, as warranted.

6.2.1 Escalation of Civil Penalties

Notwithstanding the outcome of the normal civil penalty assessment process addressed in Section VI.C of the Enforcement Policy, the NRC may either:

- propose a civil penalty where application of the normal process would otherwise result in zero penalty, or
- propose a civil penalty greater than the amount resulting from application of the normal process (i.e., greater than the base or twice the base civil penalty).

The purpose of exercising this discretion is to ensure that the proposed civil penalty reflects the significance of the circumstances. However, in no instance will a civil penalty exceed $120,000 per violation per day. This discretion is expected to be exercised on an infrequent basis.

Exercise of this discretion requires prior approval by the Director, OE and the DEDO and consultation with the EDO, as warranted. In addition to the approval of the DEDO, Commission consultation is required when the staff proposes to impose a civil penalty for a single violation or problem that is greater than 3 times the Severity Level I value shown in Table 1A for that class of licensee. All other cases require a 3-day EN to the Commission.

In proposing this exercise of discretion to OE, the regions (or the appropriate program office) should first attempt to assess an action according to the normal Enforcement Policy provisions and provide those results to OE. The office proposing the discretion should explain to OE why the resulting

action from the normal process is inappropriate for the circumstances of the case and why the proposed action under the exercise of discretion is appropriate. In the event the circumstances of a particular case do not readily lend themselves to application of the civil penalty assessment process, the proposing office should state this and provide justification for an appropriate action through an exercise of discretion. While it is not necessary to include a detailed analysis of this process in a transmittal letter to a licensee, it is imperative that a sound rationale for exercising these discretion provisions be included in the letter to the licensee, lest the agency appear arbitrary and capricious in exercising its enforcement authority (see discussion below).

In exercising this discretion, it is imperative that the cover letter to the licensee clearly addresses the basis for exercising this discretion. For example:

> Although the NRC recognizes that application of the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy would fully mitigate the civil penalty in this case, the NRC is exercising discretion in accordance with Section VII.A.1 of the Enforcement Policy and is proposing a civil penalty of $60,000 for this violation. This exercise of discretion reflects the NRC's added concern in this case due to the nonconservative actions on the part of your operations staff and the potential those actions had on reactor safety."

Examples when this discretion should be considered include, but are not limited to the following:

a. Problems categorized at Severity Level I or II.

b. Overexposures or releases of radiological material in excess of NRC requirements.

c. Situations involving particularly poor licensee performance, or involving willfulness.

d. When the licensee's previous enforcement history has been particularly poor, or when the current violation is directly repetitive of an earlier violation.

e. Situations when the violation results in a substantial increase in risk, including cases in which the duration of the violation has contributed to the substantial increase.

f. Where the licensee made a conscious decision to be in noncompliance in order to obtain an economic benefit.

g. Cases involving the loss, abandonment, or improper transfer or disposal of a sealed source or device. Notwithstanding the outcome of the normal civil penalty assessment process, these cases normally should result in a civil penalty of at least the base amount; or

h. Severity Level II or III violations associated with departures from the Final Safety Analysis Report identified after March 30, 2000, for risk-significant items as defined by the licensee's maintenance rule program and March 30, 2001, for all other issues. Such a violation or problem would consider 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 exercise of Section VII.B.3 enforcement discretion is warranted.)

6.2.2 Orders

The NRC will, where necessary, issue orders in conjunction with civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations.

6.2.3 Daily Civil Penalties

In order to recognize the added safety significance for those cases where a very strong message is warranted for a significant violation that continues for more than one day, the NRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of $120,000 for each day the violation continues. The NRC may also exercise this discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

6.3 Mitigation of Sanctions

Mitigation of NRC sanctions is addressed in Section VII.B of the Enforcement Policy. The Enforcement Policy provides that when a violation of NRC requirements is identified, enforcement action should normally be taken. However, there are situations when it is appropriate for the agency to either limit or forgo the normal use of its enforcement sanctions.

Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, the NRC may exercise discretion and refrain from issuing a civil penalty and/or issuing an NOV under certain circumstances. While the NRC may exercise this discretion for violations meeting the required criteria where the licensee failed to make a required report to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make a required report. The circumstances under which this discretion may be exercised are described in the following sections.

➜ **NOTE**: The mitigation discretion described in Sections VII.B.2 - VII.B.6 does not normally apply to violations associated with issues evaluated by the SDP. The Reactor Oversight Process will use the Agency Action Matrix to determine the agency response to performance issues. The Agency Action Matrix has provisions to consider extenuating circumstances that were previously addressed through enforcement mitigation.

6.3.1 [Reserved]

This section used to address NCVs. Guidance on NCVs has been relocated to Section 4.2.

6.3.2 Violations Identified During Extended Shutdowns or Work Stoppages (Section VII.B.2)

In accordance with Section VII.B.2 of the Enforcement Policy, the NRC may refrain from issuing an NOV or a proposed civil penalty for a violation that is identified after (1) the NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee (or a work stoppage at a construction site), or (2) the licensee enters an extended shutdown or work stoppage related to generally poor performance over a long period of time, provided that the violation is documented in an inspection report (or inspection records for some material cases) and that it meets all of the following criteria:

a. It was either licensee-identified as a result of a comprehensive program for problem identification and correction that was developed in response to the shutdown or identified as a result of an employee allegation to the licensee (Note: Even if the NRC identifies the violation, discretion may be appropriate if all other criteria are met);

b. The violation is based upon activities of the licensee prior to the events leading to the shutdown;

c. The violation would not be categorized at Severity Level I;

d. The violation was not willful; and

e. The licensee's decision to restart the plant requires NRC concurrence.

6.3.2.1 Preparing an Exercise of Enforcement Discretion (EOD) Letter (Section VII.B.2)

The cover letter to the licensee should include a reference to the Policy, the severity level of the violations, and a clear basis for exercising this discretion. For example:

> The NRC is exercising enforcement discretion in accordance with Section VII.B.2 of the Enforcement Policy and refraining from issuing citations for four Severity Level III violations. These issues satisfy the appropriate criteria in Section VII.B.2, namely (1) although the staff identified some of the violations, enforcement action was not considered necessary to achieve remedial action, (2) the violations are based on licensee activities that occurred prior to the licensee implementing an extended shutdown of the station, (3) the violations would not be categorized at Severity Level I, (4) the violations were not willful, and (5) actions specified in the June 15, 1998, Confirmatory Action Letter requires NRC concurrence prior to the licensee restarting the station.

The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION."

6.3.2.2 EOD Letter Coordination and Review (Section VII.B.2)

a. Exercise of this discretion requires the approval of the Director, OE, with consultation with the DEDO as warranted.

b. These cases require an EA number.

c. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

d. OE should be consulted by telephone for Severity Level IV issues.

e. The Commission is to be notified the first time this discretion is exercised for a plant (see Section 2.11). The EN should include the same type of information as the letter to the licensee (see the sample discussion above).

6.3.2.3 EOD Signature Authority (Section VII.B.2)

The Regional Administrator should normally sign the letter transmitting the exercise of discretion if it includes an issue that could have been considered as escalated action, had it not been for the exercise of discretion. However, the Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

6.3.3 Violations Involving Old Design Issues (Section VII.B.3)

In accordance with Section VII.B.3 of the Enforcement Policy, the NRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as an engineering, design, or installation deficiency, provided that the violation is documented in an inspection report (or inspection records for some material cases) that includes a description of the corrective action, and provided that the violation meets all of the criteria below.

a. It was licensee-identified as a result of its voluntary initiative;

b. It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

c. It was not likely to be identified by routine licensee efforts such as normal surveillance or quality assurance (QA) activities.

In addition, the NRC may refrain from issuing an NOV for cases that meet the above criteria provided the violation was caused by conduct that is not reasonably linked to present performance (normally, violations that are at least 3 years old or violations occurring during plant construction). This discretion may not apply if the licensee should have reasonably identified the violation earlier. Exercising this discretion encourages licensee efforts to identify and correct subtle violations (that would not be identified by routine efforts) before degraded safety systems are called upon.

Section VII.B.3 discretion would not normally be applied to departures from the FSAR 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. (The schedule should provide for completion of the licensee's initiative by March 30, 2000, for information in the FSAR involving SSCs of high safety significance as defined in the licensee’s maintenance rule program and by March 30, 2001, for other information. This schedule may be altered dependent on the staff’s final assessment of guidance from the Nuclear Energy Institute or issuance of a generic letter);

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.

6.3.3.1 Preparing an EOD Letter (Section VII.B.3)

The cover letter to the licensee should include a reference to the Policy, the severity level of the violations, and a clear basis for exercising this discretion. For example:

> The NRC is exercising enforcement discretion in accordance with Section VII.B.3 of the Enforcement Policy and is not issuing a Notice of Violation for a Severity Level III violation involving a design deficiency associated with the auxiliary feedwater system. Discretion was warranted because: (1) the issue was licensee-identified during a licensee-initiated design review, (2) the licensee implemented timely and effective corrective action and delineated appropriate long-term corrective actions to review and identify any similar design deficiencies, (3) the design deficiency was not likely to be identified by routine licensee efforts, and (4) the initial design error occurred more than 5 years ago and is not linked to present performance.

The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION."

6.3.3.2 EOD Letter Coordination and Review (Section VII.B.3)

a. Exercise of this discretion requires the approval of the Director, OE, with consultation with the DEDO as warranted.

b. These cases require an EA number.

c. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

d. OE should be consulted by telephone for Severity Level IV issues.

6.3.3.3 EOD Signature Authority (Section VII.B.3)

The Regional Administrator should normally sign the letter transmitting the exercise of discretion if it includes an issue that could have been considered as escalated action, had it not been for the exercise of discretion. However, the Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

6.3.4 Violations Identified Due to Previous Escalated Enforcement Action (Section VII.B.4)

In accordance with Section VII.B.4 of the Enforcement Policy, the NRC may refrain from issuing an NOV or a proposed civil penalty for a violation that is identified after the NRC has taken escalated enforcement action for a Severity Level II or III violation, provided that the violation is documented in an inspection report (or inspection records for some material cases) that includes a description of the corrective action and provided that the violation meets all of the following criteria:

a. It was licensee-identified as part of the corrective action for the previous escalated enforcement action;

b. It has a similar root cause to the violation for which escalated enforcement action was issued;

c. It does not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation;

d. It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification; and

e. It would not be characterized at Severity Level I.

6.3.4.1 Preparing an EOD Letter (Section VII.B.4)

The cover letter to the licensee should include a reference to the Policy, the severity level of the violations, and a clear basis for exercising this discretion. For example:

> The NRC is exercising enforcement discretion in accordance with Section VII.B.4 and refraining from issuing a Notice of Violation for a Severity Level III problem involving non-seismically qualified fire suppression system actuation switches and relays on emergency diesel generators and supplemental leak collection and release systems. Discretion is appropriate because the violations: (1) were identified by the your staff as part of the corrective action for a previous issue with non-seismically qualified relays in the fire protection system for the Unit 1 emergency diesel generator, (2) had the same root cause as the previous issue, (3) did not substantially change the safety significance or the character of the regulatory concern arising out of that finding, and (4) were the subject of comprehensive and reasonable corrective actions.

The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION."

6.3.4.2 EOD Letter Coordination and Review (Section VII.B.4)

a. Exercise of this discretion requires the approval of the Director, OE, with consultation with the DEDO as warranted.

b. These cases require an EA number.

c. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

d. OE should be consulted by telephone for Severity Level IV issues.

6.3.4.3 EOD Signature Authority (Section VII.B.4)

The Regional Administrator should normally sign the letter transmitting the exercise of discretion if it includes an issue that could have been considered as escalated action, had it not been for the exercise of discretion. However, the Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

6.3.5 Violations Involving Discrimination (Section VII.B.5)

a. In accordance with Section VII.B.5 of the Enforcement Policy, the NRC may refrain from taking enforcement action for cases involving discrimination when a licensee who, without the need for government intervention, identifies an issue of discrimination and takes prompt, comprehensive, and effective corrective action to address both the particular situation and the overall work environment is helping to establish a safety-conscious workplace. Aggressive licensee follow-up also provides a message that retaliation is not acceptable within its workplace. Assuming that these actions are reasonable and effective, NRC enforcement action may not be warranted.

b. Another situation in which enforcement may not be warranted is where a complaint is filed with the DOL, but the licensee settles the matter before the DOL Area Office makes a finding of discrimination. Alternatively, if a finding is made against the licensee, the licensee may choose to settle before the evidentiary hearing begins. An NRC policy of not normally citing violations in such cases might encourage licensee settlements, thereby reducing the potential for chilling effect. Settlements also provide a more timely remedy for the complainant and may be used to demonstrate the licensee's commitment to a retaliation-free environment. Therefore, the NRC may exercise its discretion not to take enforcement action when the licensee has publicized (1) that a complaint of discrimination for engaging in protected activity was made to the DOL; (2) that the matter was settled to the satisfaction of the employee (the terms of the specific settlement agreement need not be posted); and (3) that if the DOL Area Office found discrimination, the licensee has taken action to positively reemphasize that discrimination will not be tolerated. This information might be publicized by posting a notice, a newsletter, a handout, or some other means, but the information should be conveyed in a manner designed to minimize the chilling effect on others. A similar approach may be taken when a person comes to the NRC without going to the DOL and the matter is promptly settled thereafter prior to the NRC conducting an investigation or, if an investigation is initiated, prior to substantial effort on it.

c. Even if no formal enforcement action is taken, the NRC would issue a letter, as is normal practice in similar cases, to emphasize the need for lasting remedial action. The licensee would also be informed that future violations may result in enforcement action. In certain cases, the NRC may also consider entering into a consent order with the licensee, as part of the settlement process, to address remedial action.

d. Whether the exercise of discretion is appropriate will depend on the circumstances. For example, normally enforcement discretion would not be appropriate for cases that involve: (1) allegations of discrimination as a result of providing information directly to the NRC; (2) allegations of discrimination caused by a manager above first-line supervisor (consistent with the current Enforcement Policy classification of Severity Level I or II violations); (3) allegations of discrimination where a history of findings of discrimination (by the DOL or the NRC) or settlements suggest a programmatic rather than an isolated discrimination problem;

(4) allegations of discrimination which appear particularly blatant or egregious.[3] In addition enforcement discretion normally would not be exercised for cases where the licensee does not appropriately address the overall work environment (e.g. by using training, postings, revised policies or procedures, any necessary disciplinary action, etc. to communicate corporate policy against discrimination).

6.3.5.1 Preparing an EOD Letter (Section VII.B.5)

The cover letter to the licensee should include a reference to the Policy, the severity level of the violations, and a clear basis for exercising this discretion.

The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION."

6.3.5.2 EOD Letter Coordination and Review (Section VII.B.5)

a. Exercise of this discretion requires the approval of the Director, OE, with consultation with the DEDO as warranted.

b. These cases require an EA number.

c. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

d. OE should be consulted by telephone for Severity Level IV issues.

6.3.5.3 EOD Signature Authority (Section VII.B.5)

The Regional Administrator should normally sign the letter transmitting the exercise of discretion if it includes an issue that could have been considered as escalated action, had it not been for the exercise of discretion. However, the Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

6.3.6 Violations Involving Special Circumstances (Section VII.B.6)

a. Notwithstanding the outcome of the normal civil penalty assessment process, in accordance with Section VII.B.6 of the Enforcement Policy, the NRC may reduce or refrain from issuing a civil penalty or an NOV for a Severity Level II, III, or IV violation. Exercise of this discretion will be based on the merits of the case after considering the guidance in the Enforcement Policy and the NRC Enforcement Manual and such factors as: (1) the age of the violation; (2) the technical and regulatory significance of the violation; (3) the clarity of the requirement; (4) the appropriateness of the requirement; (5) the overall performance of the licensee; (6) whether the licensee reported significant information to the NRC that was not otherwise required to be reported to the NRC; and (7) other relevant circumstances, including any that may have changed since the violation. In addition, the NRC may refrain from issuing enforcement action for violations resulting from

[3] While enforcement action would normally be warranted in these four types of cases, depending on the circumstances, mitigation for corrective action may be appropriate.

matters not within a licensee's control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls.[4] Generally, however, licensees are held responsible for the acts of their employees and contractors. This discretion is expected to be exercised only where application of the normal guidance in the Enforcement Policy is unwarranted.

b. The staff may consider exercising enforcement discretion for inaccurate or incomplete performance indicator (PI) data submitted to the NRC as part of the Part 50 Reactor Oversight Process (ROP). Exercising enforcement discretion on a case-by-case basis under Section VII.B.6 takes into account the completion of the initial learning curve and the recognition of ongoing PI development activities. For example, the staff may consider exercising discretion if new PIs are developed. OE will work with the regional offices and NRR in determining whether enforcement discretion should be exercised for all future PI-related 10 CFR 50.9 violations.

c. In reaching decisions as to the appropriate sanction against licensees who qualify as small entities, the staff should also consider the intent of the Small Business Regulatory Enforcement Fairness Act (SBREFA). There may be cases, in which, after considering the normal adjustment factors and the size of a qualified small entity to whom a civil penalty may be issued, the staff believes that the penalty should be reduced or eliminated. In those cases, it is appropriate to propose such a modification based on the intent of the Act. This would be applied as an exercise of discretion.

d. In proposing this exercise of discretion to OE, the regions (or the appropriate program office) should first attempt to assess an action according to the normal Enforcement Policy provisions and provide those results to OE. The office proposing the discretion should explain to OE why the resulting action from the normal process is inappropriate for the circumstances of the case and why the proposed action under the exercise of discretion is appropriate. In the event the circumstances of a particular case do not readily lend themselves to application of the civil penalty adjustment factors, the proposing office should state this and provide justification for an appropriate action through an exercise of discretion.

6.3.6.1 Preparing an EOD Letter (Section VII.B.6)

The cover letter to the licensee should include a reference to the Policy, the severity level of the violations, and a clear basis for exercising this discretion.

While it is not necessary to include a detailed analysis of this process in a transmittal letter to a licensee, it is imperative that a sound rationale for exercising these discretion provisions be included in the letter to the licensee, lest the agency appear arbitrary and capricious in exercising its enforcement authority. In addition to a clear basis for exercising this discretion, the cover letter to the licensee should include a reference to the Policy and the severity level of the violations.

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[4] In these cases, the staff should include a conclusion such as: "The staff has reviewed your root cause analysis of the event and has concluded that the equipment failure could not have been avoided or detected by your quality assurance program or other related control measures. Therefore, in accordance with Sections VI.A and VII.B.6 of the Enforcement Policy, the NRC has chosen to exercise enforcement discretion and not issue a violation for this issue."

The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION."

6.3.6.2 EOD Letter Coordination and Review (Section VII.B.6)

a. Exercise of this discretion requires the approval of the Director, OE, with consultation with the DEDO as warranted.

b. These cases require an EA number.

c. Severity Level I, II, and III issues should be discussed during weekly enforcement panels.

d. OE should be consulted by telephone for Severity Level IV issues.

e. Where appropriate based on the uniqueness or significance of the issue, the Commission should be provided prior notice through issuance of a 5-day EN. OE will determine whether to issue an EN.

6.3.6.3 EOD Signature Authority (Section VII.B.6)

The Regional Administrator should normally sign the letter transmitting the exercise of discretion if it includes an issue that could have been considered as escalated action, had it not been for the exercise of discretion. However, the Deputy Regional Administrator or a Division Director may sign the letter, provided it includes a statement that the Regional Administrator has been consulted.

6.4 Notice of Enforcement Discretion (NOED)

Notice of Enforcement Discretion (NOED) is addressed in Section VII.C of the Enforcement Policy, and specific guidance and responsibilities for issuing NOEDs is provided in Part 9900 of the NRC Inspection Manual. (Links to the procedures are included on the “Guidance Documents” web page.)

➜**NOTE**: NOEDS should be e-mailed to “OEWEB” to ensure prompt posting to the NOED document collection.

The NRC expects all of its licensees to comply with applicable requirements and license conditions. However, there are certain situations where the staff may choose not to enforce compliance with requirements.

a. In certain cases involving operating reactor licensees, the NRC staff may choose not to enforce compliance with specific Technical Specification (TS) Limiting Conditions for Operation (LCOs) or license conditions. Specifically, on occasion, circumstances may arise where a licensee's compliance with a TS LCO or with other license conditions would involve an unnecessary plant transient or performance of testing, inspection, or system realignment that is inappropriate with the specific plant conditions, or unnecessary delays in plant startup without a corresponding health and safety benefit. The staff may also grant enforcement discretion in cases involving severe weather or other natural phenomena, based upon balancing the public health and safety or common defense and security of not operating, against the potential radiological or other hazards associated with continued operation, and a determination that safety will not be impacted unacceptably by exercising this discretion. The

Commission is to be informed expeditiously following the granting of an NOED in such situations (see Section 2.11). NRR is responsible for issuing guidance for NOEDs involving operating reactors.

b. In certain cases involving gaseous diffusion plant (GDP)s, the NRC staff may choose not to enforce compliance with a Technical Safety Requirement (TSR) or technical specification or other certificate condition. Specifically, on occasion, circumstances may arise where compliance with a Technical Safety Requirement (TSR) or technical specification or other certificate condition would unnecessarily call for a total plant shutdown or, notwithstanding that a safety, safeguards or security feature was degraded or inoperable, compliance would unnecessarily place the plant in a transient or condition where those features could be required. NMSS is responsible for issuing guidance for NOEDs involving GDPs.

The NRC staff is expected to rarely exercise enforcement discretion in this manner. Even when plant operation is impacted, the NRC staff is under no obligation to take such a step merely because it has been requested. Where enforcement discretion is to be exercised, it is to be exercised only if the NRC staff is clearly satisfied that such action is warranted from a health and safety perspective.

The decision to exercise enforcement discretion by issuing an NOED does not change the fact that a violation will occur nor does it imply that enforcement discretion is being exercised for any violation that may have led to the violation at issue. In each case where the NRC staff has chosen to exercise enforcement discretion, enforcement action will normally be taken for any violations that were part of the root causes leading to the noncompliance. Such enforcement action (i.e., associated with the root causes) is intended to emphasize that licensees should not rely on the NRC's exercise of enforcement discretion as a routine substitute for compliance or for requesting a license amendment.

For any NOED issued where the root cause of the need to request an NOED was a violation (regardless of the severity level or whether it will be dispositioned as an NOV or an NCV), an EA number is to be obtained from OE. The enforcement action should reference the NOED number. (The NOED should not include the EA number.)

➜ **NOTE**: OE approval is required if a violation is involved and the staff does not want to issue enforcement action (NOV or NCV).

If the root cause underlying an NOED request results in an escalated action, the time during which the NOED is effective will not be counted in considering the impact of the violation.

CHAPTER 7
MISCELLANEOUS GUIDANCE

7.1 Scope of the Chapter

This chapter provides guidance to the staff on a wide range of topics, including: willful violations, enforcement and administrative actions involving individuals, enforcement actions involving fitness-for-duty requirements, OI reports, referrals to the Department of Justice (DOJ), discrimination for engaging in protected activities, material false statements and completeness and accuracy of information, enforcement actions against non-licensees, violations of reporting requirements, violations of record-keeping requirements, meetings with licensees on NRC enforcement action, reopening closed enforcement actions, liability of former and successor licensees, and enforcement actions involving non-power reactor licensees.

7.2 Willful Violations

This section provides generic guidance on the issue of willful violations. Specific guidance for the different types of willful violations is addressed in the following sections of this Manual. Section 7.3 includes guidance for willful violations involving individuals. Section 7.4 includes guidance for willful failures by NRC-licensed reactor operators to comply with fitness-for-duty requirements. Section 7.5 includes guidance on processing OI reports that may or may not conclude willfulness. (It is important to note that willful violations do not necessarily require an OI report to substantiate the wrongdoing. However, the action is to be coordinated with OI.) Section 7.6 includes guidance for willful violations that have been referred to DOJ. Section 7.7 includes guidance for acts of discrimination against employees for engaging in protected activities. Section 7.8 includes guidance for failures to provide complete and accurate information that may or may not involve willfulness.

A willful violation is one in which an NRC requirement has been breached through a voluntary and intentional action or inaction other than mistake or error. Willful violations may result either from conduct which is intentional or deliberate, or from conduct which constitutes reckless or careless disregard or indifference as to whether a requirement will be violated. It is important to recognize that **careless disregard is not a subset of deliberate conduct**. Careless disregard has elements that must be established that are not elements of deliberate conduct. It is also important to recognize that the term "careless disregard" refers to conduct different in kind from the normal meaning of "careless" in that it connotes conduct which demonstrates reckless disregard or reckless indifference as to whether a requirement will be violated.

Typically, the basic elements of a deliberate violation are:

- a requirement exists (a regulation, license condition or technical specification, order or statute);
- a violation of a requirement has occurred;
- the person's actions were voluntary, as opposed to inadvertent;
- the person committing the violation knew a requirement existed, understood the requirement, and knew the requirement was applicable at the time; and
- the person knew that his or her actions were contrary to the requirement.

Generally, the elements of conduct which demonstrate careless (or reckless) disregard are:

- a requirement exists (a regulation, license condition or technical specification, order or statute);
- a violation of a requirement has occurred;
- the person's actions were voluntary, as opposed to inadvertent, constituting or resulting in the violation; and
- the person acted with reckless disregard or indifference to
  - the existence of the requirement;
  - the meaning of the requirement; or
  - whether the intended conduct conformed to the requirement.

Additional information on deliberate misconduct and careless disregard is available through OE or the regional enforcement staff.

Notwithstanding the actual safety consequence of a willful violation, the Commission has taken the position that all willful violations are of particular concern because its regulatory programs are based on licensees and their employees and contractors acting with integrity and communicating with candor.

7.2.1 Referral to OI

In accordance with MD 8.8, "Management of Allegations," the NRC staff is required to notify OI when a reasonable basis exists for belief that wrongdoing may have occurred.

7.2.2 Enforcement Sanctions for Willful Violations

Because a willful violation is normally a significant regulatory issue, enforcement sanctions should demonstrate the unacceptability of such actions. The NRC will issue an order in the event it loses reasonable assurance that licensed activities can be conducted safely.

A violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness. In determining the significance of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official[5] or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the significance assessment will be dependent on the circumstances of the violation. If a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be considered at least more than minor. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances such that it demonstrates the seriousness of the violation thereby creating a deterrent effect within the licensee's organization.

[5]The term "licensee official" as used in this policy statement means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license. Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

Every case involving a willful violation should normally be considered for escalated action. However, in an effort to encourage licensees to act responsibly in the identification and correction of such violations, the NRC may choose to disposition certain violations in accordance with either Section VI.A.1.d or VI.A.8.d, as applicable, and issue an NCV if a licensee-identified and corrected Severity Level IV violation was committed by a relatively low-level individual.

If the agency cannot make a conclusion as to whether an issue involves willfulness, it may issue a Demand for Information to the licensee, requesting information on whether the NRC can have reasonable assurance that the licensee will conduct its activities in accordance with NRC requirements.

7.2.3 Coordination and Review for Willful Violations

All cases involving willful violations (including those dispositioned as NCVs or involving discretion) require an EA number for tracking purposes, require OE concurrence, and should be coordinated with OI.

7.3 Enforcement and Administrative Actions Involving Individuals

The subject of enforcement actions involving individuals is addressed in Section VIII of the Enforcement Policy. Enforcement actions involving individuals, including licensed operators, are significant actions that will be closely controlled and judiciously applied. An enforcement action involving an individual will normally be taken only when the NRC is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew, or should have known, the required actions; and knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance.

Action may be taken directly against individuals either because they are individually licensed or because they violated the rules on deliberate misconduct. Normally, whenever action is taken against an individual, action is also taken against a licensee.

In addition, the NRC may take enforcement action against a licensee that may impact an individual, where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted. The NRC may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence, fitness-for-duty, or other matters that may not necessarily be a violation of specific Commission requirements. Enforcement actions against licensed operators for failure to meet fitness-for-duty requirements are addressed in Section 7.4 of this Manual.

Because potential enforcement actions and administrative actions involving individuals are significant actions, the Director, OE, is to be notified as soon as the staff identifies any violation or issue that could lead to an enforcement or administrative action against an individual (including a Letter of Reprimand or similar letter).

See the guidance in Section 3.10.3 regarding the process for tracking individual actions.

7.3.1 Predecisional Enforcement Conferences Involving Individuals

In those cases where the staff believes enforcement action against an individual may be warranted, the NRC will normally provide the individual with an opportunity to address the apparent violations by responding to a choice letter or participating in a predecisional enforcement conference, unless the circumstances of the case warrant immediate NRC action. There may also be cases in which the staff proposes to issue a DFI in lieu of, or in addition to, conducting a predecisional enforcement conference. Once the region determines that an conference should be conducted, it should notify OE of its intent. OE will assign the case an EA number if one has not previously been assigned. The region should subsequently contact OE to obtain an IA number to include on a conference or choice letter or DFI when the correspondence is ready to be issued. The region should use the original EA number for any subsequent action or close-out letter during the review and approval stages and include the IA number on the final correspondence to the individual.

a. For cases in which the focus of regulatory concern is the licensee, but specific individuals are involved, the region should contact the licensee to schedule the conference, but should make clear its desire to have the individual or individuals attend. For cases in which the focus of regulatory concern is the individual, the region should contact the individual to schedule the conference.

b. Written correspondence concerning the predecisional enforcement conference should normally not be made Public (ADAMS (PARS)) in a manner that identifies the individual. The identification of the individual should be withheld from the Public pending the issuance of any enforcement action, including a DFI. Letters to the licensee that describe apparent violations involving the individual should avoid publicizing the individual's identity. If necessary, the apparent violation may be described in an attachment to the letter, and the letter made available to the Public without the attachment.

c. For predecisional enforcement conferences involving only the individual, the letter requesting the conference should have an IA number and include:

    1. A clear statement of the purpose of the conference, the time and date agreed upon, and any apparent violations to be discussed. A copy of the inspection report or the OI report factual summary (see Section 7.5.4.4) should be enclosed if available. A copy of the transcript of the individual's OI interview may be included, if the individual (or individual's attorney) requests it to prepare for the conference and the OI investigation has been completed and is closed. The Director, OI and Director, OE should be consulted in these cases. In addition, the transcript of the individual's OI interview will not be made available to the Public until after the enforcement action is issued.

    2. A description of the information that the individual is expected to address.

    3. A description, in general terms, of the range of possible enforcement actions that the NRC is considering.

    4. A statement that the individual is not **required** to attend the conference, and that, should the individual choose not to attend, the NRC intends to proceed based on the facts already at hand.

5. A statement that the individual may choose to bring a personal representative. However, if the individual desires to bring another person, the individual should contact the NRC in advance of the conference.

6. A point of contact who can answer any questions about the conference.

d. As with other predecisional enforcement conferences, a meeting notice should be issued when an individual is involved; however, care should again be taken for privacy considerations. The meeting notice should avoid using names or titles in a manner to implicate a particular individual as being the focus of the conference. For a conference in which only the individual and his/her representative will be attending (i.e., no licensee representatives), the meeting notice should use a general designation (e.g., "Diablo Canyon employee") rather than the individual's name or specific title.

e. Predecisional enforcement conferences involving individuals normally will be closed and should be transcribed. Consideration should be given to having NRC counsel (regional or OGC) present. An OE staff member should also attend the more significant conferences. For a conference involving only the individual, the NRC may allow limited licensee attendance only if the individual who is the subject of the conference so desires. NRC attendance at these conferences should also be limited.

f. Appendix D includes opening remarks for a predecisional enforcement conference with licensed operators. While use of the remarks is not mandated, they cover important issues that should be addressed. The presiding official should consider these remarks and adjust them as appropriate for conferences with unlicensed individuals.

g. If the individual chooses to bring a personal representative (usually an attorney, spouse, or relative), the NRC should make it clear at the outset of the conference that the purpose of the meeting is to receive information from the individual and understand the individual's perspective. As such, the NRC's questions should primarily be addressed to and answered by the individual.

h. Subsequent to the predecisional enforcement conference, the region should determine, in coordination with OE, whether enforcement action should be issued against the facility licensee, against the individual, or both (see the guidance in Section 7.3.2). Examples of appropriate sanctions against individuals and facility licensees are discussed in Sections 7.3.3 and 7.3.4, respectively.

7.3.2 Action Against the Licensee or Action Against the Licensee and the Individual

When a potential enforcement issue involves an individual, the decision must be made whether to cite solely against the licensee or cite against the individual and the facility licensee. Paragraph "a" of this section provides guidance including examples of situations where it would be appropriate to cite solely against the facility licensee. Paragraph "b" provides examples of situations that could result in enforcement actions that may involve an individual or enforcement actions that could be taken directly against an individual (licensed or unlicensed) in addition to enforcement actions taken against the facility licensee. Paragraph "c" includes factors that should be considered in determining whether to issue enforcement action against an unlicensed person in addition to the facility licensee.

a. Most transgressions of individuals involving Severity Level III or IV violations will be handled by citing only the facility licensee. In addition, action against an individual will not be taken if the individual's improper action was caused by management failures. The following examples of situations illustrate this concept:

   1. Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee.

   2. Inadvertently missing an insignificant procedural requirement when the action is routine and fairly uncomplicated, and where no unusual circumstance exists indicating that the procedures should be referred to and followed step-by-step.

   3. A case in which compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation (unless the individual did not express his or her concern or objection to the direction).

   4. Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

   5. Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and did not attempt to get the procedure corrected.

b. More serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as against the facility licensee. Facility licensees are cited to recognize the licensee's responsibility for conduct of its employees.

   Listed below are examples of situations which could result in enforcement actions involving individuals, licensed or unlicensed. If the actions described in these examples are taken by a licensed operator or taken deliberately by an unlicensed individual, enforcement action may be taken directly against the individual. However, violations involving willful conduct not amounting to deliberate action by an unlicensed individual in these situations may result in enforcement action against a licensee that could impact an individual. The situations include, but are not limited to, violations that involve:

   1. Willfully causing a licensee to be in violation of NRC requirements.

   2. Willfully taking action that would have caused a licensee to be in violation of NRC requirements but did not because it was detected and corrective action was taken.

   3. Recognizing a violation of procedural requirements and willfully not taking corrective action.

   4. Willfully defeating alarms which have safety significance.

   5. Unauthorized abandoning of reactor controls.

   6. Dereliction of duty.

   7. Falsifying records required by NRC regulations or by the facility license.

8. Willfully providing, or causing a licensee to provide, an NRC inspector or investigator with inaccurate or incomplete information on a matter material to the NRC.

9. Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization.

10. Submitting false information and as a result gaining unescorted access to a nuclear power plant.

11. As a contractor or other person who provides testing or other services, willfully providing false data to a licensee, when the data affects the licensee's compliance with 10 CFR Part 50, Appendix B, or other regulatory requirement.

12. Willfully providing false certification that components meet the requirements of their intended use, such as an ASME Code.

13. As vendors of equipment for transportation of radioactive material, willfully supplying casks that do not comply with their certificates of compliance.

14. Willfully performing unauthorized bypassing of required reactor or other facility safety systems.

15. Willfully taking actions that violate TS LCOs (enforcement action for a willful violation will not be taken if the operator meets the requirements of 10 CFR 50.54(x), i.e., if the operator acted reasonably considering all the relevant circumstances surrounding the emergency).

c. In deciding whether to issue an enforcement action to an unlicensed person in addition to the facility licensee, the following factors should be considered:

1. The level of the individual within the organization.

2. The individual's training, experience, and knowledge of the potential consequences of the wrongdoing.

3. The safety consequences of the misconduct.

4. The benefit to the wrongdoer (e.g., personal or corporate gain).

5. The degree of supervision of the individual (i.e., how closely the individual is monitored or audited, and the likelihood of detection...such as a radiographer working independently in the field as contrasted with a team activity at a power plant).

6. The employer's response, including disciplinary action taken.

7. The attitude of the wrongdoer (e.g., admission of wrongdoing, acceptance of responsibility).

8. The degree of management responsibility or culpability.

9. Who identified the misconduct.

7.3.3 Action Against the Individual

The particular sanction to be issued to an individual should be determined on a case-by-case basis. In determining the appropriate sanction against an individual, factors to be considered are listed in Appendix D. All correspondence issued to an individual should include an IA number.

➜ **NOTE**: If the NRC determines that action will not be taken against an individual (for what ever reason) the staff should prepare a close-out letter using Form 45 in Appendix B.

Examples of sanctions, as discussed below, include: (a) Letters of Reprimand (LORs), (b) NOVs, (c) orders, (d) civil penalties, or (e) Demands for Information (DFIs). In accordance with the Enforcement Policy, an individual should normally have an opportunity to address apparent violations being considered for escalated enforcement action either in a predecisional enforcement conference or in a choice letter. In some cases, a DFI may be appropriate. In any event, if the person has not had an opportunity to dispute the NRC's proposal, the action should give the individual an opportunity to dispute the action, including the underlying facts, and include an NRC contact and telephone number. **See Section 7.3.7 for guidance on distribution of individual actions, including when and when not to make the documents available to the Public.**

a. LORs are addressed in Section VI.E.4 of the Enforcement Policy and in Section 5.10 of this Manual. A LOR is a letter addressed to an individual (licensed or unlicensed) subject to Commission jurisdiction, identifying a significant performance deficiency.

b. NOVs may be issued to licensed or unlicensed individuals. Consistent with 10 CFR 2.201, an NOV need not require a response from the individual if the action is being issued at Severity Level IV to a low-level individual who has been terminated from employment involving licensed activities, because in such cases, frequently there is not much corrective action that an individual can take. An opportunity to respond is to be given. The staff should use Form 4-IV to prepare the NOV and Form 3-III to prepare the cover letter transmitting the NOV.
➜**NOTE**: With the exception of violations against the deliberate misconduct rule, NOV "contrary to" paragraphs should **not** include the word "willful" or "deliberate misconduct." In these cases, the discussion of willfulness should be included in the cover letter as part of the significance discussion. Including "deliberate misconduct" in "contrary to" paragraphs is required when violations are based on the deliberate misconduct requirements.

c. Orders to NRC-licensed reactor operators may involve suspension for a specified period, modification, or revocation of their individual licenses. Orders to unlicensed individuals may include provisions that: (1) prohibit involvement in NRC licensed activities for a specified period of time (normally the period of suspension would not exceed 5 years) or until certain conditions are satisfied (e.g., completing specified training or meeting certain qualifications), (2) require notification to the NRC before resuming work in licensed activities, or (3) require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order.

d. An NRC-licensed operator may be assessed a civil penalty; however, such cases are rare, and require Commission approval. Section 234 of the Atomic Energy Act (AEA) gives the Commission authority to impose civil penalties on "any person." However, except for individuals subject to civil penalties under Section 206 of the Energy Reorganization Act of 1974 (see the Enforcement Policy, Section VIII, Footnote 8), the NRC will not normally impose a civil penalty against an individual.

e. Demands for Information (DFIs) are addressed in Section VI.E.5 of the Enforcement Policy, and 10 CFR 2.204 sets forth the procedures for issuing DFIs. DFIs are also addressed in Section 5.9 of this Manual. A DFI is a formal request for information that can be made to an individual for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued. An individual to whom the NRC has issued a DFI may, in his or her discretion, respond to a DFI by filing a written response under oath or affirmation. All DFIs should provide an opportunity for the individual to challenge the underlying facts, including any (apparent) violations.

7.3.4 Action Against the Facility Licensee

The particular sanction to be issued to a facility licensee should be determined on a case-by-case basis.

Examples of sanctions that may be appropriate against facility licensees, as addressed further below, are: (a) NCVs, (b) NOVs, (c) civil penalties, (d) DFIs, (e) orders, or (f) CALs.

a. In accordance with Sections VI.A.1.d and VI.A.8.d of the Enforcement Policy, the NRC may disposition a licensee-identified Severity Level IV willful violation involving a low-level individual as an NCV.

b. NRC-identified willful violations involving individuals (regardless of the severity level) should always be cited in an NOV.

c. Notwithstanding the outcome of the normal civil penalty assessment process, the Enforcement Policy provides that discretion will be considered (i.e., proposing or increasing the amount of a civil penalty) for willful violations.
➜**NOTE**: With the exception of violations against the deliberate misconduct rule, NOV "contrary to" paragraphs should **not** include the word "willful" or "deliberate misconduct." In these cases, the discussion of willfulness should be included in the cover letter as part of the significance discussion. Including "deliberate misconduct" in "contrary to" paragraphs is required when violations are based on the deliberate misconduct requirements.

d. A DFI may be issued to a licensee or applicant to obtain information regarding the competence or integrity of a particular licensee employee to determine whether the license should be granted, or if issued, whether it should be modified, suspended, or revoked, or other enforcement action taken. Cover letters and DFIs should include individuals' titles, but not include individuals' names and licensees should not get copies of DFIs that may be issued to the subject individuals, because the NRC has not made final, public conclusions about the individuals. Individuals who are the subject of DFIs should receive a copy of the action sent to the licensee. See Section 7.3.7 for additional guidance on this issue.

e. When the NRC takes an enforcement action against a licensee because of an individual employee's action, and that enforcement action may affect the employment of the individual, the individual may have rights to a hearing. Further, NRC employees may be individually liable for affecting a person's constitutional rights. Therefore, if the NRC concludes that an individual should be removed from licensed activities, an order is to be used rather than an informal action, such as a CAL, to clearly establish the opportunity for a hearing. The only exception to this is given under "f," below.

In the case of an unlicensed person, whether a firm or an individual, an order modifying the facility license may be issued to require (1) the removal of the person from all licensed activities for a specified period of time or indefinitely, (2) prior notice to the NRC before utilizing the person in licensed activities, or (3) notice of the issuance of such an order to other persons involved in licensed activities making reference inquiries. In addition, orders to employers might require retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities. Individuals who are the subject of orders should receive a copy of the action sent to the licensee. See Section 7.3.8 for additional guidance on this issue.

f. A CAL may be used instead of an order if the licensee is told that an individual may not use licensed material because the individual is not named on the license or does not meet the Commission requirements. In addition, a CAL may be used where the licensee has already, on its own, removed an individual and the NRC only seeks to be informed of any decision to reinstate that individual and the basis for that decision. Such a CAL should state clearly that the agreement does not require NRC approval for reinstatement. In such cases the person, under existing license conditions or regulations, lacks authorization to be involved in the licensed activity, and the CAL is merely being used to confirm that the licensee will adhere to existing provisions (i.e., in such a situation the CAL would not affect the individual's rights).

7.3.5 Actions Concerning Individuals Licensed by Other Authorities

Some enforcement actions are taken against individuals who are licensed by other authorities. The most common cases are enforcement actions taken against physicians who are licensed by individual State licensing boards. Others who may be subject to NRC action and may be licensed by a State board include nurses, medical technologists, professional engineers, and attorneys. If an order is issued against an individual who is licensed (or registered) by a State, the issuing office should send a copy of the order to the licensing authority for the State. The transmittal letter to the individual should show the State on the "cc" list. In addition, a copy of the enforcement action against a physician should be sent to:

Federation of State Medical Boards
of the United States, Inc.
400 Wiser Road, Suite 300
Euless, Texas 76039

The Federation is a central repository that maintains the Physician Disciplinary Data Bank. The transmittal letter to the physician should show the Federation on the "cc" list.

If the region intends to forward an order issued against an individual to a State licensing authority and/or the Federation, it should highlight this intent in the Enforcement Action Worksheet included with the region's recommended proposed enforcement action to OE.

It is **imperative** that if after issuance of the action, NRC changes its position on the matter, a copy of the NRC revised position be forwarded to the same licensing authority and the Federation, as applicable.

7.3.6 Coordination and Review for Actions Involving Individuals

Any proposed Order (other than Confirmatory) or civil penalty to be issued to an individual must be issued with the concurrence of the Director, OE and the DEDO.

A Confirmatory Order, NOV without a civil penalty, NCV, or any proposed administrative action (CAL, DFI, LOR, or similar letter) directed to an individual must be issued after appropriate coordination with OE.

7.3.7 Notification, Mailing, & Distribution of Actions Involving Individuals

Notification, mailing, and distribution of actions involving individuals should be made according to the following guidelines:

a. **Action Against the Individual**:

In order to afford individuals the opportunity to address apparent violations before issues are made Public, enforcement actions against individuals may be subject to a 45-day hold period, as discussed further below.

When NOVs and LORs are issued to individuals, they may be made available to the Public (and posted to the **Enforcement** Web site (for escalated NOVs)) **ONLY** if the individual has previously had an opportunity to present his or her views on the facts of the case to the NRC (see further discussion below). Conversely, these actions should **NOT** be made available to the Public or the licensee, when it is sent to the individual, if the individual has not been given an opportunity to present his or her views on the facts of the case to the NRC, such as during a predecisional enforcement conference, in response to a choice letter or a previously issued DFI, or during an OI investigation in which the individual was specifically provided an opportunity to challenge the alleged wrongdoing. However, a hard copy of the action should be distributed to OE and only those offices with a need for the document. In these cases, the action should provide the individual with an opportunity to respond within 30 days and state that after 45 days the action will be made available to the Public and sent to the licensee, unless the individual provides a sufficient basis to withdraw the action.

In addition, in these cases, if an enforcement action is being proposed for a licensee based on the actions of the individual, the enforcement action against the licensee should be withheld for at least 45 days while the individual is given the opportunity to respond.

If an individual provides a sufficient basis to withdraw an action, the region should issue a close-out letter to the individual stating that the action will be withdrawn. The staff should also review the proposed action for the licensee to consider whether it remains appropriate based on the individual's response.

If an individual does not respond to the action or fails to provide a sufficient basis to withdraw the action, the responsible office (the region or OE) should ensure that the action (and the individual's response, if one was provided) are distributed to the licensee and made available to the Public 45 days after the action was issued.

For an action subject to the 45-day hold, the region will forward a hard copy only to OE; and when the final enforcement decision is made, forward the electronic version to OE for posting on the Enforcement Web site (i.e., the region is responsible for tracking the 45-day hold period).

Predecisional enforcement conference letters, choice letters, and DFIs should only be made Public if the agency concludes that enforcement action should be issued to the individual. These documents should be made Public at the time the action is made Public.

Close-out letters that are issued to individuals are not made available to the Public (although they remain subject to release under FOIA). Close out letters to licensed individuals are placed on the license docket.

The region is responsible for mailing and distributing NOVs, civil penalties, LORs, and close-out letters to individuals.

OE is responsible for mailing and distributing DFIs and orders against individuals. Actions should be mailed by either Certified Mail (Return Receipt Requested) or Express Mail.

OE should be on distribution for all actions issued to individuals, including close-out letters. In addition, the facility licensee should be shown on the "cc" for all actions issued to individuals.

The issuing office should attempt to notify the individual by telephone when it is issuing an individual action. This is especially important when an order is being issued.

The region must ensure that the copies of actions against individuals and related documents that are made available to the Public do not include individuals' home addresses.

Press releases that address individual actions and enforcement actions may be issued sooner than the normal 5-day ADAMS hold after the staff has confirmed that the individual has received the action.

Exceptions to the above process will be considered on a case-by-case basis by the Director, OE.

b. **Action Against the Facility Licensee**:

Actions issued to licensees should be mailed in accordance with the normal guidance included within the applicable sections of this Manual.

If an enforcement action is being proposed for a licensee in conjunction with an individual action, then the enforcement action against the licensee should be withheld for at least 45 days while the individual is given the opportunity to respond. If an individual subsequently provides a sufficient basis to withdraw the action, the staff should review the proposed action for the licensee to consider whether it remains appropriate based on the individual's response.

Individuals who are the subject of DFIs or orders that are issued against the facility licensee should receive a copy of the action that is sent to the licensee. The transmittal letter to the licensee should include language such as, "A copy of this letter and its enclosure(s) is being sent to _(name or title of individual)_. The individual is not required to provide a response to the Demand, (order) but may do so if he or she desires within ___ days under oath or affirmation." The transmittal letter to the licensee should also include the individual's name on the "cc" list.

Exceptions to the above process will be made on a case-by-case basis by the Director, OE.

7.3.8 Orders Restricting NRC-Licensed Activities and Requiring Notice of New Employment

Orders to unlicensed individuals may include provisions that: (1) prohibit involvement in NRC licensed activities for a specified period of time (normally the period of suspension would not exceed 5 years) or until certain conditions are satisfied (e.g., completing specified training or meeting certain qualifications), (2) require notification to the NRC before resuming work in licensed activities, or (3) require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order. In addition, orders to NRC-licensed reactor operators may involve suspension for a specified period, modification, or revocation of their individual licenses.

In order to have current information available to those who make licensing and other decisions, OE includes orders to individuals on the **Enforcement** Web site within the collection of significant enforcement actions to individuals.
http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals/index.html

OE also includes any subsequent actions, such as modifications by the official authorized in the order to relax its requirements and settlements. A list of individuals who are currently subject to restrictions is included in the System of Records, NRC-3 Enforcement Actions Against Individuals, and the list can be made available to the public.

Distribution of the list is consistent with the Commission's direction when the Deliberate Misconduct Rule took effect in 1991 that a list be made available. The list is distributed (1) to assist those persons who are involved in licensing activities in making decisions as to whether an individual may be engaged in licensed activities, (2) to assist NRC staff members in responding to inquiries concerning individual actions.

a. **Employment Restrictions**

In general: Before relying on information from the **Enforcement** Web site to deny a licensing action or to initiate any contact with or to respond to an inquiry from an employer concerning a prior wrongdoer, the staff should contact Nick Hilton in OE by telephone (301) 415-3055 or e-mail (NDH) to verify the information.

In Licensing actions: License reviewers should check the **Enforcement** Web site before recommending issuance of a license that lists individuals by name, such as RSO, authorized user, etc. If any name on the proposed license or amendment matches a restricted individual, the branch chief should be consulted immediately and then OE advised. Since several people may have the same name, staff should review the order to see if the work history confirms or excludes a match of the individual. If it appears that a restricted individual is seeking to be involved in licensed activities, a compliance issue is raised and OE should be consulted.

b. **Notice to NRC of New Employment**

In general: Many orders issued to individuals also require the individual to notify the NRC when that individual accepts a new position that involves work in NRC-licensed activities. This notification requirement may apply to the first employment in NRC-licensed activities or may apply for a specified period of time. The purpose of the NRC notification requirement is to 1) let wrongdoers know and appreciate that their future activities may be subject to inspection, and 2) provide the NRC with an opportunity to inspect the functional area in which a former wrongdoer is working. When such a notification is received in a regional office, OE should be consulted to ensure that OE also is aware of the new employment; if OE becomes aware of the information, OE will advise the appropriate region of receipt of that information.

For materials licensees, the region (or program office) administering the license of the new employer should insert a notation in the employer's license docket file that notice has been received that a prior wrongdoer is now employed by that licensee. This notation should not identify the individual by name. The Regional Enforcement Coordinator will maintain a record of notifications. The note should remain in the file for as long as the order requires notice to the NRC (Notice Period). If the notice requirement applies only to the first employment, the note should remain in the file until the next inspection and then be deleted. If the docket file is made available for public review, the note should be withheld. For reactor licensees, OE will notify the NRR Enforcement Coordinator. The NRR Enforcement Coordinator will notify the operator licensing staff in NRR and the plant Project Manager and Senior Resident Inspector (SRI) of the wrongdoer's employment. The NRC should not volunteer or advise the licensee that the prior wrongdoer is employed at its facility. (This is because the order allows the person to be re-employed, and if the NRC notifies the licensee, that information could have the possible effect of suggesting to the licensee that the individual should not be employed.)

For both reactor and materials licensees, the region administering the license of the new employer, or program office for those licenses administered by headquarters, should acknowledge the notification in writing. The letter to the individual will advise that the agency expects the individual to fully understand the requirements of the license and pertinent regulations, that the NRC expects full compliance with those requirements, and will routinely inspect that facility in the future. This letter would be prepared by the Regional Enforcement Coordinator, with OE concurring. This letter would be made available to the Public in the same fashion as the letter issuing the initial action, e.g., under the IA number and without the new employer's docket number.

1. **Materials licensees (without resident inspectors)**:

After learning that a prior wrongdoer has been employed by a licensee in its region, the regional office should consider whether the circumstances warrant increasing the inspection frequency or advancing the next scheduled inspection. If the licensee is to be inspected during the notice period for that individual, the region should plan to inspect the functional area in which the subject individual is working. After seeing the note in the docket file, the inspector should check with the Enforcement Coordinator to learn the name of the prior wrongdoer. To ascertain in what functional area the individual is working, the inspector and the supervisor should discuss ways to identify unobtrusively the functional area in which the subject individual is working. For example, an inspector could look at an organization chart, staff list, film badge list, or internal telephone directory.

The inspector should not do anything that is likely to alert the licensee that a prior wrongdoer is working at the facility and the inspector should not go out of the way to speak with the individual or treat him or her in an unusual manner. It would be acceptable for the inspector to examine the functional area in which the individual works, if that can be identified. However, the inspector should err on the conservative side, and not jeopardize the individual's right to employment if locating the individual is difficult. Inspection of the functional area is a goal, not a requirement.

The Inspection Report or field notes should not indicate that the inspection focused on the performance of a prior wrongdoer. Any violations or potential wrongdoing identified during the course of the inspection should be handled in the normal manner, unless it appears that the prior wrongdoer was involved in the violation. If the prior wrongdoer was involved in the violation, contact OE.

2. **Reactors and other licensees with resident inspectors**:

An SRI who has been notified by NRR that a previous wrongdoer is now employed at that facility can often identify unobtrusively the functional area in which the subject individual is working, using sources such as the licensee's telephone directory. During routine inspection activities, the resident should inspect the functional area in which the subject wrongdoer is working. The functional area should be periodically reviewed during the notice period.

The Inspection Report should not indicate that inspection activity focused on the performance of a prior wrongdoer. Any violations or potential wrongdoing identified during the course of the inspection should be handled in the normal manner, unless it appears that the prior wrongdoer was involved in the violation. If the prior wrongdoer was involved in the violation, contact OE.

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

The requirements in 10 CFR Part 26 addressing fitness-for-duty (FFD) programs apply to licensees authorized to:

- operate a nuclear power reactor,
- possess or use formula quantities of SSNM, or
- transport formula quantities of SSNM.

The requirements in 10 CFR 55 for operators' licenses requires that licensed operators follow FFD programs.

Therefore, each FFD issue must be evaluated to determine whether enforcement action should be issued against the facility licensee for failure to adequately implement a program or against the individual licensed operator for failure to follow the program.

7.4.1 Action Against the Facility Licensee for FFD Violations

Licensees subject to 10 CFR Part 26 must establish and implement a FFD program. Among other things, the program must provide reasonable assurance that nuclear power plant personnel, transporter personnel, and personnel of licensees authorized to possess or use formula quantities of SSNM, will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impairment from any cause, which in any way adversely affects their ability to safely and competently perform their duties.

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 program, including those of its contractors and vendors, that creates the violation. For example, 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.

Enforcement actions against facility licensees should be prepared and processed in accordance with the standard guidance for escalated and non-escalated actions.

➜**NOTE**: The significance of a FFD finding at an operating power reactor should be assessed by the ROP's SDP.

The significance of a FFD violation for all other licensees should be assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy and the examples in the Enforcement Policy Supplements.

Supplement VII of the Enforcement Policy provides examples of violations where the facility licensee failed to meet the requirements of 10 CFR Part 26.

The example for Severity Level I is of very significant concern because it represents the failure to implement a FFD program. This example would be applicable to a situation where essentially the licensee does not have a program in place.

The examples of Severity Level II are also very significant because they involve the failure to take action when there is the potential to have a direct impact on safety-related activities.

The examples for Severity Level III are significant because they represent failures of an established FFD program such that an individual who should have been denied access was allowed access due to certain failures directly within the licensee's control. Typically, these failures would be significant if the individual improperly granted access is later confirmed to test positive for illegal drug use. 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.

Severity Level IV violations are matters which, while requiring correction, are less significant to the overall FFD program.

7.4.2 Action Against the Licensed Operator for FFD Violations

10 CFR Part 55 sets forth the requirements for issuance of licenses to individuals to operate nuclear power plants. 10 CFR Part 55 specifies that the conditions and cutoff levels established pursuant to the Commission's FFD programs are applicable to licensed operators as conditions of their licenses. Therefore, citing the individual operator would be appropriate if he or she is unfit for duty. Section VIII of the Enforcement Policy addresses appropriate enforcement actions against individual licensed operators who fail to meet FFD requirements.

For a licensed operator's first confirmed positive test for drugs, the NRC will normally issue only a Severity Level III NOV in the absence of aggravating circumstances, such as evidence of continued, long-term use of drugs. There may be cases where the NRC chooses to exercise discretion and issue a Severity Level IV violation if the licensed operator voluntarily reports his or her failure. The second time the licensed operator fails a drug test, an order suspending the Part 55 license for up to 3 years will be issued. If the license has less than 3 years left, consideration should be given to whether the license should be renewed.

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.

NOTE: All enforcement actions issued to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level) are required to be paneled and require EA numbers during the review and approval stages and IA numbers when the actions are issued.

7.4.2.1 Preparing FFD Actions

Fitness-for-duty actions against licensed operators are not processed like other escalated actions. First, licensed operators' failures to meet FFD requirements are typically reported to the NRC by facility licensees. The NRC will normally take enforcement action based on this notification without conducting an inspection. Second, despite the normal policy of holding predecisional enforcement conferences prior to issuing action against an individual, predecisional enforcement conferences are not normally held for FFD issues against a licensed operator. In addition, predecisional enforcement conferences are not normally held prior to issuing escalated action against a licensee for a FFD issue. This is, in part, due to the NRC basing its enforcement action on notification from the licensee. Licensed operators are, however, provided an opportunity to contest the action after it has been issued.

The regions should prepare the enforcement package consisting of either the enforcement action transmittal letter (Form 30) and NOV (Form 31) or the combination transmittal letter and NOV (Form 32). The second option would be used when the facility licensee causes the licensed operator's license to expire.

In drafting the citation, it is important to note that the licensed operator may be in violation of Part 55 license conditions either (1) because of the use, sale, or possession of illegal drugs or use of alcohol (10 CFR 55.53(j)), or (2) because of the refusal to participate in the facility licensee's FFD program (10 CFR 55.53(k)).

In the latter case (i.e., violations of 10 CFR 55.53(k)), the citation should follow this 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)

For violations of 10 CFR 55.53(j), two separate situations are possible: (1) use, possession, or sale of illegal drugs or consumption of alcohol within the protected area, and (2) performance of licensed duties while under the influence of any substance that could adversely affect an operator's ability to safely and competently perform licensed duties. Since 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," performing duties immediately before or after submitting a urine sample that later tests positive would be considered performing duties "under the influence."

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. For example:

> 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)_;

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)

7.4.2.2 Coordination and Review for FFD Actions

Fitness-for-duty actions should be coordinated and reviewed according to the following guidelines:

a. 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. All cases when enforcement action is being considered to licensed operators for failures to comply with facility licensees' FFD programs (regardless of severity level) are required to be paneled and require EA numbers during the review and approval stages and IA numbers when the actions are issued. OE, the operator licensing staff in NRR, and NSIR should participate in enforcement panels.

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. The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary). 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. 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.

    2. Regional Counsel review and statement of no legal objection is required prior to issuance by the region.

    3. 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. (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.)

1. OGC will not normally provide comments for Severity Level III NOVs without a civil penalty or order.

   OGC review and concurrence (or statement of no legal objection) is required on all orders. **OGC will review the proposed order and provide comments to OE within 5 working days of receipt of the package.** (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. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days.** (The NRR Enforcement Coordinators normally provide comments for FFD cases.) 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. **Comments should be provided (verbally, electronically, or in writing) to the Director or Deputy Director, OE within 5 working days.** (The NSIR Enforcement Coordinators normally provide comments for FFD cases.) 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.

7.4.2.3 Signature Authority for FFD Actions

Fitness for duty 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 <u>after</u> 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.

7.4.2.4 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 this type of violation, it is appropriate to delay making the action available to the Public until the individual has had an opportunity to rebut the conclusion (see Section 7.4.2.5, below).

c. Copies of all FFD actions against licensed operators should be sent both to OE and the operator licensing staff in NRR.

7.4.2.5 Licensed Operator Response to FFD Action

Licensed operators are generally required to respond to NOVs within 30 days. Licensed operators are not required to respond to NOVs where the operator's license has expired, unless the licensed operator contests the action.

As discussed further below, licensed operator's responses to NOVs can either (a) accept the violation or (b) contest the staff's facts and conclusions regarding the NOV.

a. **If the licensed operator does not dispute that the violation occurred as stated in the NOV**, 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. Licensed operator's responses should normally be acknowledged by the region within 30 days after their receipt. The acknowledgment letter should be sent to the licensed operator. 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.

b. **If the licensed operator denies the violation**, the region should coordinate the agency's response to the licensed operator with OE. In these cases, the licensed operator's response should be carefully reviewed to ensure that the staff's initial action was appropriate. 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. If the licensed operator's response does not present additional information, then the region is to prepare a brief response addressing those points of contention. Even if the licensed operator's response does not present new information, if an error in the enforcement action is identified, it is to be corrected.

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. Licensed operator's responses that contest enforcement actions should normally be responded to within 30 days.

On the other hand, 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. The home address should be deleted from all documents made available to the Public.

7.5 OI Investigations And Reports

OI conducts investigations of alleged wrongdoing by non-NRC individuals or organizations who are licensed by the NRC, have applied for NRC licenses, or who are vendors or contractors of NRC licensees.

7.5.1 Delaying Enforcement Action Pending Investigation

As a general rule, in cases where an OI investigation is being conducted, enforcement action should not be taken for matters that are within the scope of the OI investigation until it has been completed and the report issued. Section 7.5.1.1 provides guidance for those cases where, despite a pending OI investigation, immediate action is warranted. Section 7.5.1.2 provides guidance regarding the policy of addressing technical issues apart from the OI issues.

7.5.1.1 Cases Requiring Immediate Action

If immediate action is required to protect the public health and safety, the staff will not await the completion of the OI investigation and report to initiate and issue enforcement action. This may be the case when the OI investigation discloses a significant safety issue, including where the preponderance of evidence indicates that a person in a position of responsibility has engaged in wrongdoing (i.e., has committed a willful act) that causes the NRC to lose reasonable assurance (1) that licensed activities will be performed in accordance with the Commission's requirements or (2) that there will not be an undue risk to public health and safety.

Therefore, if during an OI investigation, the OI Field Office Director concludes that sufficient evidence of wrongdoing exists, the OI Field Office Director will promptly notify the appropriate Regional Administrator. This preliminary conclusion is subject to change based on additional investigation and review.

Thereafter, the Regional Administrator will promptly consult with the Director, OE, who in turn will coordinate, as appropriate, with OGC and the appropriate program office to determine whether immediate action is necessary. If it appears that immediate action is appropriate, the Regional Administrator will request OI to promptly furnish the region, OE, OGC, and the program office with the evidence gathered (not the draft OI report) in order to develop an appropriate case and to also provide briefings as necessary. If it is determined that enforcement action should be taken, the Director, OE, will advise the Director, OI, of the reasons why enforcement action should proceed during the pending investigation. In addition, OE will coordinate with DOJ (in accordance with the NRC/DOJ Memorandum of Understanding) if the Director, OI, determines that the case will likely be referred to DOJ for prosecution (see Section 7.6.2).

If the Regional Administrator does not believe immediate action is necessary, after consultation with OE, the region should prepare a brief note to the regional case file, with a copy to OE and the program office, explaining the basis for the initial decision. This note should include the caveat that the initial decision is "based on evidence to date." As with other correspondence associated with enforcement matters, the note should be labeled, "Not For Public Disclosure." If disagreement exists between the Regional Administrator, the Director, OE, and/or the program office, the matter will be promptly elevated for the DEDO's consideration. After the complete OI investigation report is issued the need for regulatory action is to be reconsidered. If action has not already been taken, action should be taken, if warranted, after DOJ completes or declines the case, if it was referred to them.

7.5.1.2 Cases Not Requiring Immediate Action

Even if there is no immediate public health and safety concern, technical issues should be addressed apart from the OI issues if they can be addressed without compromising the pending OI investigation. In circumstances in which addressing the technical issue might involve release of information that could compromise the OI investigation, OI is to be consulted before the information is released. If there are associated violations arising from an inspection that can be separated from the issues OI is investigating, the region may proceed with an enforcement action for those violations before issuance of the OI report, but only after consultation with the Director, OE. However, once the OI report is issued, it is to be reviewed to determine if the separated action should be reopened.

7.5.2 Release of OI Transcripts of Interviews

Transcripts of interviews conducted to support enforcement action should **NOT** be released to licensees or the public without prior approval by the Director, OE and the Director, OI, until after the action has been issued. On the other hand, transcripts of interviews may be released to individuals, if an individual (or individual's attorney) requests a copy of the transcript of their OI interview to prepare for a predecisional enforcement conference (of which they are the subject), provided that the related OI investigation is complete and closed. The Director, OI and Director, OE should be consulted in these cases. In addition, the transcript of the individual's OI interview will **NOT** be made available to the Public until after the enforcement action is issued. Additional information is included in Management Directive 3.4, “Release of Information to the Public.”

7.5.3 Processing Administratively Closed OI Cases

OI may choose to administratively close a case for several reasons including a lack of resources or because of an ongoing activity by another agency associated with the case.

a. **Lack of Resources:** Whenever OI closes a case for lack of resources, OE will review the case and make an initial determination of the action, if any, that appears warranted. OE will first review the OI priority criteria and make a determination of whether the OI priority should be changed or whether the case should be reopened. If so, OE will either issue a memorandum to the applicable Regional Administrator or schedule a multi-office meeting involving the region, OGC, and the applicable program office to discuss the merits of changing the priority or reopening the investigation.

OE will also review the case to determine whether there is sufficient information in the report to conclude that a violation exists and whether enforcement action appears warranted.

If OE concludes that a non-willful violation exists, OE will issue a memorandum to the applicable Regional Administrator forwarding the case for the region to process.

If OE concludes that a willful violation exists, OE will schedule a multi-office meeting with the region, OGC, and the applicable program office to discuss the general direction of any enforcement action that may be appropriate.

If OE concludes that neither a violation nor wrongdoing exists, it will issue a memorandum to the Regional Administrator, the Associate General Counsel for Hearings, Enforcement & Administration, and the appropriate Office Director, indicating this and inviting them to respond to the OE proposal of no enforcement action. If, after 3 weeks, OE has not received differing views, the matter will be considered closed. Subsequently, the requesting office should send a letter to the licensee or vendor to notify them that the matter has been resolved or closed. A copy of the OI report synopsis should be attached to the letter to the licensee.

Release of the synopsis should be coordinated with the OI Field Office Director, unless authorization for release was previously granted. The office sending the close-out letter should also coordinate with OE to verify that the matter is in fact closed and that no other office has an open issue.

Additional information is included in Management Directive 3.4, "Release of Information to the Public."

b. **Activity by Another Agency:** OI may administratively close a case because another agency, such as DOL or DOJ, may be considering action associated with the case. In these cases, OE will assign an EA number to the case in an effort to ensure that the staff revisits the case after the other agency has completed its activity.

7.5.4 Processing OI Reports

Enforcement actions involving violations addressed in OI Reports, whether willful or not, require coordination with OE.

➜**NOTE**: The staff should treat OI assists like OI reports in those cases where the OI assist includes a conclusion (i.e., willful, not willful, violation, no violation).

This section and its subsections provide guidance on the steps associated with processing OI reports and OE coordination. The "responsible office" indicated below is the region or program office responsible for the allegation(s) that were the subject of the OI investigation.

Step 1: Receipt and initial screening of the OI report by the responsible office (Section 7.5.4.1).

- Immediate safety concern (Section 7.5.4.1.a), or
- Enforcement action appears warranted (Section 7.5.4.1.b), or
- Enforcement action does not appear warranted; responsible office proposes to close case (Section 7.5.4.1.c), or
- Disagreements with OI conclusions (Section 7.5.4.1.d)

Step 2: OGC completes analysis of the OI report to determine if sufficient evidence exists to support enforcement action (Section 7.5.4.2).

Step 3: Enforcement panel to determine the general direction of any enforcement action that may be appropriate. (Section 7.5.4.3).

Step 4: Preparing and processing enforcement action. (Section 7.5.4.4)

Regardless of the age of issues addressed by OI reports, processing OI reports is considered an enforcement priority. Therefore, timeliness goals stated within the steps of these procedures should be followed, if possible. Notwithstanding the stated timeliness goals, it is recognized that additional review time may be necessary for unusually complex cases or those with an unusually large number of exhibits.

7.5.4.1 Receipt and Initial Screening of OI Report

Upon receipt of the OI report, OE, the region, and the appropriate program office will determine from the OI report and exhibits whether safety concerns are identified, and whether, on the basis of these concerns, immediate regulatory action is warranted. The review of the OI report should recognize the importance of the exhibits as the evidence to support NRC conclusions. **Conclusions should be based on the evidence in the exhibits of the OI report. The OI report should serve as an overview to guide review of the exhibits.**

Within 1 week of receiving an OI report, the responsible office will review the case and make an initial determination that: (a) an immediate safety concern exists, (b) no immediate safety concern exists, but enforcement action appears warranted, or (c) no enforcement action appears warranted.

a. **Immediate Safety Concern**: If the responsible office or program office believes an immediate safety concern exists, they will immediately notify OE. The region, program office, and OE together will evaluate the need for immediate regulatory action, such as the issuance of an immediately effective order. If immediate enforcement action is warranted, OE will coordinate the action with the other offices, including OGC, and expedite the process. This should be a rare occurrence, in light of the coordination that should have occurred when the matter was first identified. If any other office or region believes that immediate action is warranted, OE should be immediately contacted. For cases which have been referred to DOJ, refer to the Memorandum of Understanding for guidance.

b. **Enforcement Action Appears Warranted**: If the OI report findings indicate that no immediate safety concern exists, but enforcement action may be appropriate, the responsible office will coordinate with OE to schedule an enforcement panel with the region, OE, the program office, and OGC to discuss the findings of the OI report and the development of possible enforcement action. The panel should be scheduled for approximately 4 weeks from the receipt date of the OI report. The responsible office should invite OI to participate.

   If the OI report does not indicate willfulness, but there are still violations present, the responsible office may, in its 3-week e-mail message (see Section 7.5.4.1.c), indicate that barring a differing view, the non-willful violations will be treated in accordance with normal enforcement processes.

c. **No Enforcement Action Appears Warranted**: If there does not appear to be a violation of NRC requirements, the responsible office enforcement coordinator will normally issue an electronic mail (e-mail) message within 1 week after receiving the OI report indicating that no enforcement action is being considered. This message (formerly a memo) is commonly

referred to as a "3-week e-mail" based on the allowed response time specified in the message. The e-mail message, addressed to the Director of OE, the Assistant General Counsel for Materials Litigation and Enforcement, and the appropriate Office Director or Regional Administrator, will invite others to respond to the proposal of no enforcement action. Copies of the e-mail message should also be sent to "OEMAIL" and the Regional Enforcement Coordinator and program office Enforcement Coordinator.

If, after 3 weeks from the date of the e-mail message, the responsible office has not received differing views, the matter will be considered closed. Subsequently, the requesting office should send a letter to the licensee or vendor (if individuals other than the alleger were interviewed during the investigation) to notify them that the investigation is complete and that no enforcement action is being proposed. A copy of the OI report synopsis normally should be attached to the letter to the licensee. Release of the synopsis should be coordinated with the OI Field Office Director, unless authorization for release was previously granted. (The region, in coordination with OI, will ensure that the identity of any alleger or confidential source will not be compromised through the release of the synopsis.) A closure letter is also sent to the alleger in accordance with Management Directive 8.8, "Management of Allegations."

d. **Disagreements With OI Conclusions**: In cases where any NRC staff (other than OI) disagrees with an OI report conclusion regarding willfulness, the assigned OGC attorney should be promptly informed. If the disagreement is not subsequently resolved, Commission consultation is needed unless the Director, OI agrees that it is not warranted. The Director, OE, will coordinate with OI (Headquarters) if the Commission is not consulted, and OE should document the nature of the disagreement, how it was resolved, and the concurrence of the Director, OI, in proceeding with the agreed upon disposition without Commission consultation.

7.5.4.2 OGC Analysis of OI Report

Within 2 weeks of receiving an OI report which substantiates discrimination or other willful violations, OGC should complete its review of the OI report and exhibits and inform the responsible office enforcement coordinator and OE Enforcement Specialist whether there is sufficient evidence to support enforcement action. At that time, the assigned attorney should discuss the apparent willful violations and the evidence which supports those violations with the assigned OE Enforcement Specialist and/or the responsible office enforcement staff to assist the region or program office in preparing for the enforcement panel. If OGC determines that there are significant legal concerns with the OI conclusions or that there is insufficient evidence to support them, OGC should promptly inform OE. OE will coordinate with OI and the other offices to determine the appropriate course of action during the enforcement panel. If OE, the region, or the program office identify weaknesses in the evidence, they should promptly inform the assigned OGC attorney so that their views can be considered.

7.5.4.3 Enforcement Panel for OI Report

The responsible region or program office should prepare for an enforcement panel by preparing an enforcement panel worksheet, including the responsible office's enforcement recommendation. For discrimination cases, OE will prepare a written analysis of the evidence for purposes of the enforcement panel discussion, see Section 7.7.5. Within approximately 4 weeks of receiving an OI report, OE, the region, OGC, and the applicable program office will

participate in an enforcement panel to determine the general direction of any enforcement action that may be appropriate. Therefore, it is important that participants be authorized to speak for their office. If OGC's determination of the sufficiency of the evidence takes longer than 2 weeks, the panel may need to be delayed; however, it should be held within 2 weeks following OGC's determination.

During the panel, the participants, among other things, may or may not:

- agree with the OI findings,
- agree on the issue of willfulness and the degree (i.e., careless disregard or deliberate intent),
- conclude that additional information is required, and
- agree on the appropriate enforcement action approach.

For the first two scenarios, it may be appropriate for the OI Field Office Director or the investigator to provide a briefing to the rest of the staff on the details of the case. For the third situation, additional information may be necessary for a number of reasons. Occasionally, OGC may identify a weaknesses in the evidence and at the panel, OI may be asked as to the likelihood of obtaining further information through investigation. Alternatively, after consulting with OI, it may be appropriate to issue a Demand for Information to request additional information from the licensee. Finally, in discrimination cases where DOL determined discrimination occurred and OI did not substantiate, it may be appropriate, depending upon the basis of the DOL decision, for the panel to review the DOL documentation (e.g., Final Investigative Report, ALJ hearing transcripts, etc.). For the fourth situation, if consensus cannot be reached during this panel regarding the enforcement action approach, OE will promptly arrange a meeting with the Regional Administrator, the Director, OE, the appropriate program office representative, and the DEDR. For disagreements with OI report conclusions that willful violations occurred, see the guidance in section 7.5.4.1.d.

➜**NOTE**: If the panel participants decide that action will not be taken against an individual (for what ever reason) the staff should prepare a close-out letter using Form 45 in Appendix B.

7.5.4.4 Enforcement Action for Willful Violations

If the case has not been referred to DOJ (see Section 7.6 for guidance on cases referred to DOJ), the region should, if applicable, schedule a predecisional enforcement conference with, or issue a choice letter to the licensee. The conference letter or choice letter will normally include a factual summary which provides notice to the conference participants of the factual basis for the staff's preliminary conclusion that NRC regulatory violations occurred. The summary should provide sufficient factual detail to fully apprize conference participants of the operative facts involved in the apparent violation. It is not intended to provide a full discussion of the evidence gathered in the course of the NRC's investigation. The summary should not normally include the names of individuals involved in the potential enforcement matter, rather titles or other generic description should be utilized. Other personal or proprietary information should not be included. While the length of the summary in each case depends on the facts, it should not ordinarily exceed two single-space pages. (An example of such a summary is provided in Appendix D.) In most cases the factual summary will provide the same information that is contained in the OI report synopsis; therefore, the synopsis need not normally be enclosed.

In certain cases, typically when the proposed enforcement action is based upon a decision by an Administrative Law Judge of the Department of Labor, no factual summary should be necessary, since the participants will be fully conversant with the facts to be discussed at the predecisional

enforcement conference. In addition, there may be other matters in which the parties have investigated or adjudicated the issues and, thus, the staff need not automatically prepare a summary when it proposes an enforcement conference. A recommendation to forgo preparation of a factual summary should normally be agreed to at the enforcement panel.

The conference letter or choice letter should be provided to the licensee at least 2 weeks in advance of the conference. The letter should be coordinated with OE and OI. (The region, in coordination with OI, will ensure that the identity of an alleger or confidential source will not be compromised through the release of the factual summary or synopsis.) In employment discrimination cases, a separate letter should be sent to the individual subject to the alleged discrimination providing the individual an opportunity to attend the licensee's conference. The individual should also be provided with a copy of the letter to the licensee.

Generally, OI reports and exhibits are not available to the licensee or public until after the enforcement action has been issued, except in cases involving DOL hearings. In these cases, the region is to prepare a transmittal letter, using Form 44, to send the OI report synopsis to the parties involved in the DOL action. The letter notes that the full report may be requested under the FOIA. The Director, OE should be consulted before release of any OI report (and/or exhibits) associated with an enforcement action.

Reports will not normally be provided if OI concludes that disclosure could interfere with ongoing investigation activities. If this situation arises, the Regional Administrator and Director, OE, will consult on how to proceed. In addition, in any case, exhibits will normally be provided only if requested through the FOIA process. Additional information is included in Management Directive 3.4, "Release of Information to the Public."

Within 11 weeks of receiving an OI report, the region should prepare and submit the recommended enforcement action to headquarters.

➜**NOTE**: With the exception of violations against the deliberate misconduct rule, NOV "contrary to" paragraphs should **not** include the word "willful" or "deliberate misconduct." In these cases, the discussion of willfulness should be included in the cover letter as part of the significance discussion. Including "deliberate misconduct" in "contrary to" paragraphs is required when violations are based on the deliberate misconduct requirements.

The region should prepare a Commission paper as part of the recommended enforcement action package, if the Enforcement Policy or guidance in this Manual so requires. If a Commission paper is required because of disagreements concerning willfulness, the Commission paper should include a summary of the rationale upon which OI based its conclusions and a summary of the non-OI staff's basis for reaching different conclusions.

7.6 Department of Justice (DOJ) Referrals

Alleged or suspected criminal violations of the AEA and other relevant Federal laws are referred to DOJ. OI refers cases to DOJ during or upon completion of an OI investigation where willful violations are suspected.

7.6.1 Policy on Withholding NRC Action

As a general policy, if a matter has been referred to the DOJ, unless immediate action is necessary for health and safety reasons, issuance of an enforcement action should be withheld to avoid potential compromise of the DOJ case, pending DOJ determination that the enforcement action may be issued. All enforcement cases involving referrals to DOJ should be coordinated with OE.

7.6.2 Memorandum of Understanding (MOU) Between NRC and DOJ

The MOU between the NRC and DOJ is included on the **Enforcement** Web site.
http://www.nrc.gov/what-we-do/regulatory/enforcement/moudoj.pdf

As stated in Section I of the MOU, this document provides for (1) coordination of matters that could lead to enforcement action by the NRC as well as criminal prosecution by DOJ and (2) the exchange of information. Section II of the MOU addresses, among other things, the responsibilities of each agency. Section III addresses areas of cooperation and is the substance of the MOU.

Section III.A of the MOU describes DOJ's responsibility to provide NRC with safety information. Section III.B describes the NRC's responsibilities to notify DOJ of suspected criminal violations. That section not only addresses NRC referrals after an investigation is completed but also describes special circumstances in which the NRC is to notify DOJ before completion of an investigation. The Director, OI, is responsible for notifications concerning referrals of suspected criminal violations and of investigations involving special circumstances.

Section III.C of the MOU addresses coordination with DOJ on NRC regulatory activities that run parallel to or may affect DOJ activities. Under this section, potential NRC actions are divided into three categories.

Section III.C.1 covers actions the NRC needs to take when it concludes that (a) it lacks reasonable assurance that activities authorized by a licensee are being conducted without endangering the health and safety of the public and that (b) immediate action is required to protect the public health, safety, or interest. Within this category, the NRC will take those actions necessary to fix the immediate problem. NRC is to notify DOJ in advance if time permits and, if not, as soon as possible after the action is taken. This category applies when time does not allow for reasonable consultation.

Section III.C.2 addresses regulatory actions not covered by C1 or C3. This category provides for consultation. NRC is required to consider the views and concerns of DOJ **to the fullest extent possible** consistent with the regulatory action that the NRC believes is required.

Section III.C.3 addresses civil penalty actions. Before issuing a civil penalty based on a referred case or one involving "special circumstances," the NRC will notify DOJ of the contemplated action. NRC should defer initiation of the action until DOJ either concludes its criminal investigation or prosecution, or consents to the NRC action. One exception is provided, pertaining to matters involving statutes of limitations.

If NRC proceeds with a case that DOJ is still processing, NRC has agreed to seek a stay in any resulting hearing, provided DOJ is prepared to support the staff with appropriate affidavits and testimony. The Director, OE, is the staff official responsible for coordinating regulatory activities with DOJ. OGC also has certain coordination responsibilities.

Section III.D describes the time frames for consultation. Under this section, NRC is committed to notify the DOJ of contemplated civil enforcement action, **normally** within 45 days of a referral to DOJ. DOJ is required, in turn, to notify NRC of its preliminary position on criminal prosecution or investigation, **normally** within 60 days of the referral.

Sections III.E and F of the MOU address exchanges of information between the two agencies and NRC assistance to DOJ.

7.6.3 NRC Enforcement Action

Notwithstanding the policy on withholding NRC enforcement action for those cases referred to DOJ, the staff should take certain actions to ensure timely processing of enforcement actions upon DOJ release or declination.

Within 6 weeks of receiving an OI report, or 2 weeks after the enforcement panel (see Section 7.5.4.3 for guidance concerning this panel), the Director, OE, will normally contact DOJ to advise them of the NRC's intended direction in terms of any potential enforcement action. This will enable DOJ to advise OE if an NRC enforcement action will interfere with planned DOJ action.

If DOJ does not object to the conduct of a predecisional enforcement conference, then the region should conduct an enforcement conference and submit a preliminary recommended enforcement action in accordance with the guidance in Section 7.5.4.4.

If DOJ requests that the NRC stay the conduct of a predecisional enforcement conference, the region should consult with OE on whether a preliminary action should be drafted pending DOJ review.

If DOJ determines that a referred case lacks prosecutive merit, it will normally notify the NRC (Director, OI) by a letter of declination. OI should promptly call OE upon receipt of the letter and should send copies of the letter to OE and the applicable region as soon as possible so that the enforcement process can proceed in a timely manner.

Following DOJ release or declination, the region should promptly hold a predecisional enforcement conference, if one has not already been held. After the conference, the region should make any necessary adjustments to the draft enforcement action based on the information provided during the conference. The region should submit its revised recommendation to OE within a week of the conference and OE will then process the case on an expedited basis.

7.7 Discrimination for Engaging in Protected Activities

The NRC places a high value on nuclear industry employees being free to raise potential safety concerns, regardless of the merits of the concern, to both licensee management and the NRC. Therefore, one of the goals of the NRC's Enforcement Policy is to ensure, through appropriate enforcement action against a licensee or licensee contractor (and when warranted, against the individual personally responsible for the act of discrimination), that employment actions taken against licensee or contractor employees for raising safety concerns do not have a chilling effect on the individual or others on the reporting of safety concerns.[1] For purposes of this guidance, discrimination should be broadly defined and should include intimidation or harassment that could lead a person to reasonably expect that, if he or she makes

[1] Although licensees will be held responsible in enforcement actions for the discriminatory actions of their contractors, they are not required to specifically report allegations of harassment, intimidation, or discrimination.

allegations about what he or she believes are unsafe conditions, the compensation, terms, conditions, and privileges of employment could be affected.

Section 211 (formerly 210) of the ERA provides that no employer may discharge or otherwise discriminate against any employee with respect to compensation, terms, conditions, or privileges of employment because the employee engaged in certain protected activities. These protected activities include notifying an employer of an alleged violation of the AEA or ERA, refusing to engage in any practice made unlawful by those acts, testifying before Congress or in a Federal or State proceeding regarding any provision of these acts, or commencing, testifying, assisting, or participating in a proceeding under these acts. NRC regulations that are related to the protection of whistle blowers include: 10 CFR 19.20, 30.7, 40.7, 50.7, 60.9, 61.9, 70.7, 72.10, and 76.7. In addition, 10 CFR Part 50, Appendix B, Criterion I provides that persons and organizations performing quality assurance functions shall have sufficient authority and freedom to identify problems and provide solutions.

Allegations of discrimination can be made directly to the NRC or to the Department of Labor (DOL) or both. This section describes:

- the Memorandum of Understanding between the NRC and the DOL (Section 7.7.1),
- how to handle discrimination complaints filed directly with the NRC (Section 7.7.2),
- the process for dispositioning discrimination complaints filed with the DOL (Section 7.7.3),
- the action the NRC should take to address the potential chilling effect at a licensee's facility when discrimination complaints are raised (Section 7.7.4),
- the documentation of the analytical process in discrimination matters (Section 7.7.5),
- the preparation of NRC enforcement actions for discrimination violations (Section 7.7.6),
- the options for exercising discretion for discrimination violations (Section 7.7.7),
- the handling of continuing violations involving discrimination (Section 7.7.8),
- whether to take enforcement action against contractors and individuals for acts of discrimination (Section 7.7.9), and
- application of the *Corrective Action* civil penalty assessment factor (Section 7.7.10).

7.7.1 Memorandum of Understanding (MOU) Between NRC and DOL

The MOU between the NRC and DOL is included on the **Enforcement** Web site. http://www.nrc.gov/what-we-do/regulatory/enforcement/moudol.pdf

The MOU describes the responsibilities of the NRC and DOL in protecting the rights of employees as specified in Section 211 of the Energy Reorganization Act (ERA) of 1974, as amended. Section 3 of the MOU provides that the two agencies will "...cooperate with each other to the fullest extent possible in every case of alleged discrimination involving employees of Commission licensees, applicants, or contractors or subcontractors of Commission licensees or applicants."

Under the MOU between NRC and DOL, if DOL receives a complaint concerning a possible violation of Section 211, it will promptly notify the NRC and inform the NRC whether DOL intends to investigate the matter. DOL also will notify the NRC of the results of the Occupational Safety and Health Administration's (OSHA's) Notice of Determination (the results of the DOL investigator's conciliation effort and investigation), of the Recommended Decision and Order of the Administrative Law Judge (if the Notice of Determination is appealed by either party), and of the Final Order of the Secretary of Labor, rendered by the Administrative Review Board. The NRC will facilitate DOL's

investigations by taking all reasonable steps to assist DOL in obtaining access to licensed facilities and any necessary security clearances.

The two agencies also developed procedures for implementing the MOU to ensure prompt notification, investigation, and followup of complaints involving alleged discrimination against employees who have contacted or attempted to contact the NRC. These procedures are also included in the MOU.

The division of responsibilities between the two agencies for processing discrimination complaints that have been filed with the DOL is detailed in the Sections 7.7.3.1 and 7.7.3.2.

7.7.2 Processing Discrimination Complaints Filed With NRC

If an employee does not file an allegation of discrimination with DOL, but instead raises the concern directly to an NRC employee, then that NRC employee should be sensitive to the NRC responsibilities in this area and should make sure that the alleger understands that the NRC is concerned about these complaints. The NRC employee who receives the complaint is to follow the guidance in MD 8.8.

7.7.3 Processing Discrimination Complaints Filed With DOL

The division of responsibilities between the two agencies for processing discrimination complaints that have been filed with the DOL is detailed in the Sections 7.7.3.1 and 7.7.3.2.

7.7.3.1 Department of Labor Process

The Department of Labor is authorized by the Energy Reorganization Act to order personal remedies for an individual found to have been discriminated against by an NRC licensee. On the other hand, the NRC is not authorized to order personal remedies, but is responsible for regulating the nuclear industry and can take enforcement action against a licensee for discriminating against an employee for engaging in protected activities. In accordance with these different responsibilities, whereas the NRC may receive an anonymous allegation which it may decide to investigate and could later act on the findings, the DOL process starts when an individual files a complaint with the DOL seeking personal remedies.

The following guidance describes the steps in the DOL process. In accordance with the MOU between DOL and NRC, the DOL will send copies of official correspondence and decisions to the NRC to assist the NRC in tracking complaints of discrimination at licensed facilities. The NRC tracks these complaints through NRC-6, "Discrimination Cases", a system of records that has been noticed in the Federal Register.

a. **OSHA**

In accordance with Section 211, a complaint filed with the Department of Labor is first reviewed by OSHA to determine whether the complainant has established a prima facie case. If he or she has, OSHA will acknowledge the complaint by letter and assign a compliance officer to investigate the allegation. The compliance officer will interview individuals associated with the allegation of discrimination, compile a "narrative report" of these interviews, and make a recommendation as to whether discrimination occurred. **[NOTE: The information provided by DOL to the NRC, especially the compliance officers' narrative reports, should not be publicly released without the permission of DOL other than documents NRC knows to be public.]**

OSHA will then issue a decision and will send copies of this decision to the complainant and his or her employer. Note that sometimes the employer of record is a licensee contractor and, in some cases, the licensee may not know at this point that a complaint was even filed against its contractor.

b. **Appeal**

An appeal of OSHA's decision can be filed within 5 days of the decision with the Office of Administrative Law Judges (ALJ). If no appeal is filed within that time, OSHA's decision is considered a final decision of the Secretary of Labor.

c. **Administrative Law Judge**

If there is an appeal, an "ERA" number will be assigned by DOL and the ALJ assigned to the case will schedule and conduct a hearing on the issues involved in the complaint. The ALJ will then issue a Recommended Decision and Order which can be appealed to the Secretary of Labor. If no appeal is sought by either party, the ALJ's decision becomes the final DOL decision.

d. **Secretary of Labor**

The Secretary of Labor will review the ALJ's Recommended Decision and Order, if one of the parties requests review. Where the Recommended Decision and Order finds discrimination and recommends relief, the Secretary is required to issue a preliminary order providing that relief, not including compensatory damages, pending the Secretary's decision on the matter. The Secretary, on May 3, 1996, delegated this authority to the Administrative Review Board of the Department of Labor.

e. **Additional Appeals beyond the Secretary of Labor**

The party against whom the Secretary rules may appeal the decision to U.S. Court of Appeals.

f. **Settlements**

The individual and the employer may settle the matter after a complaint is filed with the Department of Labor but before a final decision is reached by the DOL.

7.7.3.2 NRC Process

The following guidance describes the steps of the NRC enforcement process in terms of the steps of the DOL process identified in Section 7.7.3.1 above. It should be noted that if OI investigated the matter, it may not be necessary to wait until DOL completes its process.

a. **OSHA**

If the complaint is withdrawn or settled before OSHA issues a finding, or if OSHA concludes that the complaint was not timely filed, the NRC should review the complaint and any associated documents and an Allegation Review Board should be convened to determine whether an OI investigation is necessary. If additional information is needed from the DOL, it can be requested using Form 29.

If OSHA concludes that discrimination occurred and:

- the licensee or contractor appeals the decision, the region should request a copy of the DOL compliance officer's narrative report and should prepare a chilling effect letter (CEL) (see Section 7.7.4.1), or

- the licensee or contractor does not appeal the decision, it is considered a final order of the Secretary of Labor and enforcement action may be appropriate. Before initiating enforcement action, the region should request a copy of the DOL compliance officer's narrative report and should coordinate the matter with OE and OE will consult OGC to determine if a CEL or enforcement action should be issued (see Section 7.7.6).

If OSHA concludes that no discrimination occurred and:

- the individual does not appeal the decision, the region should request a copy of the DOL compliance officer's narrative report. This report should be reviewed to ensure that the NRC can close the matter with no further action, or

- the individual appeals the decision, the region should request a copy of the DOL compliance officer's narrative report to determine if some action, e.g., a CEL, is necessary while the NRC awaits the ALJ's Recommended Decision and Order.

b. **Appeal**

If OSHA's finding of discrimination is appealed by the licensee or contractor, the region should prepare a CEL (see Section 7.7.4.1). If OSHA's finding of no discrimination is appealed by the individual, the NRC should await the ALJ's Recommended Decision and Order.

c. **Administrative Law Judge**

After conducting a hearing, the ALJ will issue a Recommended Decision and Order. The Energy Policy Act of 1992 revised Section 211 of the Energy Reorganization Act to, among other things, require the Secretary of Labor to issue a preliminary order providing certain relief specified by the ALJ while awaiting the final order of the Secretary. The Secretary of Labor has delegated responsibility for reviewing ALJ determinations to the Administrative Review Board (ARB).

If the ALJ finds that discrimination occurred, the region should request an EA number and initiate the enforcement process. The appropriate enforcement action should be issued following the issuance of the ALJ's Recommended Decision and Order. If a civil penalty is proposed, the enforcement action will require a response in accordance with the provisions of 10 CFR 2.201. However, the action should delay the licensee's response to the provisions of 10 CFR 2.205 (i.e., payment of any civil penalty) until 30 days after the DOL decision becomes final. If no appeal from an ALJ's Recommended Decision and Order is filed, the 30 day period should commence 10 business days after the ALJ's decision is rendered..

The region should also consider whether it would be appropriate to take some action against the contractors or individual(s) found by the ALJ to be responsible for the discrimination. (See Section 7.3 for guidance on enforcement actions involving individuals.

If the ALJ finds no discrimination, the NRC should await issuance of the Secretary of Labor's decision, if an appeal is filed.

If the ALJ dismisses the complaint for procedural reasons (withdrawal, settlement, or untimely), the region should review the record, including the earlier OSHA decision, and determine whether it is appropriate to initiate the enforcement process, to request additional OI investigation, or wait for the ARB's ruling, if an appeal is filed.

d. **Administrative Review Board (ARB)**

If, on a timely appeal, the ARB affirms the ALJ's finding of discrimination, the licensee is expected to respond to any civil penalty already issued by the NRC. Although no specific action is required by the NRC at this point, the region should ensure that the licensee has received notice of the ARB Order, especially in cases in which the Respondent is a licensee contractor, to avoid a delay in the licensee's response.

If the ARB affirms the ALJ's finding of no discrimination, the region would normally close the case without further action. If the ARB reverses the ALJ's finding that discrimination occurred and dismisses the case, normally NRC would withdraw the enforcement action if it was based solely on the DOL process (i.e., without independent findings from an OI investigation that discrimination had occurred).

If the ARB reverses the ALJ's finding that no discrimination occurred, concluding instead that discrimination did occur, the region should request an EA number and initiate the enforcement process.

If the ARB dismisses the case for procedural reasons, (withdrawal, settlement, or untimely), the region should review the record, including the earlier ALJ's decision, and determine whether earlier enforcement was appropriate, whether to impose the civil penalty, or withdraw the proposed civil penalty.

e. **Additional Appeals beyond the Secretary of Labor**

The party against whom the Secretary rules may appeal the decision to U.S. Court of Appeals. Absent a stay issued by the Court, the NRC enforcement action is not stayed. Therefore, the region should consult with OE in such cases.

f. **Settlements**

The individual and the employer may settle the matter after a complaint is filed with the Department of Labor but before some final decision is reached by the DOL. In such cases, the NRC will normally need to develop the evidence to support an enforcement action if it is to prevail.

7.7.4 Chilling Effect of Actual or Potential Discrimination

In addition to concerns about the appropriate enforcement action in cases of actual discrimination (Section 7.7.3.2), the NRC must also consider the impact of such discrimination in the workplace, i.e., whether the awareness of the discriminatory act will discourage other licensee and contractor employees from raising safety concerns.

Section 7.7.4.1 describes the use of chilling effect letters; Section 7.7.4.2 describes the action the NRC should take when there are repetitive findings of discrimination at a licensed facility; and Section 7.7.4.3 describes the action the NRC should take when there are numerous settlements without findings of discrimination at a licensed facility.

7.7.4.1 Chilling Effect Letter (CEL)

In each case of a finding of discrimination, the NRC should bring the matter to the attention of the licensee. This correspondence, referred to as a chilling effect letter (CEL), serves three purposes: (1) to notify the licensee of the NRC's concern, (2) to understand the basis for the licensee's position on whether or not discrimination occurred, and (3) to obtain a description of any remedial action the licensee plans to take to address the potential chilling effect. Remedial action may be warranted, even if the licensee disagrees with the finding of discrimination, because of the potential for a chilling effect.

The NRC should normally issue a CEL after the DOL investigation has been completed and a finding has been made of discrimination. However, if the licensee settles a case soon after the DOL finding and does not challenge the finding in an adjudication, the chilling effect may be minimized and a CEL need not be issued.

The CEL requires that the licensee describe: (1) its position regarding whether the actions affecting the individual violated 10 CFR 50.7 (or other requirement) and the basis for its position, including the results of any investigations it may have conducted to determine whether a violation occurred, and (2) the actions taken or planned to ensure that the matter is not having a chilling effect on the willingness of other employees to raise safety and compliance concerns within its organization, and as discussed in NRC Form 3, to the NRC.

The licensee's response to the CEL is mandatory under the provisions of the AEA, 10 CFR 2.204 (Demand for Information), and the provision of the applicable part of 10 CFR implementing Section 182 of the AEA. A sample CEL is included in Appendix B, as Form 28.

When a CEL is to be issued, the region should request an EA number which allows OE and the region to track CELs for each licensee. Since the EA should be closed upon issuance of the CEL itself, the region must send a copy of the letter to OE. Any subsequent enforcement action proposed will be given a separate EA number.

➜**NOTE**: There may be special cases involving allegations of a chilled work environment (i.e., no DOL complaint or finding) where issuance of a CEL is appropriate. The region should consult with an OE Enforcement Specialist to discuss the issuance of a CEL and determine the appropriate coordination with OE. If a CEL is to be issued, the region should request an EA number. Because the CEL in this case is in response to an allegation versus a DOL finding, NRC OI investigation, or NRC inspection, the letter should not include the mandatory licensee response language in a traditional CEL (i.e., DFI). Form 28 should NOT be used to draft the CEL. The CEL should address the NRC's concerns and *request* a response from the licensee.

7.7.4.2 Repetitive Findings of Discrimination

As additional findings of discrimination are reached, the NRC's response (in addition to any enforcement action) should escalate on the premise that a pattern may be developing.

If two investigative findings of discrimination by the same licensee are made within 18 months (either by OI or OSHA), the region should request an EA number and schedule a multi-office enforcement panel to discuss the agency's strategy for requesting the licensee to ascertain whether a cultural problem exists and to identify any particular areas within the workplace in which supervisors do not appreciate the importance of raising concerns. To do this, the NRC can require the licensee's senior management to meet with the Regional Administrator to explain the employment actions in question, and to address what actions the licensee is taking to ensure that employees are not "chilled." The licensee should also be expected to address: (1) whether it has confidence that remedial actions have been effective; and (2) the basis for this view. The letter establishing this meeting can be in lieu of, or combined with the CEL.

If more than two investigative findings of discrimination occur within an 18-month period, the NRC should consider stronger action. As part of that consideration, a DFI might be issued as to why the licensee should not be ordered to obtain an outside independent contractor (1) to review the licensee's programs for maintaining a safety-conscious work environment or safety culture; (2) to survey employees to determine whether they feel free to raise concerns without fear of retaliation; and (3) to develop recommendations, if warranted, to improve the workplace environment. If an adequate response is not received to this DFI, then the NRC should consider an order.

7.7.4.3 Numerous Settlements Without Findings of Discrimination

If a licensee has numerous cases which end in settlement agreements before DOL reaches a finding of discrimination at any level, the region should consider whether this is: (1) indicative of true, though uninvestigated, discrimination, or (2) a chilling effect. The NRC must be careful in such considerations not to be perceived as discouraging settlements.

7.7.5 Documented Analytical Process in Discrimination Matters

In every discrimination matter the staff considers for enforcement action, it will prepare, prior to and for purposes of the enforcement panel discussion, a written summary of the evidence that may support each element of a discrimination case. Those elements are as follows:

- Did the employee engage in "protected activity" as that term is defined in Section 211 of the Energy Reorganization Act of 1974, and the Commission's discrimination requirements, e.g., 10 CFR 50.7(a)(1), and interpreted by the Department of Labor and the courts?

- Was the employer (an NRC licensee, applicant for an NRC license, contractor or subcontractor of a licensee or applicant) aware of the protected activity at the time of the adverse action?
- Was an adverse action taken by the employer against the employee, which affected the employee's terms, conditions or privileges of employment?
- Was the adverse action taken, at least in part, because of the protected activity?

The purpose of the written analysis is to reach a determination in each discrimination matter as to whether, based on all the available evidence, there is information sufficient to provide a reasonable expectation that a violation of the Commission's discrimination requirements, e.g., Section 50.7, can be shown by a preponderance of the evidence. The written analysis should include a statement of OGC's position, if available, as to whether the evidentiary standard is satisfied. The written analysis for each matter should be utilized as a basis for the enforcement panel discussion and will be placed in the enforcement file.

The analysis may well be revised during the deliberative process, as the matter is further considered by all NRC components involved in the enforcement process. Revised analyses should be distributed to the principal participants in the deliberative process. The length of the analysis should normally be limited to one or two pages. Its purpose is to summarize the basic facts of the case as it relates to the required elements. It is not intended to serve as a full analysis of all of the evidence reviewed by the staff. OGC should work with the staff in preparing and revising the analysis.

Appendix D includes a sample written analysis of a discrimination matter that the staff may use as a guide in preparing summaries.

OE will coordinate with the region to determine who will prepare the analysis on a case-by-case basis. The staff and OGC's conclusion may be added after the panel.

7.7.6 Preparing NRC Enforcement Action and Severity Level Categorization for Discrimination Violations

The particular sanction to be issued for a discrimination violation should be determined on a case-by-case basis. Examples of sanctions that may be appropriate include NCVs, NOVs, civil penalties, orders, or DFIs.

Supplement VII of the Enforcement Policy includes examples of Severity Level I, II, and III violations based on discriminatory acts by senior corporate management, plant management or mid-level management, and first-line supervision or other low-level management, respectively. Notwithstanding an individual's specific job title or relationship to the person subject to discrimination, severity level categorization should consider several factors, including the position of the individual relative in the licensee's organization, the individual's responsibilities relative to licensed activities, and the potential chilling effect that the action could have on the licensee's organization based on the individual's position.

Where the level of a supervisor is concerned, e.g., first-line supervisor versus plant management, the supervisor's sphere of influence is a guide to determining the appropriate severity level. While a vice president is the first-line supervisor for his or her personal secretary, the vice president's sphere of influence is great and the impact of his or her decision could affect the atmosphere throughout the

site. The examples in Supplement VII are provided as a guide; the final severity level categorization for discrimination actions should reflect the regulatory concern the cases represent. For example, a second-line supervisor may not necessarily be appropriately categorized at Severity Level II.

Supplement VII of the Enforcement Policy also includes an example of a Severity Level II violation involving a hostile work environment. Such a violation may be very significant because the failure by a licensee's management to correct a hostile work environment can have a potentially significant adverse impact on employees raising issues. In such cases, employees may not believe that they are free to raise concerns.

Supplement VII of the Enforcement Policy also includes an example of a Severity Level III violation involving threats of discrimination or restrictive agreements, both of which are violations under NRC regulations such as 10 CFR 50.7(f). This type of violation is categorized at a Severity Level III because the potential impact on future protected activity may be of significant regulatory concern.

Some discrimination cases may occur which, in themselves, do not warrant a Severity Level III categorization. Example D.6 of Supplement VII is an example of a Severity Level IV violation to address these situations. An example of such a case might be a single act of discrimination involving a first-line supervisor, in which the licensee promptly investigates the matter on its own initiative, takes prompt, decisive corrective action to limit the potential chilling effect, and thereby provides a clear message to other supervisors and employees that such conduct will not be tolerated. Another example might involve a threat of adverse action against an employee for going around the supervisor to raise a concern; if the licensee took prompt, aggressive corrective action before any adverse action was taken toward the employee, such a case might be considered as having minimal potential for a widespread chilling effect. These cases would be categorized at a Severity Level IV because they are of more than minor concern and, if left uncorrected, could lead to a significant regulatory concern. Severity Level IV violations would normally be considered for exercising enforcement discretion if warranted under Section VII.B.5. However, citations would normally be made if one of the four exceptions in that section were applicable.

If the staff believes that a predecisional enforcement conference is necessary, the region should prepare a letter to the licensee using Form 1-I in Appendix B and include a factual summary of the report as described in Section 7.5.4.4 and included in Appendix D. Normally the complainant will be provided an opportunity to participate in the predecisional enforcement conference with the licensee/employer. This participation will usually be in the form of a complainant statement and comment on the licensee’s presentation, followed in turn by an opportunity for the licensee to respond to the complainant’s presentation. The complainant will be allowed a personal representative of their choosing, typically an attorney, spouse, or relative. The personal representative will not normally participate in the conference unless they are providing comments for the complainant, such as an attorney responding to legal arguments put forward by the licensee.

When the enforcement action is prepared, the transmittal letter to the licensee should note that the licensee is not required to respond to the 10 CFR 2.201 questions until after the DOL ALJ decision and the 10 CFR 2.205 questions (if a civil penalty has been proposed) until 30 days after a final DOL decision has been made. If no appeal from an ALJ’s decision is filed, the 30-day period should commence 10 business days after the ALJ’s decision is rendered. The response paragraphs in the citation should also note this provision.

If a Commission paper is required for the enforcement action and the action is based on a decision and finding of discrimination by the DOL, the Commission paper must contain a brief but reasonably precise description of the acts of discrimination, a brief summary of the DOL's (ALJ or Secretary of

Labor) reasoning, copies of the DOL decisions, and, in cases where the staff differs with the DOL decision, the staff's reasons for differing.

7.7.7 Discretion For Violations Involving Discrimination

It is recognized that there are some cases of discrimination where enforcement action may not be warranted. Section VII.B.5 of the Enforcement Policy provides an explanation of the types of cases in which the NRC may refrain from taking enforcement action and those in which the NRC normally would not exercise such discretion. See Section 6.3.5 for specific guidance on the issue of exercising discretion for violations involving discrimination.

7.7.8 Continuing Violations Involving Discrimination

Most violations of prohibitions on discrimination (e.g., 10 CFR 50.7), such as a discriminatory termination or a failure to grant a promotion as the result of engaging in protected activities, are not considered "continuing."

An exception may apply to cases involving a hostile work environment. Usually acts of discrimination or a pattern of activities or events would need to be identified as having produced a hostile work environment. If, following the initiating event, the hostile environment persisted, a continuing violation may exist such that daily civil penalties may be appropriate for each day that the hostile work environment continued. This is an area in which the law is evolving. OE will consult with OGC on cases involving a hostile work environment or the potential for "continuing" discrimination.

7.7.9 Enforcement Actions In Cases Involving Contractors

This section provides guidance concerning taking enforcement action in cases in which a contractor of the licensee discriminates against an individual.

7.7.9.1 Enforcement Actions Against Licensees For Actions of Contractors

The Commission's long-standing policy has been and continues to be to hold its licensees responsible for compliance with NRC requirements, even if licensees use contractors for products or services related to licensed activities. Thus, licensees are responsible for having their contractors maintain an environment in which contractor employees are free to raise concerns without fear of retaliation.

Nevertheless, certain NRC requirements apply directly to contractors of licensees (see, for example, the rules on deliberate misconduct, such as 10 CFR 30.10 and 50.5 and the rules on reporting of defects and noncompliances in 10 CFR Part 21). In particular, the Commission's prohibition on discriminating against employees for raising safety concerns applies to the contractors of its licensees, as well as to licensees (see, for example, 10 CFR 30.7 and 50.7).

Accordingly, if a licensee contractor discriminates against one of its employees in violation of applicable Commission rules, the Commission intends to consider enforcement action against both the licensee, who remains responsible for the environment maintained by its contractors, and the employer who actually discriminated against the employee. In considering whether

enforcement actions should be taken against licensees for contractor actions, and the nature of such actions, the NRC intends to consider, among other things:

a. the relationship of the contractor to the particular licensee and its licensed activities;

b. the reasonableness of the licensee's oversight of the contractor environment for raising concerns by methods such as licensee's reviews of contractor policies for raising and resolving concerns and audits of the effectiveness of contractor efforts in carrying out these policies, including procedures and training of employees and supervisors;

c. the licensee's involvement in or opportunity to prevent the discrimination; and

d. the licensee's efforts in responding to the particular allegation of discrimination, including whether the licensee reviewed the contractor's investigation, conducted its own investigation, or took reasonable action to achieve a remedy for any discriminatory action and to reduce potential chilling effects.

7.7.9.2 Enforcement Actions Against Contractors and Individuals

The region should consider in each case application of the deliberate misconduct rule against an individual or contractor found to have committed the act of discrimination. See Section 7.3 for guidance on enforcement actions involving individuals. A Demand for Information or a predecisional enforcement conference should normally be used for each case in which discrimination is found, to put the burden on the licensee and the individual supervisor to explain why they believe that an individual enforcement action should not be taken. In addition, predecisional enforcement conferences or a Demand for Information should normally be used with contractors and their personnel where discrimination is caused by contractor personnel.

7.7.10 Application of *Corrective Action* Civil Penalty Assessment Factor for Discrimination Violations

Application of the *Corrective Action* factor is generally discussed in Section 5.4.2.4. Section VI.C.2.c of the Enforcement Policy provides an explanation of the *Corrective Action* factor as applied to discrimination cases. The NRC can require broad remedial action to improve the workplace environment, but it cannot require a licensee to provide the individual with a personal remedy. DOL has the authority to require that a personal remedy be provided. A violation involving discrimination is not completely corrected without the personal remedy, and the chilling effect may well continue if a personal remedy is not provided. Thus, the Commission does not believe that any proposed penalty should be mitigated if a personal remedy is not provided (59 FR 60697, November 28, 1994). Credit for *Corrective Action* should normally only be considered if the licensee takes prompt, comprehensive corrective action that (1) addresses the broader environment for raising concerns in the workplace; and (2) provides a remedy for the particular discrimination at issue. In the determination of whether or not a remedy has been provided, the NRC considers whether a settlement has been reached or if a remedy ordered by DOL has been implemented. Where a remedy has been accepted by DOL, NRC intends to defer to DOL on the adequacy of the remedy. Cases where a licensee offers an employee a reasonable remedy, but the employee declines, will be handled on a case by case basis.

The promptness and scope of corrective action should also be considered in applying the *Corrective Action* factor. If settlement occurs early in the administrative process, credit may be warranted based

on corrective actions as the chilling effect may have been minimized by the promptness of the remedy and remedial action. However, if settlement occurs after the evidentiary record closes before the Administrative Law Judge, then any existing chilling effect may have existed for a substantial time, and the complainant may have had to spend substantial resources to present his or her case. Under such situations, credit normally would not be warranted. If the licensee does not take broad corrective action until after a Secretary of Labor's decision, and the Secretary's decision upholds an Administrative Law Judge's finding of discrimination, corrective action may be untimely making credit unwarranted. If the licensee chooses to litigate and eventually prevails on the merits of the case, then enforcement action will not be taken and, if already initiated, will be withdrawn. Assuming that evidence of discrimination exists, enforcement action that emphasizes the value of promptly counteracting the potential chilling effect is warranted.

7.8 Material False Statements and Completeness and Accuracy of Information

Inaccurate and incomplete information is addressed in Section IX of the Enforcement Policy. Supplement VII of the Enforcement Policy provides examples of violations involving inaccurate or incomplete information or the failure to provide significant information. The Statements of Consideration for the Final Rule on Completeness and Accuracy of Information (52 FR 49362, December 31, 1987), provide useful background information on applying this rule.

Submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The decision to view a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations.

The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as (1) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience, (2) the opportunity and time available prior to the communication to ensure the accuracy or completeness of the information, (3) the degree of intent or negligence, if any, involved, (4) the formality of the communication, (5) the reasonableness of NRC reliance on the information, (6) the importance of the information that was wrong or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, if a record of the oral information such as a transcript of the communication or meeting summary containing the error was provided to the licensee, thereby giving an opportunity to correct the oral information, and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue an NOV will consider the ease of detecting the error, the timeliness of the correction, whether the NRC or the licensee identified the communication problem, and whether the NRC relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee prior to

reliance by the NRC, or before the NRC raised a question about the information, no enforcement action will be taken for the inaccurate or incomplete information. On the other hand, if the misinformation is identified after the NRC relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken. If the initial submittal was thought to be accurate when made but later turned out to be erroneous because of newly discovered information or an advance in technology, a citation would not normally be appropriate (if, when the new information became available, the initial submittal was corrected).

The failure to correct inaccurate or incomplete information which the licensee knew of, but did not regard as significant, normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be relevant to determining enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

If enforcement action appears warranted for incomplete and inaccurate information, the region should prepare the appropriate enforcement action cited against the applicable regulation (e.g., 10 CFR 30.9, 40.9, 50.9, 55.9, 60.10, 61.9a, 70.9, 71.6a, 72.11, and 110.7a). Section 150.20 provides that when an Agreement State licensee is operating within the NRC's jurisdiction under the general license granted by Section 150.20, the licensee is also subject to the completeness and accuracy requirements.

The provisions of the applicable regulation address two elements: (a) A general provision that requires that all information provided to the Commission by an applicant or licensee or required by the Commission to be maintained by the applicant or licensee shall be complete and accurate in all material respects; and (b) a reporting requirement that requires applicants and licensees to report to the NRC information identified by the applicant or licensee as having a significant implication for the public health and safety or common defense and security. (The provisions in Part 55 contains the first element only.) Violations are most commonly cited against the first element.

If the inaccurate or incomplete information was provided to the NRC, after citing the requirement paragraph, the "contrary to" paragraph should establish:

- when the information was provided to the NRC,
- how the information was provided and to whom in the NRC, (e.g., oral presentation to the NRC staff in the NRC Region IV office; letter to the Director, Nuclear Reactor Regulation),
- what the specific information was that the licensee provided (use direct quote if possible),
- how the information was either inaccurate or incomplete, and
- how the inaccuracy or incompleteness was material (e.g., the inaccuracy was material in that the NRC relied on the information in granting a license amendment, the incompleteness was material in that the NRC subsequently requested the licensee to make a submittal clarifying the information).

It is important to note that information provided to the NRC relating to a licensee’s commitment to perform or complete an activity in the future is normally not a violation of 10 CFR 50.9 if it turns out that the licensee subsequently did not perform or complete the activity. This is because at the time the

commitment was made, the licensee intended to perform or complete the activity; therefore, the information was accurate at the time.

If the inaccurate information was required by the Commission to be maintained, the requirement section should include the requirement for maintaining the information and the "contrary to" paragraph should establish:

- when the inaccurate or incomplete information was identified,
- that the information was required to be maintained by the Commission,
- how the information was either inaccurate or incomplete, and
- how the inaccuracy or incompleteness was material.

7.9 Enforcement Action Against Non-Licensees

For actions involving individuals, see also Section 7.3.

The Enforcement Policy is also applicable to non-licensees, including:

- contractors and subcontractors,
- holders of NRC approvals, e.g., certificates of compliance (CoCs), early site permits, standard design certificates, quality assurance program approvals, or applicants for any of them, and
- employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation.

The prohibitions and sanctions for any of these persons who engage in deliberate misconduct or knowing submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct, e.g., 10 CFR 30.10 and 50.5.

Contractors who supply products or services provided for use in nuclear activities are subject to certain requirements designed to ensure that the products or services supplied that could affect safety are of high quality. Through procurement contracts with licensees, suppliers may be required to have quality assurance programs that meet applicable requirements, e.g., 10 CFR Part 50, Appendix B, and 10 CFR Part 71, Subpart H. Contractors supplying certain products or services to licensees are subject to the requirements of 10 CFR Part 21 regarding reporting of defects in basic components.

When inspections determine that violations of NRC requirements have occurred, or that contractors have failed to fulfill contractual commitments (e.g., 10 CFR Part 50, Appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken.

Notices of Violation and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements.

Notices of Violation will be issued for contractors who violate 10 CFR Part 21. Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(d)(1).

Notices of Violation or orders will be used against non-licensees who are subject to the specific requirements of Part 72. See additional discussion in the FRN for the Policy revision in 1999 http://www.nrc.gov/reading-rm/doc-collections/enforcement/history/fr101599.html.

Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.

Actions should be prepared using Forms 4-III, 9, 10, and 11 in Appendix B, as appropriate.

7.10 Violations of Reporting Requirements

A licensee may be cited for violating reporting requirements if the licensee (1) did not file a required report, (2) filed an incomplete or incorrect report, or (3) filed a report late. A licensee normally will not be cited for failing to report an issue if the licensee was not aware of the information that was reportable. However, a licensee should be cited for failure to report an issue if the licensee knew of the information to be reported, but did not recognize that a report was required. (Ignorance of the reporting requirement is not an excuse).
The severity level assigned to the licensee's failure to submit a required, acceptable, and timely report on a violation that occurred at the licensee's facility is normally the same as would be assigned to the violation that should have been reported. However, the severity level for submitting a late report may be reduced, depending on the individual circumstances.

7.11 Violations of Record-Keeping Requirements

When a licensee is required to perform a task and to keep a record of having performed it, but cannot produce that record, an NOV may be issued for "failure to keep the record." The citation may be considered supporting evidence that a licensee did not perform a required task. However, without additional evidence that the task was, indeed, not performed, the absence of the record is normally insufficient to support an NOV for "failure to perform" the task. Collaborating information, such as interviews or other evidence, should be used to determine whether the licensee **failed to perform** the task or merely **failed to record** that the task was performed.

7.12 Meetings With Licensees on NRC Enforcement Action

In a few escalated enforcement cases, licensees have requested a meeting be held after an enforcement action has been issued but before the enforcement process has been completed. From the time an enforcement action is issued through the hearing process, the NRC is considered to be in the enforcement process. Throughout the enforcement process, the licensee is given numerous opportunities to discuss in detail the inspection findings, including: during the inspection, at the inspection exit interview, after receipt of the inspection report, during the predecisional enforcement conference, in the formal response to the Notice of Violation, in the reply to the Order Imposing Civil Monetary Penalty, and in a hearing, if requested. Additional discussion beyond these opportunities normally would not be useful, unless new information has been discovered which has a significant effect on the outcome of the NRC enforcement action.

If, however, the licensee insists on holding a meeting with the NRC, the following guidelines should normally apply. The licensee is to be informed that: (1) an official transcript of the meeting will be taken in order to provide a clear record of the discussion should the staff desire to rely on it, since information may be provided that has not been previously provided in a written submittal; and (2) this transcript (absent exempt information) will be made a public record and will be made available to the Public. (Note that there may be occasions when the meeting will need to be closed because the new information involves privacy, safeguards, or proprietary information.) If the meeting occurs after a hearing request has been made, the decision to have a transcript should be made in consultation with OGC.

If, after consultation with the Regional Administrator, the Director, OE, concludes that such a meeting should be held, it is to be conducted with the Director or Deputy Director, OE present.

7.13 Reopening Closed Enforcement Actions

If significant new information is received or obtained by NRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the DEDO.

As an alternative, in cases where the severity of an original enforcement sanction was inappropriately low, consideration may be given to issuing a separate sanction against a different applicable requirement, categorized at the appropriate severity level to reflect the level of NRC concern and convey the appropriate message to the licensee.

7.14 Liability of Former and Successor Licensees

The termination of an NRC license does not invalidate the former licensee's liability for actions taken under the license. Depending on the circumstances of a particular case (former licensees not in bankruptcy or out of business), escalated action may be taken against a former licensee for actions occurring during the time it held its license. The NRC's philosophy is that civil penalties should deter future violations not only for the involved licensee but also for other licensees conducting similar activities. Thus, it may be appropriate to issue a civil penalty (for a particularly significant violation) to a licensee who is terminating licensed activities, to deter future violations by other licensees.

For cases in which an OI investigation or inspection is ongoing (and therefore enforcement action could still be taken based on the results of that investigation or inspection), OE should be notified before a license is terminated. OE should also be notified before terminating a license in a case where enforcement action is pending and the licensee has not been responsive.

In addition, the transfer of control of a license to a new individual or business is a matter requiring NRC consent. Enforcement action should therefore be taken if a person is found to have obtained a business or commenced operations under these conditions without obtaining NRC approval. In addition, the NRC considers the successor licensee to have assumed responsibility for violations occurring under the previous license that are not yet resolved.

7.15 Deliberate Misuse of Licensed Material

NRC licensees are required to control and limit their use of byproduct material to that authorized by the license or by regulation. However, there have been several instances of deliberate misuse of byproduct material in a frivolous or malicious way by workers at commercial power reactor and materials facilities. This section provides guidance as to the extent to which an NRC licensee should be held liable for deliberate, frivolous or malicious misuse of NRC-licensed material at its facility.

In general, licensees are accountable for the use of their licensed material by their employees and should normally receive at least a citation for violations involving deliberate misuse of their licensed material by their employees or agents. Since the underlying issue of misuse normally would be categorized at Severity Level IV or higher, and since the Enforcement Policy states that the severity level of a willful violation may be increased, these violations normally would be categorized at Severity Level III or above

and a notice of violation should be issued at Severity Level III or above. This applies whether or not the individual was engaged in the conduct of the licensee's business at the time the act was committed.

Although there may be cases where the ownership of the material and/or the identity of the perpetrator cannot be established definitively, in the absence of reasonable evidence to the contrary, normally the NRC will presume that: (1) the NRC-licensed material used in the incident belonged to the licensee, assuming that the licensee has possessed the type, quantity and form of the material involved; and (2) the individual who perpetrated the act was an employee or agent of the licensee, and obtained the material while acting in the capacity of employee or agent.

Enforcement discretion should be considered for each case involving deliberate misuse of licensed material by licensee employees; however, it is not necessarily appropriate to seek a civil penalty against the licensee in every case.[2] Where there is a need to convey a specific message about some particular facet of the case, a civil penalty may be assessed based on enforcement discretion, notwithstanding the normal application of the civil penalty factors. The following are examples where it may be appropriate to use discretion to highlight a concern such as: (1) inadequate actions to prevent deliberate misuse; (2) the effort put forth by the licensee in investigating the deliberate misuse; (3) whether deliberate misuse has occurred previously; (4) whether the licensee had some basis to suspect that deliberate misuse might occur; (5) the corrective actions taken by the licensee; (6) the past performance of the licensee in controlling the use of licensed material, including training, labeling, posting, surveys, and security; or (7) the actual and potential consequences of the deliberate misuse. These seven examples are not intended to be exhaustive.

If the individual responsible for the deliberate misuse of licensed material is identified, enforcement action also may be taken directly against that individual in accordance with the existing Enforcement Policy.

[2] If civil penalties are automatic for deliberate misuse, licensees may have a disincentive to conclude that the misuse was a result of a deliberate action. NRC should encourage licensees to prevent, investigate, report, and correct violations involving deliberate misuse of licensed material.

CHAPTER 8
GUIDANCE ON ACTIVITY AREAS

8.0 Scope of the Chapter

This chapter provides guidance on a variety of activity areas:

8.1 Reactor operations
8.2 Facility construction
8.3 Safeguards
8.4 Health physics
8.5 Transportation
8.6 Fuel Cycle and Materials operations
8.7 Miscellaneous matters
8.8 Emergency preparedness

8.1 Reactor Operations

This section provides specific guidance on enforcement practices for reactor operations.

➜ **NOTE**: The significance of findings associated with operating power reactors is normally determined by the SDP. 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 Section IV of the Enforcement Policy and the guidance in Supplement I, and the guidance in this section.

8.1.1 Actions Involving Inoperable Equipment

➜ **NOTE**: This section is currently being re-examined. Questions should be directed to OE.

This section provides guidance on the issues of (a) whether to take enforcement action for equipment inoperability and (b) how to cite for equipment inoperability. Additional guidance on inoperable and degraded equipment is included in Generic Letter 91-18, "Degraded Conditions and Operability."

a. **Whether to take enforcement action for equipment inoperability**: Although equipment operability is an important factor in establishing the safety significance of a violation, judgement should be exercised in expending resources to determine operability. Clearly, some analyses may be required to frame the safety significance of the deficiency and discover all relevant aspects of the discrepant condition. However, in view of the limited resources of both NRC and licensees, it is not always necessary to absolutely resolve operability issues.

   For some cases it is obvious that the system, subsystem, train, or component is inoperable. Examples include cases where the valves are closed or circuit breakers are open such that no flow or power is available and the complete function is lost. In these cases, it would be appropriate to cite directly against the TS requirement for operability. In accordance with example B.1 of Supplement I of the Enforcement Policy, 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. When a redundant safety train or subsystem (or for BWRs, a diverse system), is available, then a Severity Level III violation should be considered.

For those cases where it is not obvious that a degraded system is inoperable, extensive resources may be needed to determine operability, especially since, from an enforcement perspective, the NRC has the burden of proof to demonstrate inoperability in an enforcement hearing. 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. However, 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 regional staff believes that there is a significant operability issue, but does not believe that they can justify an operability citation (without expending significant resources), OE should be consulted before escalated action is ruled out. (In addition, OE should be consulted if, in order to make an operability judgment, excessive resources must be expended.) 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 (such as inadequate corrective action, procedures, reviews, design, or tests) rather than against the operability requirement for the system. Section 8.1.2 gives additional guidance concerning enforcement actions involving degraded equipment.

b. **How to cite for equipment inoperability**: Technical Specifications for operating reactors include a section specifying Limiting Conditions for Operation (LCOs), which 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. As inferred, the APPLICABILITY statement specifies when the LCO is applicable (e.g., MODES 1, 2, and 3). For the current construction of many Technical Specifications (TSs), the ACTION statement prescribes remedial measures required under designated conditions in a narrative paragraph format. 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. For improved Standard Technical Specifications (STS) (i.e., NUREG-1430 through NUREG-1434), the ACTION statements are written in a matrix format and are separated into discreet parts: Conditions, Required Action(s), and Completion Time(s). Conditions typically describe ways in which the requirements of the LCO can fail to be met. Specified with each stated Condition are Required Action(s) and Completion time(s). The Completion Time is the amount of time allowed for completing a Required Action. 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 STSs, the term and concept of "AOT" is being used for the purposes of this guidance.

Upon discovery of a failure to meet an LCO, a violation does not necessarily exist based solely on the failure to restore the equipment to operable status within the AOT. A violation would exist when an LCO is not met and all necessary actions have not been completed within all applicable completion times. This is important to emphasize because STSs may have more than one Required Action and Completion Time for a Condition.

AOT Examples

The following two examples illustrate the use of Completion Times with different types of Conditions and changing Conditions.

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. AND B.2 Be in MODE 4.	12 hours 36 hours

Example 1:

When a pump is declared inoperable, Condition A is entered. If the pump is not restored to OPERABLE status within 7 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 6 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 7 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 7 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.

Again, a violation does not exist unless all actions are not completed within all applicable Completion Times.

LCO Background

The previous discussion addressed compliance with TS ACTION statements based upon discovery of an inoperability or degraded condition. However, there has also been a long-standing recognition of the need to also consider potential enforcement based on the total duration that the condition may have existed (i.e., from the time of occurrence), where it can be

readily determined, and the extent to which the licensee should have identified the condition earlier.

In order to address the issue of potential enforcement for a pre-existing condition, it is necessary to make a clear distinction between compliance with the TS ACTION statements and compliance with the TS LCOs. This distinction is evident in the general TS usage rules, as they are presented in the improved STS:

> 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.

In other words, the determination of whether an ACTION statement (LCO 3.0.2) is met is based on when the condition is discovered. Once discovered, the question is whether the actions to be completed are completed on time. Therefore, 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.

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.

The purpose of this guidance is to emphasize the importance of licensee's taking appropriate actions upon discovery of inoperable equipment, rather than focusing resources to attempt to determine when the condition occurred, to the extent that a licensee might choose to shutdown the plant in a less than an orderly fashion, solely to comply with the TS.

In determining whether to make a citation against the LCO, consideration should also be given to other citations, 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. However, 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. For example, 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.

LCO Examples

The following examples illustrate these guidelines. (Use TABLE 1 as the applicable TS for these examples.)

Example 1:

Upon discovery of an inoperable pump, Condition A is entered. The licensee is able to restore the pump in 7 days and 3 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 7 days and 9 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 7 days and 9 hours...a time greater than the AOT of 7 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 7 days and 3 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 6 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 6 days...a time less than the AOT of 7 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.

In summary, 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. 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. The time between discovery and occurrence should be compared to the AOT to determine if a violation of the TS LCO has occurred.

Using the example below, proper citations against equipment operability should include a paragraph describing the requirement and a paragraph describing how the requirement was not met. 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.

The next part of the citation should establish how the requirement was not met. This "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.

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 (3)
Release Systems (SLCRS) shall be operable.
The TS ACTION statement requires that,
"with one Supplemental Leak Collection and (4)
Release System inoperable, restore the
inoperable system to operable status within
7 days or be in at least hot standby within the
next 6 hours and in cold shutdown within the
following 36 hours."

Contrary to the above, between June 9, 1998 and (5)
June 27, 1998, while the plant was in Mode 1, (6)
the "A" train of the SLCRS was inoperable, in (7)
that the fire damper in the train was closed,
thereby stopping the flow of air in the system,
and action was not taken to either restore the (8)
system to operable status within 7 days or place the
unit in cold shutdown within the following 36 hours.

When a situation exists that exceeds the designated conditions of a specific TS ACTION statement, then it may be necessary to include the generic (or "Motherhood") LCO (traditionally TS 3.0.3) as part of the citation. The following example illustrates this point. In this case, 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 1 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 6 hours, at least in HOT SHUTDOWN within the following 6 hours, and at least COLD SHUTDOWN within the subsequent 24 hours.

Contrary to the above, between July 15, 1998 and August 13, 1998, 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 1 hour to place the unit in a MODE in which TS 3.5.2 does not apply.

There may be cases when it is not clear exactly when a piece of equipment became inoperable. In these cases, the burden is on the agency to establish realistic time-frames of when it is most likely that the piece of equipment was rendered inoperable. In establishing realistic time-frames, consideration should be given to issues such as when the equipment was last tested as operable, whether other activities were conducted that could have impacted equipment operability, whether prior indication of inoperability existed, and when the inoperable piece of equipment was discovered. 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.

> Technical Specification (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 1 hour to place the unit in at least HOT STANDBY within 6 hours, at least HOT SHUTDOWN within the following 6 hours, and at least COLD SHUTDOWN within the subsequent 24 hours.
>
> Contrary to the above, on December 23, 1997 <u>between at least 12:07 a.m. and 12:30 p.m.</u>, 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 6 hours.

In this example, 12:07 a.m. represents 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 when the licensee declared both SI pumps inoperable. Although it is highly likely that the recirculation line was frozen before 12:07 a.m., it is not necessary to support the TS violation.

8.1.2 Actions Involving Degraded Equipment

For those cases where inoperability is difficult to establish, such as cases that involve significant differences in system performance capabilities as compared to 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 where complicated or complex analyses are required to determine the safety significance, it may be better to focus the enforcement action on the root cause of the problem rather than on the issue of operability. Substantial time may be spent both by licensees and the staff in determining whether or not a piece of equipment or a system was, in hindsight, operable. In many cases, resources would be better spent in focusing on identifying and correcting root cause issues that, corrected, will prevent future failures.

Therefore, in cases involving degraded (but not clearly inoperable) equipment, the enforcement action should not cite the TS for the piece of equipment (since being degraded is not of itself a violation), but instead should cite the requirement that addresses the root cause of the problem, such

as the licensee's failure to take corrective action (i.e., 10 CFR Part 50 Appendix B, Criterion XVI) that ultimately caused the piece of equipment to be significantly degraded. Additional examples of requirements that might be applicable to the root cause include failure to follow procedures (administrative TS requirement Appendix B, Criterion V), failure to control design (Appendix B, Criterion III), failure to control tests (Appendix B, Criterion XI), or failure to perform a safety analysis (10 CFR 50.59).

The root cause failures may still be evaluated at Severity Level III, because of the significant regulatory concern associated with degraded equipment where the system's continued operability is only fortuitous. Example C.2.b in Supplement I of the Enforcement Policy can be used as the basis for categorization at Severity Level III because it provides an example of a Severity Level III violation involving "a system designed to prevent or mitigate a serious safety event being degraded to the extent that a detailed evaluation would be required to determine operability (e.g., component parameters outside approved limits such as pump flow rates, heat exchanger transfer characteristics, safety valve lift setpoints, or valve stroke times)." For systems having less safety significance, where a violation for inoperability would normally be categorized at Severity Level IV, a root cause violation involving a degraded system would also be categorized at Severity Level IV.

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).

Additional guidance on inoperable and degraded equipment is included in Generic Letter 91-18, "Degraded Conditions and Operability."

8.1.3 Enforcement of 10 CFR 50.59 and Related FSAR

The FSAR is required by 10 CFR 50.34 to be submitted as part of the application for an operating license. 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.

Consequently, a licensee who fails to meet an FSAR commitment that describes how it intends to meet a regulatory requirement may, depending on the circumstances, have violated that requirement. If this is the case, enforcement action may be taken directly against the underlying requirement (e.g., TS or regulation). Therefore, a departure from an FSAR commitment that directly involves a specific legally binding NRC requirement can cite that specific requirement.

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 quality assurance requirements. In such a case, the Notice of Violation may cite the particular criterion of 10 CFR Part 50, Appendix B (e.g., Criterion III, Design Control) as the basis for the violation.

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 subject to enforcement action by means of 10 CFR 50.59. This regulation was changed on October 4, 1999 (64 FR 53582), as amended on December 21, 2001 (66FR 64738). Under either the revised or current 10 CFR 50.59, the Commission can take enforcement action concerning departures from FSAR provisions if a licensee: (1) 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[3]; (2) fails to conduct a safety evaluation for a change; or (3) fails to report the change to the NRC or to keep a record of the change as required by the regulations.

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. Citations against 10 CFR 50.59 are not generally appropriate when the facility never matched its description in the FSAR. This type of citation, known as a "defacto 50.59 violation" had been used in the past to avoid statute of limitation concerns. Instead, latent design defects should be treated as degraded, nonconforming conditions consistent with Generic Letter 91-18, Revision 1. Sections 4.7 and 4.8 of the Attachment to GL 91-18 correctly describe how 10 CFR 50.59 is to be applied to degraded, nonconforming conditions. It is recognized that the final paragraph of the Attachment to GL 91-18 still acknowledges the concept of the "defacto 50.59" violation for enforcement purposes. This will be deleted the next time the Generic Letter is revised. Latent nonconformances with FSAR specifications should be dispositioned as Appendix B violations (normally Criterion III or Criterion V), when applicable.

A citation against 10 CFR 50.59 should: (1) set out the specific FSAR language at issue and describe how it was not met, (2) establish that an evaluation was not performed, and/or (3) 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.

It is expected that for the foreseeable future, there will 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:

For situations that violate the "old" requirements, but that would not be violations had the evaluation been performed under the revised rule, 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. 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.

However, for those 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, licensees still need to take the required corrective actions. By definition, however, if it is not a violation under the revised rule, then the significance of the violation is low and corrective actions are required to be taken in a time frame commensurate with the significance of a violation.

➜**NOTE:** Violations of 10 CFR 50.59 are defined as violations that potentially impede or impact the regulatory process. As such, violations of 10 CFR 50.59 are not processed through the ROP's SDP and are processed through the examples of Supplement I of the Enforcement Policy. 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 result of a 10 CFR 50.59 violation can be assessed significance through the SDP. As such, the Supplement I 10 CFR 50.59 violation severity

[3]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 <u>any</u> increase in probabilities of accidents or malfunctions, or consequences, or <u>any</u> 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.

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. This will ensure a consistent approach for significance determinations. 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). 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). Violations will be considered minor if there was not a reasonable likelihood that the change requiring 10 CFR 50.59 evaluation would ever require Commission review and approval prior to implementation. Violations of 10 CFR 50.71(e) will be considered minor if the failure to update the FSAR would not have a material impact on safety or licensed activities.

Notwithstanding the above guidance, each potential violation of 10 CFR 50.59 is reviewed by an enforcement panel with OE, the region, NRR, and OGC participation to determine if a violation exists, the appropriate severity level, and the need to exercise enforcement discretion. This panel will remain active until the revised rule is implemented and the staff and industry gain sufficient experience with the application of the revised rule.

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 constitute a material false statement.

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 strongest citation (i.e., most defendable).

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

In the event a violation of 10 CFR 50.59 results in an SDP finding of white, yellow, or red, it may be necessary to assess corrective actions under the traditional enforcement approach. Corrective action should normally be considered prompt and comprehensive only if the licensee: (1) makes a prompt decision on operability, and either: (2) 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 (3) 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 these actions because until such actions are taken the violation continues unabated.

8.1.3.2 Exercise of Enforcement Discretion for FSAR Issues

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.

a. **Mitigation: Section VII.B.3 - Old Design Issues.** Under this section, the staff may refrain from issuing civil penalties and, in some instances, citations for a 2 year period where a licensee

undertakes voluntary initiative to identify and correct FSAR noncompliances that will be completed within that 2 year period. This discretion would not normally be applied if:

1. 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. (The schedule should provide for completion of the licensee's initiative by March 30, 2000, for information in the FSAR involving SSCs of high safety significance as defined in the licensee's maintenance rule program and by March 30, 2001, for other information. This schedule may be altered dependent on the staff's final assessment of guidance from the Nuclear Energy Institute or issuance of a generic letter);

2. 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;

3. 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;

4. There is willfulness associated with the violation;

5. The licensee fails to make a report required by the identification of the departure from the FSAR; or

6. 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.

b. **Escalation: Section VII.A.1 - Civil Penalties.** Under this section, the staff may escalate the amount of the civil penalties for FSAR/50.59 noncompliances identified by the NRC subsequent to the 2 year voluntary initiative period. The staff should use this discretion to increase the fine and consider assessing civil penalties for each violation or problem of $120,000 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 exercise of Section VII.B.3 enforcement discretion is warranted), rather than the normal assessment factors. This approach is intended to increase the incentive for licensees to take timely action to ensure that their facilities match the FSAR. For example, if a single Severity Level III violation is identified by the NRC and it lasted for more than 1 day, a civil penalty of $240,000 could be assessed. If the licensee identified the same violation and application of enforcement discretion under Section VII.B.3 was not warranted, a civil penalty of $120,000 ($60,000 x 2 days) could be assessed for the example cited above which will provide some recognition of the licensee's efforts.

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

The General Design Criteria in 10 CFR Part 50, Appendix A are described in the "Introduction" to Appendix A as the "minimum requirements for the principal design criteria for water-cooled power plants similar in design and location to plants for which construction permits have already been issued by the Commission." When the Commission developed and adopted Appendix A, the GDC were intended to provide a basis for judging the adequacy of the preliminary design of the facility at the construction permit stage, and the adequacy of the detailed design and construction at the

operating license stage. However, they function as criteria for assessing the design criteria for the plant and therefore carry over into the requirements for the FSAR (50.34(b)) for analyses of SSCs.... with emphasis upon performance requirements, the bases... upon which such performance requirements have been established....” Technical specifications (TSs) are required to be derived from the analyses in the FSAR (50.36(b)). While the GDC were not intended in and of themselves to constitute the controlling parameters for operation of nuclear power plants, there is the above connection established between the GDC and the TS.

The GDC are not directly applicable to operating requirements. Technical Specifications provide the controlling parameters on operation of a nuclear power plant, as is contemplated by Section 182.a of the AEA.[4]

As such, citations against the GDC are expected to be rare and require OE approval prior to issuance.

8.1.5 Citations Against 10 CFR Part 50, Appendix B

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. (Note that 10 CFR Part 50, Appendix B applies to safety-related structures, systems, and components.) Normally, it is not necessary to include a reference to 10 CFR 50.54(a) or 50.55(f) as the underlying regulation when citing Appendix B. It is also normally not necessary to 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. In most circumstances, the licensee's QA program is consistent with and amplifies the provisions of Appendix B and, therefore, a reference to the licensee's QA program is not normally necessary. 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.

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. However, it may be appropriate in a particular case to utilize Appendix B for the citation if broader corrective action is appropriate.

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, 1995 to August 3, 1995, the licensee failed to take prompt and adequate corrective action for a condition adverse to quality. Specifically, on June 10, 1995, 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.

[4]Excerpted from October 21, 1997 memorandum from the General Counsel to the Chairman.

Note in this particular example of an Appendix B citation, that the "contrary to" paragraph indicates that the licensee failed to take corrective action for a condition adverse to quality. This element is essential for Criterion XVI citations.

As noted above, Appendix B applies to safety-related structures, systems, and components. As such, the provisions of Appendix B do not generally apply to the radiation protection and safeguards areas. There may be cases, however, where procedures relating to security and radiation protection might be subject to Appendix B quality assurance criteria under some circumstances (where "quality assurance" as defined in Appendix B comprises all those **planned and systematic actions** necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.). See Sections 8.3.6 and 8.4.3 for further guidance on citations against Appendix B in the safeguards and radiation protection areas, respectively.

8.1.6 Enforcement Actions in Conjunction With Plant Shutdowns

Enforcement actions based on findings at plants with major shutdowns should be processed substantially before restart is contemplated. Therefore, cases should normally be submitted to OE at least 2 months before scheduled startup, if possible. This should permit the case to be issued and the licensee's corrective action to be assessed prior to startup and will avoid issuing sanctions at the same time or after startup is authorized. A similar logic should be followed for plants to be licensed.

8.1.7 Actions Involving Fire Protection

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; and other legally binding requirements, as applicable.

Failures to meet regulatory requirements for protecting trains of equipment required for achieving and maintaining safe shutdown constitute serious violations. Fire protection violations may involve inoperable or inadequate fire barriers; separation, suppression, or detection systems; repair parts; procedures; or 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.

The significance of fire protection violations is normally determined by the SDP. To the extent that the SDP does not apply or that the reactor oversight process is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy and assigned a severity level commensurate with the significance.

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 structures, systems, and components 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.

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.

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.

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.

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. Note that licensees may exercise engineering judgement as to the threshold for documenting detailed analysis for spurious equipment actuations following a fire. Thus, potential spurious actuations judged by the licensee to not involve substantial risk to safe shutdown capability may not be covered by documented evaluations. 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.

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.

8.1.7.1 Fire Induced Circuit Failures

NRR staff and regional inspectors have found a number of plant specific problems related to potential fire-induced electrical circuit failures which could prevent operation or cause maloperation of equipment needed to achieve and maintain post-fire safe shutdown. Fire protection inspections conducted in each region have found that there may exist noncompliance with the regulations that require that facilities be designed such that fire induced circuit failures (e.g., hot shorts, open circuits, and shorts to ground) do not adversely impact the ability to achieve and maintain a safe shutdown condition.

An example of the consequences of this type problem is reported in Information Notice (IN) 92-18, "Potential for Loss of Remote Shutdown Capability During a Control Room Fire," which alerted licensees that the circuit logic associated with certain motor-operated valves, when subjected to a single fire-induced hot short, could result in a spurious permissive signal. The spurious signal could cause the valve to operate, bypassing the protective features, and resulting in mechanical valve damage. Such fire-induced damage could impair the capability to shut down the plant and maintain it in a safe shutdown condition. However, the vulnerability extends beyond the scope of just control room fires.

In general, the noncompliance appears to stem, in part, from misunderstanding and confusion relative to the regulatory requirements. Poor understanding of design requirements has also been cited as a contributing factor. In multiple correspondence, the Nuclear Energy Institute (NEI) has asserted that the staff's interpretation of the regulatory requirements is, at a minimum, inconsistent with many licensee's understanding and different from past staff interpretations. In a letter dated March 11, 1997, the Director, NRR, reiterated the staff's position to the Nuclear Energy Institute (NEI) that the potential for fire-induced circuit failures to impair the capability to achieve and maintain safe shutdown was within the scope of the existing fire protection

regulations. The letter can be viewed through ADAMS Accession No. ML003716454. The letter focused on NEI's questions regarding IN 92-18. The information included in the enclosure to the letter explains the NRC staff positions germane to the larger issue of fire-induced circuit failures. In follow-up letters, including one received on September 14, 1998 (ADAMS Accession No. ML003716457), that requested that guidance provided in the initial guidance (EGM 98-002) be changed, NEI continued to assert that the current staff interpretations of the requirements are beyond the licensing basis of many facilities and represent a change in previous NRC staff positions.

The staff and the industry are currently working to resolve questions raised by the industry about the adequacy of the existing staff guidance concerning fire-induced circuit failures and the consistency of staff interpretations of both the guidance and the underlying regulatory requirements.

Until this guidance is revised or superseded, staff actions with respect to noncompliances associated with fire induced circuit failures are as follows:

a. For licensees that assert that a particular nonconformance associated with a fire induced circuit failure vulnerability does not constitute a violation of regulatory requirements, the NRC will document the nonconformance, based on the staff position reflected in the March 11, 1997, NRR correspondence (ADAMS Accession No. ML003716454), as an apparent violation.[5] The NRC will defer enforcement actions for disputed apparent violations provided the licensee implements reasonable compensatory actions for the identified vulnerabilities.

   Inspectors should include language in the cover letter to document the apparent violations similar to the following.

   > During the inspection, apparent violations of [state applicable requirement(s)] were identified. These circuit vulnerabilities, could, under certain postulated fire scenarios, adversely affect the ability to achieve and maintain safe shutdown of the facility. It is the NRC's understanding that you do not consider these vulnerabilities to be violations of NRC requirements. In order to allow the industry to develop an acceptable approach to resolving this issue, that the NRC can endorse, the NRC will defer any enforcement action relative to these matters while the staff evaluates NEI's proposed resolution methodology and you have time to implement the resolution methodology, once approved, provided you take adequate compensatory measures for the identified vulnerabilities.

b. For licensees that assert that a particular nonconformance associated with a fire induced circuit failure vulnerability does not constitute a violation of regulatory requirements and refuse to take compensatory measures during this interim period, normal enforcement processes will be followed and the licensees may be subject to formal enforcement action.

c. For those cases where licensees do not dispute that a violation of regulatory requirements has occurred with respect to a nonconformance, the guidance is as follows.

[5] An apparent violation, as defined by the Enforcement Manual and Inspection Manual Chapter 0610 is merely "a potential noncompliance with a regulatory requirement that has not yet been formally cited as a violation in a Notice of Violation or order."

Enforcement discretion will be exercised to not cite the violations provided licensees take prompt compensatory actions and take corrective action within a reasonable time frame. Each case will have to be evaluated on its own merits. The reasonableness of the corrective actions schedule is expected to be based on the safety significance of the nonconformance, the established outage schedule, and the scope of the modifications necessary. Compensatory measures will normally be acceptable as an interim measure, but the circuit vulnerabilities must be resolved. This discretion will be exercised regardless of who identifies the nonconformance.

8.1.8 Actions Involving Loss of Decay Heat Removal (DHR)

➜ **NOTE**: The significance of decay heat removal violations is normally determined by the SDP. To the extent that the SDP does not apply or that the reactor oversight process is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy and the guidance below.

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. 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.

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 decay heat removal or shutdown cooling require prior OE notification.

TSs may not always be specific about the amount of time allowed to restore DHR after an interruption. Therefore, a citation against a TS Limiting Condition for Operation may not be available, except in a rare case where the licensee took little or no action to immediately correct the problem. Such rare cases would clearly warrant consideration for escalated enforcement no matter what caused the DHR loss. However, the majority of DHR problems do not involve prolonged losses or losses for which the licensee does not take at least some action. 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.

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 (87-12 and 88-17), Information Notices, meetings with various industry groups, and letters to licensed operators. 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. As stated above, much of the NRC guidance focuses on losses of DHR during reduced reactor coolant system (RCS) inventory operation. However, 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.

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.

It must be re-emphasized that **there is no exact formula for arriving at a severity level** and the factors discussed below may be weighted differently or not applicable in any given case. The factors to consider are:

a. How similar was the root cause of the loss of DHR to the deficiencies addressed in NRC generic guidance such as Generic Letters 87-12 and 88-17?

b. Given that a deficiency similar to that in NRC guidance occurred, how sensitive were the operators to the problem?

   1. How quickly did they 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.)

   2. Did they respond using detailed procedural guidance, and if they did not, was their training sufficient of itself?

   3. Given that the operators procedurally treated the "symptoms," did they recognize the problem as a loss of DHR?

   4. Did they have other available indications not specified in the procedures that could have been consulted, and did they use them?

c. Does the plant have a history of interruptions of DHR? (This may indicate a continuing lack of sensitivity to this issue.)

d. 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.)

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 is 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 to 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 walkdown of the tygon hose, discovers the blockage, and removes it before resuming draindown.

Recommendation: The licensee should either be assessed 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 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.

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.

8.1.9 Actions Involving Service Water Systems

➜ **NOTE**: The significance of service water system violations is normally determined by the SDP. To the extent that the SDP does not apply or that the reactor oversight process is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy and the guidance below.

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.

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, and inadequate original design margin.

Therefore, the first decision in SWS cases, is whether the agency should cite against SWS operability. 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. As discussed in Sections 8.1.1 and 8.1.2 of this Manual, it may be

preferable to cite against the root cause of the deficiency rather than to expend resources to perform complex operability analyses.

If it is not prudent to cite against the SWS being unable to perform its intended function under certain circumstances (e.g., one train of SWS not available), then enforcement action citing the requirement that best reflects the root cause failure may base a Severity Level III categorization on the example in Supplement I for a degraded system (C.2.b). 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, 1995 and August 31, 1995, 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.

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), or failure to control tests (Appendix B, Criterion XI).

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.

Additional information on SWSs is addressed in Generic Letter (GL) 89-13, "Service Water System Problems Affecting Safety Related Equipment." As discussed in Section 3.4.a of this Manual, failure to comply with a GL is not a violation unless the commitment is incorporated into the licensee's license or is addressed by a legal requirement. Generic Letter 89-13 may, however, constitute prior notice in assessing a civil penalty for a particular action.

8.1.10 Actions Involving Emergency Core Cooling Systems

➜ **NOTE**: The significance of emergency core cooling violations is normally determined by the SDP. To the extent that the SDP does not apply or that the reactor oversight process is not applicable, violations should be assessed in accordance with the guiding principles for assessing significance in Section IV of the Enforcement Policy and the guidance below.

The NRC's Enforcement Policy states that enforcement action should be used as a deterrent to emphasize the importance of compliance with requirements and to encourage prompt identification and prompt, comprehensive correction of violations. The enforcement policy discussed here for the acceptance criteria for emergency core cooling systems for light-water nuclear power reactors (10 CFR 50.46) is consistent with this philosophy, and also reflects the requirements of the regulation for assessing, reporting, and correcting errors in loss-of-coolant accident (LOCA) computer codes (also called ECCS models or evaluation models).

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. The effect of the error on predicted peak clad temperature (PCT) must be estimated, and the error must be reported to the NRC on a schedule determined by the magnitude of the change in PCT. In addition, 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.

Enforcement action could be taken against a licensee, related to non-compliance with 10 CFR 50.46 acceptance criteria, in the following circumstances:

- A licensee discovers an error in an approved ECCS model and does not follow the requirements for assessing and reporting the error.

- 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).

- 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. (Enforcement action in this case could be taken against the licensee per the requirements of 10 CFR Part 50, Appendix B, for failure to provide adequate QA.)

The staff does not believe that it is normally appropriate to take enforcement action for 10 CFR 50.46 against a licensee who discovers an error in an approved LOCA code and 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. However, enforcement action might be warranted for violations of Appendix B. The staff views situations where the 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. Enforcement action is generally not taken in such circumstances. Rather, the NRC would generally require that the failure be evaluated, once identified, to determine if the latent flaw could be a generic problem, which would require reporting under 10 CFR Part 21. The equipment would also require repair and testing to demonstrate it could meet its functional requirements. These types of actions, including a Part 21 evaluation, 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

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. Determination of whether hardware can accomplish a specific function is, in many cases, a relatively straightforward process. 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.) Functionality can even 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, the assumption is often made that it would not have met its functional requirements for some period prior to the most recent assessment.

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. 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. 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. In such cases, enforcement action against 10 CFR 50.46 or Appendix B would not be taken. However, as noted above, if the errors were preventable by reasonable QA measures, a violation of Appendix B might be warranted.

In addition, it must be recognized that there is not a unique, "correct" result for any given plant's LOCA analysis. If a licensee's analytical model conforms to the requirements of Appendix K to Part 50, 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. This is because Appendix K-mandated phenomenological models are known to intentionally over- or underpredict specific parameters to bias the PCT result in a conservative direction. A "best-estimate" (or "realistic") calculation of plant response, using identical initial and boundary conditions, would give a much lower PCT. Furthermore, 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.

8.1.11 Actions Involving the Maintenance Rule

This section provides enforcement guidance concerning enforcement of 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," (the Maintenance Rule) including a joint NRR/OE/OGC/region review panel that can be utilized when needed to resolve case-specific enforcement issues regarding the Maintenance Rule.

Because of the non-prescriptive nature of the rule language, enforcement of the maintenance rule represents a continuing challenge to inspectors. Since implementation of the maintenance rule in July 1996, enforcement of the rule has evolved as lessons were learned. However, this guidance cannot possibly address every conceivable maintenance rule compliance issue, but it does address issues typical of those which are more frequently raised by inspectors. This guidance reviews the requirements of 10 CFR 50.65 and provides examples of violations and examples of issues that are not violations.

a. Maintenance Rule Enforcement Panel

The maintenance rule enforcement panel includes appropriate personnel from NRR, OE, OGC, and the region. (Personnel are normally designated by their office.) The regional panel member should normally be the projects branch chief responsible for the site for which the violation was written, the Division of Reactor Safety (DRS) branch chief responsible for the inspection, or another person designated by regional management. In addition, Senior Executive Service (SES) managers from NRR and the region, and the Deputy Director, OE, should attend. Others, including the regional inspector, resident inspector, project manager, etc., may be asked to attend the meeting or provide input to the discussions.

General Procedure:

- The panel will meet when requested by a region to discuss proposed maintenance rule enforcement actions when the region requires such assistance. The panel shall usually meet in conjunction with the weekly regional enforcement/SERP panel.

- The region will provide sufficient background information, e.g., the draft inspection report section describing the issue and a draft Notice of Violation (NOV). A draft NOV is requested even for proposed Non-cited Violations (NCVs) to ensure that a legally defensible violation exists. Consult the regional enforcement staff if guidance for this is needed.

- It is expected that all decisions regarding the enforcement action will be made by consensus, all members agreeing. If there is no consensus, the matter will be referred to the appropriate NRR Division Director and the director of the Office of Enforcement for resolution. If needed, they may refer the matter to the Office of General Counsel.

- Each case with a confirmed violation, regardless of significance, will be assigned an enforcement action (EA) number and will be documented on a Strategy Form.

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

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.

Regulatory Guide (*RG*) 1.160, Monitoring the Effectiveness of Maintenance at Nuclear Power Plants, endorses NUMARC 93-01, Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants. NUMARC 93-01 provides methods that are acceptable to the NRC for complying with the provisions of 10 CFR 50.65. However, this guidance is non-binding and thus, does not represent requirements and can neither be the basis for nor cited in a maintenance rule violation. However, *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.

The maintenance rule does not require licensees to establish program procedures. Thus, 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. Further, there cannot be a violation of the administrative section of technical specifications which invokes *RG* 1.33, Quality Assurance Program Requirements. This is because *RG* 1.33 does not cover the maintenance rule process. Therefore, 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. As a reminder, the Maintenance Rule covers many non-safety-related systems, structures and components *(SSC*s).

Additionally, a violation of Appendix B, Criterion XVI for failure to identify or correct conditions adverse to quality cannot be cited for failure to identify or correct deficiencies with a licensee's

maintenance rule implementation. This is because the maintenance rule process is not safety-related. This reasoning also applies to violations of Criterion V. [6]

Except in section (a)(4), there is no distinction in the Maintenance Rule for varying degrees of *SSC* risk significance. The scope of (a)(4) 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. This scope reduction does not apply to any other section of the Maintenance Rule.

Throughout this guidance, 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 and are not further explained in this guidance. When used in this guidance, those acronyms and terms are *italicized*.

Section 8.1.11.1 of this guidance lists some maintenance rule-related activities which are and are not violations of the rule. Section 8.1.11.2 gives examples of maintenance rule violations for each section of the rule. Section 8.1.11.3 is the text of 10 CFR 50.65 with excerpts from the Statements of Consideration (*SOC*). This is provided as a reference and provides the regulatory history of the rule and insight as to the Commission's intentions with respect to the rule.

c. Significance of Maintenance Rule Violations

This guidance will not address the significance of maintenance rule violations. The SDP will be used to determine the significance of a violation or maintenance rule finding.

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

I. Paragraph (a)(1)

A. <u>Issues that are violations of (a)(1):</u>

1. Failure to establish goals for *SSC*s in (a)(1).

2. Failure to establish goals which are justifiable. Goals must be defensible and supported by either an adequate *Expert Panel* determination, adequate use of Probabilistic Risk Assessment (*PRA*), or some other reasonable basis and be commensurate with safety.

3. Failure to monitor performance or condition against established goals. The monitoring program must be sufficient in scope and frequency to adequately support a determination as to whether *SSC*s are meeting their assigned goals. Performance monitoring must include tracking of both availability and reliability, where goals of this nature are appropriate, since that provides the maximum assurance that *SSC*s are capable of fulfilling their intended functions.

4. Failure to take appropriate corrective action when performance or condition goals are not met. Corrective actions should sufficiently address actions to achieve goals, be commensurate with

[6] However, 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*.

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. 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.

5. Failure to consider industry operating experience, where practical. Industry operating experience could include specific vendor recommendations, generic communications issued by the NRC or vendors, information communicated via industry working groups or owners groups, etc.

B. Issues that are not violations of (a)(1):

1. Failure to meet a goal. If a goal is not met, appropriate corrective action shall be taken.

2. Failure to establish goals based on industry-wide operating experience. 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. A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.

3. Failure to subdivide *SSC*s into high safety significant *(HSS) SSCs*, low safety significant (*LSS*) *SSC*s, and low safety significant (LSS) standby *SSC*s. The rule does not require this.

4. Failure to link goals to the licensee's *PRA*. The rule does not require this.

5. 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. However, when established goals are not met, appropriate corrective action shall be taken to achieve the goals or the goals must be changed with adequate justification.

6. Failure to perform a cause determination when a performance criterion or goal is exceeded. 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. For corrective action issues involving safety-related *SSC*s, Appendix B, Criterion XVI, may be more easily used for enforcement purposes.

➜**NOTE**: The description of activities that are not violations of (a)(2) (described below) are also applicable to (a)(1).

II. Paragraph (a)(2)

➜**NOTE**: The focus of the rule is on the results achieved through maintenance. With that in mind, 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?

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.

A. Issues that are violations of (a)(2):

1. Failure to move an *SSC* to (a)(1) when performance indicates that the *SSC* is not being effectively controlled through appropriate preventive maintenance. The performance demonstration must be technically justifiable and reasonable. 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. For example, 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. For example, 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.

2. Failure to consider both reliability and availability when evaluating whether an *SSC's* performance or condition has been demonstrated to be effectively controlled. In order for an *SSC* to remain capable of performing its intended function, it must be both reliable and available. If the degree of reliability and availability are not technically justifiable and reasonable, a violation may exist.

B. Issues that are not violations of (a)(2):

1. Failure to establish *performance criteria*, establish appropriate *performance criteria*, link *performance criteria* to the licensee's *PRA,* or to meet established *performance criteria*.

2. 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.)

3. Failure to correctly characterize a failure as a *functional failure (FF) or maintenance preventable functional failure (MPFF).*

4. Failure to correctly consider a failure or unavailability period as potentially impacting the (a)(2) demonstration, but when considered, the demonstration remains valid.

5. Failure to document the demonstration. The rule has no explicit requirements to document the demonstration.

6. Failure to consider *SSC* failures caused by activities other than preventive maintenance. (a)(2) specifically applies to preventive maintenance. Thus, 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.

➜**NOTE**: These activities, 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). The items listed above **are not violations** of 10 CFR 50.65 because the methods to demonstrate performance, which they represent, are not specifically required by 10 CFR 50.65. 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. 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).

III. Paragraph (a)(3)

A. <u>Issues that are violations of (a)(3):</u>

1. Failure to perform the required periodic evaluation at least every refueling cycle. In any case, not to exceed 24 months.

2. Failure to evaluate (a)(1) activities (performance and condition monitoring activities and associated goals) and (a)(2) activities (preventive maintenance activities).

3. Failure to make adjustments, where necessary, to goals and monitoring to ensure that unavailability and reliability are balanced. The licensee's evaluation process must be reasonable and technically justifiable and should include a reasonable basis for making or not making adjustments. The intent of the evaluation is to provide an opportunity to feedback lessons learned into the process. Similarly, "taking into account, where practical, industry-wide operating experience" was not intended to force compliance with industry operating experience, but rather was intended to require licensees to consider industry experience as an information source when conducting the evaluation. A decision not to use industry experience, on the basis that it is not practical to do so, should be justifiable. Industry operating experience could include specific vendor recommendations, generic communications issued by the NRC or vendors, information communicated via industry working groups or owners groups, etc.

B. <u>Issues that are not violations of (a)(3):</u>

1. Failure to document the evaluation. The rule has no explicit requirements to document the evaluation. Licensees should use documentation to the extent necessary to assure themselves that the requirement for an evaluation has been acknowledged and performed adequately.

2. 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.

3. Failure to apply industry-wide operating experience. 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. A decision not to take into account industry experience, on the basis that it is not practical to do so, should be justifiable.

IV. Paragraph (a)(4)

A. Issues that are violations of (a)(4):

1. Failure to perform a risk assessment prior to performing maintenance activities. Required assessments may be limited to those *SSC*s 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; and hence, are significant to public health and safety.

2. Failure to perform an adequate assessment. To support a violation, there should be a technically justifiable reason as to why the assessment is determined to be inadequate. Keep in mind that the rule does not give guidance on what constitutes an adequate assessment. The sophistication of the assessment should be commensurate with the complexity of the configuration and should meet the test of reasonableness. If the assessment is sufficient in complexity, technically justifiable, and reasonable, it would be difficult to conclude that the assessment was inadequate. In any case, 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).

3. Failure to update a prior assessment due to emergent work or changing plant conditions that could have an impact on the existing assessment. Included in this would be the identification of external factors including changed environmental conditions. 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. For example, 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.

4. Failure to manage the increase in risk that may result from the proposed maintenance activity. The process for managing risk involves using the result of the assessment in plant decision making to control the overall risk impact. However, the licensee is not bound to keeping risk below some threshold or for taking particular actions when risk exceeds some threshold. 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.

B. Issues that are not violations of (a)(4):

1. Failure to document the assessment. The rule has no explicit requirements that the assessment be documented. Licensees should use documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately.

2. Failure to use probabilistic analyses to perform a risk assessment. See the statements of consideration in section 8.1.11.3. Depending on the complexity of the *SSC*s 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.

3. Failing to perform an adequate assessment that is questioned and corrected prior to commencement of maintenance activities. This includes occasions when an NRC inspector questions an assessment prior to the maintenance activity commencing. "Commencement" of maintenance activities is considered the point when the *SSCs* of concern are disabled or prevented from performing their safety function.

V. Paragraph (b)(1)

A. Issues that are violations of (b)(1):

1. Failure to include a safety-related *SSC* in scope.

B. Issues that are not violations of (b)(1):

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*.

VI. Paragraph (b)(2)

A. Issues that are violations of (b)(2):

1. Failure to include in the scope those types of non-safety related *SSC*s described in (b)(2).

B. Issues that are not violations of (b)(2):

1. No specific guidance is provided.

8.1.11.2 Examples of Violations

I. Paragraph (a)(1)

A. Examples of violations of (a)(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 (*SSC*s) 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, 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 (date) after the preventive maintenance program was shown to be ineffective due to repeat preventive maintenance preventable functional failures.

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 (*SSC*s) 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, are capable of fulfilling their intended functions. Such goals shall be established commensurate with safety. When the performance or condition of a structure, system, or component 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.

II. Paragraph (a)(2)

A. <u>Examples of violations of (a)(2):</u>

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

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 (*SSC*s) 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, 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 *SSC*s was not being effectively controlled through the performance of appropriate preventive maintenance and, as a result, that goal setting and monitoring was required.

2. 10 CFR 50.65(a)(1) requires, in part, that holders of an operating license shall monitor the performance or condition of *SSC*s 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 *SSC*s 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.

III. Paragraph (a)(3)

A. Examples of violations of (a)(3):

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 through maintenance (reliability) is appropriately balanced against the objective of minimizing unavailability of structures, systems, and components (*SSC*s) 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.

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).

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).

IV. Paragraph (a)(4)

A. Examples of violations of (a)(4):

A. 10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillances, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and mange 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.

B. 10 CFR 50.65(a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillances, 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 HSS SSCs or others within the licensee-established risk assessment scope) that was/were concurrently out of service.

3. 10 CFR 50.65 (a)(4) requires, in part, that before performing maintenance activities (including but not limited to surveillances, 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.

V. Paragraph (b)(1)

A. Example of a violation of (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 (*SSC*s)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 *SSC*s 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 *SSC*s are relied upon during and after design basis events to maintain the reactor in a safe shutdown condition.

VI. Paragraph (b)(2)

A. Examples of violations of (b)(2):

3. 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 whose failure can prevent safety-related structures, systems and components 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.

4. 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 that are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (*EOP*s).

   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 *EOP*s. As a result, the preventive maintenance on the system was not assessed following three maintenance preventable functional failures occurring between (dates).

8.1.11.3 10 CFR 50.65 and Excerpts from Statements of Consideration

➜**NOTE**: The statements of consideration (*SOC*) provide insight on the Commission's intentions with respect to the rule. However, licensee actions, which are inconsistent with the *SOC*s alone, do not constitute a violation of the rule. The *SOC* excerpts provided in this guidance are intended for use as background information only. The *SOC* excerpts were taken from the Federal Register, 56 FR 31308-31310, dated July 10, 1991 and 64 FR 38554-38555, dated July 19, 1999.

50.65 Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.

The requirements of this section are applicable during all conditions of plant operation, including normal shutdown operations.

Statements of Consideration

An introductory paragraph has been added to 10 CFR 50.65 clarifying that the rule applies under all conditions of operation, including normal shutdown. The intent of this paragraph is to ensure that assessments are performed before maintenance activities when the plants are shut down as well as when the plants are at power.

I. Paragraph (a)(1)

A. 10 CFR 50.65(a)(1)

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

B. Statements of Consideration

1. The intention of paragraph (a)(1) of the rule is 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 *SSC*s 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.

b. Where failures are likely to cause loss of an intended function, monitoring should be predictive in nature, providing early warning of degradation.

3. Monitoring activities for specific *SSC*s can be performance oriented (such as the monitoring of reliability and availability), condition-oriented (parameter trending), or both.

4. 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.

5. Where available, the assumptions in and results of probabilistic risk assessments (*PRAs*) or individual plant examinations (*IPEs*) should be considered when establishing goals.

6. *SSC*s 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.

II. Paragraph (a)(2)

A. 10 CFR 50.65(a)(2)

Monitoring as specified in paragraph (a)(1) of this section 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.

B. Statements of Consideration

1. The purpose of paragraph (a)(2) of the rule is to provide an alternate approach (a preventive maintenance program) for those *SSC*s where it is not necessary to establish the monitoring regime required by (a)(1).

2. 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. Hence, it is expected that, where one or more maintenance-preventable failures occur on *SSC*s treated under this paragraph, the effectiveness of preventive maintenance is no longer demonstrated. As a result, the *SSC* 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. Once such a demonstration has been made, it would be acceptable to return to treating the *SSC* under paragraph (a)(2).

III Paragraph (a)(3)

A. 10 CFR 50.65(a)(3)

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.

B. Statements of Consideration

1. This provision requires that *SSC* 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 *SSC* reliabilities and availabilities. In the case of *SSC*s 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. 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. In the case of *SSC*s treated under paragraph (a)(2), adjustment of preventive maintenance requirements may be warranted where *SSC* availability is judged to be unacceptable.

2. *SSC*s 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.

IV. Paragraph (a)(4)

A. 10 CFR 50.65(a)(4)

Before performing maintenance activities (including but not limited to surveillances, 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.

B. Statements of Consideration

1. 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.

2. In general, a risk assessment is necessary before all planned maintenance activities. Assessments should also be performed when an unexpected *SSC* 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 *SSC* 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.

c. 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.

4. 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 *SSC*s paired against each other. However, more detailed assessments are required if a licensee proposes to remove multiple *SSC*s 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.

5. 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.

6. 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 *SSC*s subject to the pre-maintenance assessment to those *SSC*s 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 *SSC*s modeled in the licensee's *PRA*, in addition to all *SSC*s evaluated as risk significant (high safety-significant) by the licensee's maintenance rule expert panel. Typically, these *SSC*s have been analyzed as causing potential initiating events, if failed, and as accident mitigators, or as high safety-significant *SSC*s with their support systems. Such *SSC*s may be identified by operating experience or by deterministic or probabilistic analyses.

7. 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.

V. Paragraph (b)

The scope of the monitoring program specified in paragraph (a)(1) of this section shall include safety related and non-safety related structures, systems, and components, as follows:

VI. Paragraph (b)(1)

A. <u>10 CFR 50.65(b)(1)</u>

Safety-related structures, systems, or components 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.

B. <u>Statements of Consideration</u>

The scope of *SSC*s subject to the final maintenance rule includes safety-related *SSC*s, and certain "non-safety" *SSC*s in the balance of plant (*BOP*) which meet one or more of four specific criteria. (Note: refers to the one general criterion, safety-related, described in (b)(1) and the three criteria of non-safety related described in (b)(2).

VII. Paragraph (b)(2)

A. 10 CFR 50.65(b)(2)

Non-safety related structures, systems, or components:
(i) That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (*EOP*s); 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.

B. Statement of Considerations

The scope of *SSC*s subject to the final maintenance rule includes safety-related *SSC*s, and certain "non-safety" *SSC*s in the BOP which meet one or more of four specific criteria. (Note: refers to the one general criterion, safety-related, described in (b)(1) and the three criteria of non-safety related described in (b)(2).

VIII. Paragraph (c)

A. 10 CFR 50.65(c)

The requirements of this section shall be implemented by each licensee no later than July 10, 1996.

8.2 Facility Construction

No detailed guidance is being issued for this activity area at this time. Supplement II of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

8.3 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.

8.3.1 Compliance With the Security Plan Versus 10 CFR Part 73

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. Once these plans are approved, they are incorporated into the license by amendment and the licensee is required to meet the approved plans. Citations for violations of these requirements must be made against the applicable section of the NRC-approved security plan and not against Part 73. If there is a conflict between a plan and a regulation, NSIR, NRR or NMSS (as appropriate) should be consulted.

However, 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.

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.

8.3.2 Access Control

The severity level of an access control violation is determined by: (1) the ease of exploitation of the vulnerability including its predictability and the ease of passage created by that violation, (2) the intent of the intruder, and (3) the combined integrity of both protected area and vital area/material access area barriers.

In determining the vulnerability of the area, one must consider whether it could be seen easily by a potential intruder (e.g., height above the ground, intervening structures, and light and color characteristics).

The predictability of the vulnerability refers to the ease with which the intruder can anticipate the opportunity created by the opening. For example, since the operational status of an alarm system is not usually apparent to a potential intruder, the fact that a particular alarm zone allows access will probably not be obvious, and therefore the vulnerability is less significant.

The ease of passage of a vulnerability refers to the type of opening and the environment in or surrounding the pathway. For example, 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 the intruder to maneuver along the inside of it. Ease of passage also refers to whether the opening, for example a tunnel, has constant or periodic flushing or high temperatures, or is under water.

The intent of the intruder must also be considered. Unauthorized intrusions by licensee employees without malicious intent are not by themselves of significant concern.

Lastly, the significance of a vital area barrier breach is less if the protected area barrier is fully operational and functioning as intended. Similarly, a protected area barrier failure is less significant when all vital area doors are appropriately locked and alarmed and when vital area barriers are properly constructed and/or monitored.

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

a. **Barrier Integrity**: The integrity of the barrier may be compromised by breaches in that barrier, but it may also be compromised by procedural errors.

   Lost keys and/or lost keycards have the potential to allow unauthorized and undetected access to controlled areas of the plant. The significance of such violations is a function of: (1) whether the keys/keycards were truly lost, (2) whether they were marked as to what areas they allowed access, (3) whether and when they were recovered, and (4) whether there is any evidence of use before being recovered.

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

b. **Compensatory Measures for Unlocked/Unalarmed Portals**: The significance of guards being inattentive while posted as compensatory measures is determined by what functions they are intended to provide. If the guard is posted at an unalarmed and locked door, the guard represents only the monitoring function and, if the guard is inattentive, only one element of access control is inadequate. If the guard is posted at an unlocked and unalarmed door, two elements are inadequate. For guards not posted as compensatory measures (e.g., if the guard is posted inside a bullet-resistant structure to issue access badges), no elements would be inadequate (although there may be other bases for a violation).

c. **Authorization versus Clearance for Access**: Individuals are considered cleared for access as soon as they have successfully completed all the screening steps committed to by the licensee. However, they are not authorized access at that point and may not have unescorted access until they are added to the licensee's authorized access list and issued a proper badge. Actual entry of a cleared but as-yet unauthorized individual is a violation, but is not as significant as actual entry of an uncleared, unauthorized individual.

d. **Improper Access by Authorized Persons**: 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. Tailgating or using another employee's badge is a violation, though usually a Severity Level IV violation. However, it is more significant if the system broke down in a way that permitted an unauthorized individual or a disgruntled employee to gain access who was recently terminated for cause.

e. **Vital Areas Within Vital Areas**: As a general rule, when vital areas are contained within other vital areas, the barrier and access control requirements are not required at each barrier. The licensee is only required to have one vital area barrier to protect all vital areas, and access control functions must be operative at only the necessary vital area barrier. However, the inner barrier and access control functions must be fully operative. Therefore, if an inner vital area barrier remains intact while the outer vital area barrier is discovered to have vulnerabilities, there isn't necessarily a violation unless the failed outer barrier allows access to vital equipment.

8.3.3 Searches

Searches of individuals, vehicles, and packages are not considered adequate unless they are reasonably sufficient to detect the items for which they are conducted. For example, a vehicle search must include an examination of the inside of the glove compartment and the area under the seats.

When a vehicle that has entered the site is later found to have contained contraband (weapon, drugs, camera) in an accessible area, it is assumed that the search was inadequate.

8.3.4 Protection of Safeguards Information

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, (2) the significance of the material, and (3) the amount of time left unprotected. Safeguards information left in an unlocked container within the locked and continuously-staffed primary access control point is less significant than safeguards information left unprotected outside the protected area.

If the material left unprotected is sufficiently extensive or descriptive of the security system as to significantly assist an intruder in an act of radiological sabotage or theft of strategic special nuclear material (SSNM), the severity level would be greater than if the material would not have significantly assisted the intruder.

8.3.5 Protection Against Vehicle Bomb Threats

10 CFR 73.55(c)(7) requires licensees to establish vehicle control measures, including vehicle barrier systems, to protect against land vehicle intrusion. 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. 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. 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. By allowing the 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. This is common in the area of physical security and already exists in 10 CFR 73.55 itself.

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. 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".

8.3.6 Citations Against 10 CFR Part 50, Appendix B

Appendix B to Part 50 addresses quality assurance criteria for nuclear power plants and fuel reprocessing plants. As discussed in the introduction, Appendix B applies to structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. As such, the provisions of Appendix B do not generally apply to the safeguards area.

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."

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

8.4 Health Physics

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

8.4.1 Substantial Potential for Overexposure

The Severity Level III example in C.7 of Supplement IV involves situations that present a "substantial potential for exposures or releases in excess of the applicable limits in 10 CFR 20.1001 - 20.2401 whether or not such exposure or release occurs." An event presents a substantial potential when it was fortuitous that the resulting exposure or release did not exceed the limits of 10 CFR Part 20. The concern is not the significance of the resulting or potential exposure (example C.1 of Supplement IV addresses exposures in excess of Part 20 limits), but whether the licensee provided adequate controls over the situation, as required, to prevent exceeding the Part 20 limits. No credit is given for luck.

When considering whether the circumstances of a particular case meet the threshold for escalated enforcement action for this example, the staff should attempt to construct a reasonable scenario in which a minor alteration of circumstances would have resulted in a violation of the Part 20 limits. Circumstances such as (a) timing, (b) source strength, (c) distance, and (d) shielding should be considered.

a. **Timing**: Could the exposure period have reasonably been longer?

Example: An individual in the proximity of an unknown source of radiation receives an unplanned excessive exposure. Because of the duration of the exposure, no limits were exceeded; however, the individual could reasonably have stayed in proximity to the source long enough to be overexposed.

b. **Source Strength**: Could the radiation source have reasonably been stronger?

Example: An inadvertent release results from a worker venting the wrong waste gas decay tank. Although the release did not exceed Part 20 limits, the same mistake could have as easily resulted in venting a decay tank with enough activity to exceed the limits.

c. **Distance**: Could the person have reasonably been closer to the source?

Example: In the example in paragraph (a) above, the individual could have been overexposed by standing closer to the source of radiation.

d. **Shielding**: Could some unintended shielding have reasonably been removed?

Example: Radioactive source was accidently left in an office area. Shielding afforded by a desk prevented the overexposure of an individual worker in the office. However, nothing prevented the source from being left in a area of the office that would not have been shielded by the desk, such that the individual would likely have been overexposed.

8.4.2 Citations Against 10 CFR Part 50, Appendix B

Appendix B to Part 50 addresses quality assurance criteria for nuclear power plants and fuel reprocessing plants. As discussed in the introduction, Appendix B applies to structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. As such, the provisions of Appendix B do not generally apply to the health physics area.

If the region desires to use the Appendix B criteria as the basis for a citation in the health physics 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."

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

8.4.3 Severity Level of Violations Involving Security and Control of Licensed Material

The guidance in this section does not address loss, release, or disposal of licensed material, which is covered under Section 8.4.4, "Loss, Abandonment, or Improper Transfer or Disposal of Licensed Material." This guidance applies to violations of 10 CFR 20.1801 and 1802, security and control of licensed material.[1]

Supplement IV of the enforcement Policy includes examples of violations at Severity Level III , IV, and minor. The examples are based on a risk-informed, performance-based approach to determine the types of security violations that should be considered significant, vs. those of less serious concern and those of minor significance.

The guidance is intended to focus licensees' attention on assuring a program of training, staff awareness, detection (auditing), and corrective action (including disciplinary action) to detect and deter security violations. Such a program normally is not a specific regulatory requirement, but rather a function that licensees need to perform as an inherent part of their compliance program. Normally, security violations that occur despite such a program will be considered *isolated*.

Security and control violations, absent willfulness, do not meet the criteria for citation at Severity Level II. Exposures to individuals as a result of a security and control violation would result in the citation of two violations; the licensee would be cited for a security and control violation at Severity Level III and would be cited for an overexposure violation at the appropriate Severity Level in accordance with the Enforcement Policy.

As with other examples in the Policy, the severity level may be increased if the violation involves willfulness, and may be increased or decreased as other circumstances warrant. Such circumstances to take into consideration are: size and weight of the device or storage container; material identifiable as radioactive; degree and time of access to the radioactive material; and actual and potential consequences (e.g., theft, exposures).

[1]This guidance is not meant to imply that the release of an individual following decontamination conducted in accordance with the licensee's decontamination procedure is a violation of 10 CFR 20.1801 or 1802.

Security violations categorized at Severity Level IV may be dispositioned as NCVs or in NOVs by the Regions. All other security violations, including those where the violation meets the criteria for a Severity Level III, but is reduced because of the circumstances, require an EA number and should be coordinated with OE (normally by telephone or e-mail).

The following are examples where the severity level was modified based on the safety significance and circumstances:

- A locked, large radiography camera, weighing approximately 300 pounds, raised up on a forklift inside of a large vessel, inside of a posted and roped off area was left without surveillance was considered a minor violation because of the short duration (approximately 10 minutes), inaccessibility to the source, and size and weight of the device even though members of the public entered the area.

- A moisture density gauge, used temporarily for college class demonstrations, stored in a locked classroom, under a desk, behind a brick-type wall, was considered a Severity Level IV violation because individuals without any training had access to the keys to the room.

- A hot lab in a nuclear medicine department, containing radioactive material in unit doses (Tc-99m), capsules (I-131), and sealed sources which exceeded 1000 times Appendix C to 10 CFR 20 quantities, was unattended and the door to the hot lab was left open with a stopper was considered a Severity Level IV violation because, the duration of the violation was short (approximately 10 minutes), the capsules were in a lead pig in a fume hood, the receptionist generally stops individuals when they approach the area, and several technicians constantly frequent the area.

8.4.4 Loss, Abandonment, or Improper Transfer or Disposal of Licensed Material

a. **Applicability:** The guidance in this section applies to violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device, regardless of the use or the type of licensee. It does not apply to violations that involve security and control of licensed material unless the failure to secure or control results in loss, abandonment, improper transfer or disposal, or other unauthorized release of sealed sources and devices containing NRC-licensed material. Otherwise, see Section 8.4.3, "Severity Level of Violations Involving Security and Control of Licensed Material."

   ➜**NOTE:** If the licensee exercises adequate security and control but the source/device is still lost (e.g., stolen), there is no violation and, therefore, no enforcement issues.

b. **Interim Policy:** Violations involving the loss of generally licensed sources and devices may warrant an exercise of enforcement discretion in accordance with the Interim Enforcement Policy for Generally Licensed Devices Containing Byproduct Material. Specifically, the policy provides that the NRC will not normally take enforcement action for violations of 10 CFR 31.5. Staff guidance for implementing the interim policy is included in EGM 99-005 (revised) in Appendix A. No consultation with OE is required if the staff follows the guidance for exercising this enforcement discretion.

c. **Significance:** Violations of NRC requirements involving loss, abandonment, or improper transfer or disposal of sealed sources and devices containing NRC-licensed material will be

considered for escalated enforcement action. This is consistent with the examples in Supplement IV of the Enforcement Policy. However, there may be instances when violations can be dispositioned as Severity Level IV violations. The staff should assign the violation the appropriate severity level based on the normal factors for considering significance, including taking into account the chemical and physical characteristics of the radioactive material, safety and environmental significance, and whether the circumstances represents an isolated, rather than programmatic, weakness. The staff should also consider increasing the significance for willfulness. The following are examples of Severity Level III and IV violations involving the loss, abandonment, or improper transfer or disposal of sealed sources and devices.

Examples of Severity Level III Violations:

- A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 and 40 mCi of Am-241 resulting in the loss of the gauge. The gauge was recovered eight hours later at the same time that the licensee was reporting the loss to the NRC. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

- A licensee failed to maintain control of a portable moisture density gauge containing 8 mCi of Cs-137 resulting in the gauge being stolen. While the amount of the radioactive material was less than 1000 times the 10 CFR Part 20, Appendix C value and the licensee had a functional program to detect and deter security violations that included training, staff awareness, detection, and corrective action, the NRC issued a Severity Level III violation and proposed imposition of a civil penalty. This violation was significant since the gauge contained more than a nominal amount of material.

- A licensee failed to maintain control of brachytherapy sources containing 7.7 mCi of Ir-192 resulting in the loss of the material. The NRC issued a Severity Level III violation and proposed imposition of a civil penalty.

Examples of Severity Level IV Violations:

- A licensee lost a static eliminator containing 10 mCi of Po-210. Due to the low actual safety significance associated with the isotope and small amount of material and the difficulty in gaining access to material, the NRC issued a Severity Level IV violation.

- A licensee lost a sealed source containing 0.7 mCi of I-125. Due to the low actual safety significance associated with the small amount of material, the fact that the quantity was less than 1000 times the 10 CFR Part 20, Appendix C value, and the licensee had a functional program, the NRC issued a Severity Level IV violation.

- A licensee lost a sealed source containing 0.246 mCi of Cs-137. Due to the low actual safety significance associated with the small amount of material, the fact that the quantity was less than 1000 times the 10 CFR Part 20, Appendix C value, and the licensee had a functional program, the NRC issued a Severity Level IV violation.

➜**NOTE:** All cases being considered for disposition at Severity Level IV should be coordinated with OE (normally by phone or e-mail) and should receive an EA number.

d. **Base Civil Penalties:** Although the NRC imposes different levels of penalties for different severity level violations and different classifications of licensees, contractors, and other persons

(see Tables 1A.a through e, and 1B), violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device will be assessed under Table 1A.f, or will consider the actual cost of proper disposal, *regardless of the use or the type of licensee*.

The three levels of civil penalties listed in Table 1A.f are intended to better relate the civil penalty amount to the costs avoided by the failure to properly dispose of the source or device. The December 18, 2000, change to the base civil penalty structure considers both the cost of proper disposal and the relative risk to the public from sources that are lost, abandoned, or improperly transferred or disposed of. The Commission believes that a base civil penalty equivalent to three times the cost of proper disposal will provide for sufficient deterrence and an economic incentive for licensees to expend the necessary resources to ensure compliance.

Sources and devices containing small amounts of radioactive material, such as gas chromatographs, and devices containing hydrogen-3 (tritium) have a base civil penalty in the amount of $6,000 for a severity level I violation, $4,800 for a severity level II violation, and $3,000 for a severity level III violation.

Devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, and 37 MBq (1mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)) are considered to present a higher risk for potential exposure to the public and for loss of property (due to contamination) if the device is lost, abandoned, or improperly transferred or disposed of. Based on the higher risk, violations involving loss, abandonment, or improper transfer or disposal of sources and devices in this category have been assigned a base civil penalty amount of $15,000 for a severity level I violation, $12,000 for a severity level II violation, and $7,500 for a severity level III violation.

With the exception of sources and devices containing hydrogen-3 (tritium), the highest activity sources and devices (i.e., those with activities greater than 3.7×10^4 MBq (1 Curie)) have been assigned a base civil penalty amount of $45,000 for a severity level I violation, $36,000 for a severity level II violation, and $22,500 for a severity level III violation.

e. **Adjustment of Civil Penalty Amounts Based on Disposal Costs:** In assessing the amount of a civil penalty, the NRC may consider information concerning the actual expected cost of authorized disposal instead of using the civil penalty amounts in Tables 1.A.f and 1B. The actual expected cost of authorized disposal should be the expected cost for an individual or organization that may find and take possession of the source or device. Normally, the burden of determining the actual expected cost of authorized disposal should rest with the licensee. If a licensee requests that the civil penalty amount be reduced based on the actual expected cost of disposal, the licensee should provide a copy of a written estimate from a waste disposal site, waste broker, or the source or device manufacturer. The licensee may provide this in response to a choice letter or proposed action or at a predecisional enforcement conference. NRC may also adjust (increase or decrease) the value of the civil penalty if it has reliable specific information on the expected cost of disposal (e.g., assessment of a civil penalty amount for a similar case).

Based on current information and recent cases, the NRC has determined that the expected authorized costs of disposal of portable moisture density gauges containing approximately 10 mCi of Cs-137 and 40 mCi of Am-241 is less than $1000. Therefore, rather than have licensees provide disposal information for such cases, the NRC will typically propose imposition of civil penalties in the amount $3000 for Severity Level III violations involving the loss, abandonment, or improper transfer or disposal of these types of devices.

The NRC will evaluate the merits of each specific case and may mitigate or escalate the amount of a civil penalty based on other information, such as the actual consequences of the loss, abandonment, or improper transfer or disposal. While NRC may adjust the civil penalty based on actual consequences (e.g., cost of recovery, decontamination, etc.), NRC will not normally mitigate the civil penalty for quick recovery or other fortuitous results. In addition, NRC would typically only consider mitigating the civil penalty for identification or corrective action if such actions were extraordinary.

In considering adjustment of the civil penalty amounts, NRC will typically adjust the civil penalty amount to correlate to one of the base civil penalty amounts for violations involving loss, abandonment, or improper transfer or disposal. For example, if the base civil penalty amount is $22,500, based on the violation being at Severity Level III and involving material described in Table 1Af.1., and a licensee provides adequate information demonstrating that three times the cost of authorized disposal is $6,000, the NRC would likely assess a $7,500 civil penalty (the amount a Severity Level III violation for material described in Table 1A.f.2.). In cases that the NRC decides to mitigate a civil penalty, the NRC will only mitigate the civil penalty down to the lowest base civil penalty in Tables 1A.f and 1B, currently $3000.

f. **Coordination:** Consultation with OE is required for all cases involving loss, abandonment, or improper transfer or disposal of licensed material that do not meet the criteria for exercising enforcement discretion under the interim policy (see additional guidance in EGM 99-005). A regularly scheduled enforcement panel should be held for potential escalated action, while phone or e-mail consultation is appropriate for Severity Level IV cases.

g. **Choice Letters:** In some cases, NRC may have sufficient information to make an enforcement decision and would not need to hold a predecisional enforcement conference. In such cases, NRC may send a choice letter to the licensee. However, if NRC is considering a civil penalty, the choice letter should explicitly state that NRC is considering the use of discretion in accordance with Section VII.A.1.g. to issue a civil penalty. The standard choice letter includes an optional paragraph that informs the licensee that they may submit information regarding the expected costs of authorized disposal.

h. **Conference Letters:** If the staff chooses to invite the licensee for a conference, the licensee should be informed that Section VII.A.1.g. of the NRC Enforcement Policy states that the NRC should normally exercise discretion to propose imposition of a civil penalty of at least the base amount for violations involving the loss, abandonment, or improper transfer or disposal of a sealed source or device, that NRC may consider adjusting the civil penalty amount to a more appropriate base amount if a licensee can demonstrate that three times the actual cost of disposal would be significantly less than the base amount, and that the license may provide information regarding the actual expected costs of authorized disposal as part of the conference. The standard conference letter includes an optional paragraph to address such situations.

i. **Cover Letters for Cases Using Discretion:** Cover letters for NOVs with civil penalties typically discuss the complete civil penalty assessment process, including how NRC considered credit for identification and corrective action. However, for cases where NRC chooses to use discretion in accordance with Section VII.A.1.g. to issue a civil penalty, the staff should use the standard paragraph in the cover letter that specifically discusses the use of discretion and, if applicable, the consideration of the actual costs of disposal in determining the civil penalty.

8.5 Transportation

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

10 CFR Part 71 establishes requirements for packaging, preparation for shipment, and transportation of licensed material. Part 71 also establishes standards for NRC approval of packaging and shipping procedures for fissile material and for quantities of other licensed material in excess of Type A quantity. The packaging and transport of licensed material are also subject to other parts of Title 10 (e.g., Parts 20, 21, 30, 39, 40, 70, and 73) and the regulations of other agencies (e.g., U.S. Department of Transportation (DOT) and the U.S. Postal Service (USPS)) or Agreement States having jurisdiction over means of transport. In addition, individual States may take enforcement action for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements.

Section 8.5.1 of this Manual addresses the inter-agency agreement between the NRC and DOT on transportation issues. Section 8.5.2 provides guidance on NRC enforcement action in conjunction with individual State enforcement action for transportation issues. In addition, Section 8.6.4 provides guidance on generic enforcement activities in conjunction with Agreement States.

8.5.1 Memorandum of Understanding (MOU) Between NRC and DOT

The MOU between the NRC and the Department of Transportation (DOT) is included on the **Enforcement** Web site. http://www.nrc.gov/what-we-do/regulatory/enforcement/moudot.pdf

In accordance with the MOU, DOT is required to regulate safety in the transportation of hazardous materials, including radioactive materials; NRC is authorized to license and regulate the receipt, possession, use, and transfer of "byproduct material," "source material," and "special nuclear material." Each agency has its own inspection and enforcement programs within its jurisdiction to assure compliance with its requirements. The NRC will assist DOT, as appropriate, in inspecting shippers of fissile materials and other radioactive materials exceeding Type A limits. The DOT and the NRC will consult with each other on the results of their respective inspections in the areas where the results are related to the other agency's requirements, and each will take enforcement action as it deems appropriate within the limits of its authority.

In accordance with Section IV of formalized working arrangements based on the MOU, the NRC normally carries out enforcement actions for violations of the requirements of 10 CFR 71 and 49 CFR (except 49 CFR Parts 390 through 397) by NRC licensees. DOT normally carries out enforcement actions for violations of 49 CFR (including Parts 390 through 397) by carriers of radioactive materials and shippers of radioactive materials from Agreement States, or any other shippers otherwise not subject to NRC requirements (shippers of radium, for example).

8.5.2 NRC Action in Conjunction With State Action

Individual States may take enforcement action against shippers for transportation incidents that also involve violations of NRC, Agreement State, or DOT requirements. The following guidance is provided to address the NRC's enforcement approach for those cases where a State takes action (be it the imposition of a civil penalty or suspension or revocation of the licensee's burial permit or both) against a licensee for activities that also represent violations of NRC requirements.

a. Notwithstanding the severity level of a violation, the NRC will not normally propose a civil penalty in cases where a State issues a civil penalty. However, even if a State has taken enforcement action for the violation, the NRC may consider enforcement action beyond an NOV, such as the issuance of a civil penalty or order, if the violation is repetitive. If the region believes that a civil penalty should be assessed in a particular case, the region should submit a recommendation to the Director, OE.

b. The region may issue NOVs with Severity Level III, or IV violations without prior review and approval by the Director, OE or the DEDE. Predecisional enforcement conferences need not be held if the region is satisfied with the corrective action and the licensee understands the significance of the violation. NOVs including Severity Level III violations should have an EA number and be signed by the Regional Administrator and subsequently sent to OE for information.

c. The region should submit NOVs with Severity Level I or II violations to headquarters for review and approval prior to issuance.

d. Regardless of the severity level, all NOVs and accompanying documents should require the licensee to submit to the sending office a description of the corrective action taken or planned to prevent similar future violations. This corrective action will be reviewed by the region and, if the region deems the corrective action unsatisfactory, further enforcement action to ensure compliance with NRC regulations should be considered.

Violations that are discovered by the NRC at the licensee's facility, or in other cases where the State has not taken action, will continue to be processed in accordance with normal policy and practice.

8.5.3 Accessibility of Areas With Excessive Radiation Levels

If the area of the transport vehicle with excessive radiation levels is not easily accessible, consideration may be given to categorizing the violation at a lower severity level.

8.5.4 Exercise of Enforcement Discretion Involving Transportation Casks

Section VII.B.6 of the Enforcement Policy provides that, "...licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls." Enforcement may not be warranted for certain cask contamination issues. Enforcement of the removable contamination limits in 10 CFR 71.87(i)(2) may not be appropriate where the licensee had taken comprehensive steps to ensure compliance, i.e., the licensee had decontaminated the cask several times before providing it for transportation and the staff is not aware of any further reasonable actions that the licensee could have taken to prevent the violation (see EA 93-306).

Exercise of this discretion requires an EA number and should be coordinated with OE.

8.6 Fuel Cycle and Materials Operations

This section provides specific guidance concerning enforcement practices for fuel cycle and materials operations. Supplement VI of the Enforcement Policy provides examples of violations in each of the four severity levels as guidance in this activity area.

8.6.1 Activities of Unqualified Persons

The Severity Level III example C.3 in Supplement VI of the Enforcement Policy involves "Conduct of licensed activities by a technically unqualified or uncertified person." The routine inspection program of materials licensees discloses many cases of unauthorized and potentially unqualified persons using material or performing licensed activities, such as users of certain gauges. In taking escalated enforcement action for this example, consideration should be given to whether the individual is in fact unqualified to use the materials or perform the activities.

The inspector may ask the materials licensee to explain whether or not the current unauthorized user is actually technically qualified.

a. If the **user is not qualified**, a Severity Level III violation should be cited. The licensee's corrective action should preclude the person from further licensed activity without appropriate supervision.

b. If the **user is qualified**, the violation may be categorized at a Severity Level IV. OE concurrence is not required. The licensee should take corrective action to preclude further unsupervised activity by the unauthorized user of licensed material until the license has been amended.

c. If the **only user of licensed material is not qualified**, an order suspending the license until an authorized, qualified user is obtained may be appropriate in cases involving more hazardous materials, such as in medical programs. Alternatively, if radiation hazards are minimal, as in the use of stationary liquid-level-measuring gauges or stationary thickness-measuring gauges, a Confirmatory Action Letter (CAL) suspending the user or preventing the user from using licensed material until becoming qualified may be appropriate. The CAL could also state, at the licensee's option, that the licensee will suspend further activities until it finds another qualified user and amends its license to reflect this change. If the CAL is ineffective, an order suspending the license should be considered.

8.6.2 [Reserved]

The guidance previously included in this section has been revised and is now included in Section 8.4.4, “Loss, Abandonment, or Improper Transfer or Disposal of Licensed Material.”

8.6.3 NRC Action Against Agreement State Licensee

Regulatory guidance concerning Agreement States is addressed in 10 CFR Part 150. An Agreement State is defined as any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1974, as amended, by which those States have assumed regulatory responsibility over byproduct and source materials and small quantities of special nuclear material. A non-Agreement State is defined as any other State. Approximately 31 Agreement States administer approximately 16,000 radioactive materials licenses (approximately 75 percent of all radioactive materials licensees issued in the U.S.).

Under reciprocity, the provisions of 10 CFR 150.20 establish a general license authorizing any person who holds a specific license from an Agreement State to conduct the same activity in areas under NRC jurisdiction provided, that the specific license does not limit the activity authorized by the general license to specified installations or locations. This regulation requires that the licensee

submit an NRC Form-241 at least 3 days before engaging in the activities permitted under the general license.

The NRC can take enforcement action against an Agreement State licensee if: (1) it is improperly conducting activities in areas under NRC jurisdiction in conjunction with the general license in 10 CFR 150.20, (2) it is improperly conducting activities in areas under NRC jurisdiction in conjunction with an NRC specific license, or (3) it failed to submit an NRC Form-241 in accordance with 10 CFR 150.20. Areas under NRC jurisdiction are areas within non-Agreement States, areas under exclusive Federal jurisdiction within Agreement States, or offshore waters.

For those cases in which the NRC identifies an immediate public health and safety issue concerning the Agreement State licensee, the office that identified the issue should provide immediate notification to the Agreement State that issued the specific license.

Example C.7 in Supplement VI of the Enforcement Policy is an example of a Severity Level III violation involving a failure to submit an NRC Form-241. The NRC considers this failure significant because it results in the NRC not being aware of licensed activities being conducted in NRC jurisdiction, so that the NRC is not in a position to inspect the activity and address public health and safety issues. The NRC also recognizes that some licensees may decide not to file an NRC Form-241 because of its associated license fee.

For those cases where the NRC proposes enforcement action against an Agreement State licensee, the office proposing enforcement action should ensure that the Agreement State that issued the specific license receives copies of any enforcement correspondence. If the staff proposes to conduct a predecisional enforcement conference, the office proposing the conference should notify the Agreement State and forward a copy of the meeting notice for the conference. In addition, **for proposed escalated enforcement actions, the office issuing the enforcement action should discuss the enforcement action with the Agreement State before the enforcement action is issued.** The office proposing the action should ensure that the Agreement State understands the NRC's rationale for issuing the action.

8.6.3.1 Use of Material in Areas Under Exclusive Federal Jurisdiction Within Agreement State

Under the Atomic Energy Act and NRC regulations, in order to use byproduct material, a person must obtain a license either from the NRC (for those areas under NRC jurisdiction) or from an Agreement State (for those areas under Agreement State jurisdiction). As discussed in Section 8.6.3, any person who holds a specific license from an Agreement State can conduct the same activity in areas under NRC jurisdiction, provided that the licensee submits an NRC Form-241 at least 3 days before engaging in the activities permitted under the general license or the licensee obtains an NRC license. A complication exists for those areas under exclusive Federal jurisdiction within an Agreement State, because notwithstanding the location within an Agreement State, these areas are not under the jurisdiction of the Agreement State; rather, these areas are under NRC jurisdiction. Consequently, in order for an Agreement State licensee to use material in these areas of exclusive Federal jurisdiction within the Agreement State, they must either obtain a license from the NRC as required by 10 CFR 30.3 or file NRC Form-241 pursuant to 10 CFR 150.20.

Because Agreement State licensees may not fully understand the requirements of working in areas under exclusive Federal jurisdiction within the same Agreement State, and because of the

frequent difficulty in recognizing these areas, each case involving the failure to file an NRC Form-241 or obtain an NRC license will need to be reviewed based on its own merits to determine the appropriate enforcement action.

It should be noted that prior to February 27, 1997, the regulations in 10 CFR 150.20 did not specifically require Agreement State licensees to file NRC Form-241 prior to using byproduct material in areas under exclusive Federal jurisdiction within Agreement States. An amendment to 10 CFR 150.20 (62 FR 1662), which became effective on February 27, 1997, required licensees to file NRC Form-241 under such circumstances. Therefore, special consideration should be given for these cases. The scenarios below provide guidance as to how such cases should be dispositioned:

a. For violations that occurred prior to February 27, 1997 the region should ascertain whether the licensee was aware of the need to file NRC Form-241 (e.g., the licensee previously filed NRC Form-241, the requirement to follow reciprocity procedures in areas where NRC or an Agreement State maintains jurisdiction was included as an Agreement State license condition, or the NRC had previously made the licensee aware of the requirements through written correspondence), and aware of the status of the Federal property. If the Agreement State licensee was not aware that it was operating within NRC jurisdiction or was given erroneous information concerning the status of the Federal property[2], enforcement discretion in accordance with Section VII.B.6 of the Enforcement Policy may be appropriate. While no enforcement panel with OE is needed, coordination with OE staff is warranted given the exercise of discretion. In addition, the region needs to obtain an enforcement action number for tracking purposes.

   If other violations of NRC requirements exist, the region should issue an NOV for these failures and the "contrary to" paragraph and cover letter should indicate that the location was an area under exclusive Federal jurisdiction. Enforcement action for other violations should only be taken in accordance with the provisions in 10 CFR 150.20. The subject line in the letter to the licensee should either read or include, "EXERCISE OF ENFORCEMENT DISCRETION." The cover letter to the licensee should include the following:

   > If, in the future, you operate at a temporary job site that is a Federally controlled site in an Agreement State and which may be subject to exclusive Federal jurisdiction (e.g., a military facility, or VA hospital) you should obtain a written jurisdictional determination from the Federal agency which controls the facility or land in question. If possible, obtain this determination in writing. If that is not available, you should keep a written record, signed and dated, that reflects the name and title of the person at the Federal agency who provided the information that the work site was not in an area of exclusive Federal jurisdiction and the date that the determination was provided. Absent this documentation, the NRC would expect to take enforcement action for future violations of this nature.

b. For violations that occurred prior to February 27, 1997, and the Agreement State licensee was aware that it was operating within NRC jurisdiction, <u>or</u> for violations that occurred after

[2] This information may be a written statement from the Federal agency or a written statement signed and dated by the licensee documenting the name and title of the person at the Federal agency who provided the determination that the work site was not in an area of "Exclusive Federal Jurisdiction" and the date the determination was provided.

February 27, 1998 (regardless of the licensee's awareness), the following guidance should be used:

1. For an isolated failure to file for reciprocity with no evidence of willfulness by a gauge licensee, a Severity Level IV violation may be issued by the region without an enforcement panel with OE. An enforcement action number is not warranted in this case.

2. For an isolated failure to file for reciprocity with no evidence of willfulness by a radiography licensee, a Severity Level III violation may be issued by the region without an enforcement panel with OE. A civil penalty may be included if determined to be warranted by the normal civil penalty assessment process. An enforcement action number is warranted for this case.

3. For multiple failures by either radiography or gauge licensees, cases involving willfulness, or all others cases, including those involving a second Severity Level III violation in two years/two inspections, the case should be paneled with OE, and the severity of the violation will depend on the merits of the case. An enforcement action number is warranted for these cases.

Any proposed enforcement action should be prepared using the standard citation in Appendix C for failure to comply with 10 CFR 30.3, "Activities requiring license." The violation should normally be categorized at Severity Level III (the same severity level for failure to file NRC Form-241, i.e., example C.9 in Supplement VI). The cover letter transmitting the enforcement action should specifically state that the licensee conducted NRC-licensed activities in an area under exclusive Federal jurisdiction. If additional violations of NRC requirements exist, the "contrary to" paragraph should also indicate that the location was an area under exclusive Federal jurisdiction. In addition to the action against the Agreement State licensee, Form 43 should be sent to the head of the Federal facility.

8.6.4 Actions Involving Quality Management Programs

On April 2, 1993, Supplement VI of the Enforcement Policy was modified (58 FR 17321) to revise certain examples of severity levels for violations associated with the quality management programs (QMPs) required by 10 CFR 35.32. The basic thrust of the revision was to provide greater emphasis, and attach greater importance, to violations indicative of or flowing from programmatic deficiencies (i.e., Supplement VI, Example C.6 for a Severity Level III). Such deficiencies are preventable and are more likely to have a widespread or severe impact than are isolated mistakes involving human error made in the treatment of individual patients.

The revision also reflected a reduced severity level assignment for individual violations that represent isolated mistakes or errors but are not indicative of or due to any programmatic failure or weakness (i.e., Supplement VI, Example D.3 for a Severity Level IV).

As modified, the examples categorize two types of violations at Severity Level III: (1) violations that involve a substantial failure to implement the QMP that do not result in a misadministration, and (2) programmatic weakness in the implementation of the QMP that results in a misadministration. A substantial failure to implement the QMP applies in cases where the licensee fails to establish or effectively implement one or more of the QMP objectives in 10 CFR 35.32(a)(1) - (5).

The failure to meet the objective(s) could be due to an inadequate QMP, such as licensee omissions in the written QMP procedures, or deficiencies in training such that licensee employees are not instructed to follow procedures established to meet one or more QMP objectives. This substantial failure could potentially result in a misadministration. Programmatic violations are closely related or repetitive violations that represent a pattern or trend in a specific program area (QMP objective).

As an example: suppose that a given licensee's employees are trained to check dose calculations prior to the administration of a teletherapy dose and normally do so, but that there have been failures to meet this requirement on a number of occasions and one of those occasions results in a misadministration. This example is representative of a programmatic weakness in meeting the objective that final plans of treatment and related calculations are in accordance with the respective written directive (10 CFR 35.32(a)(1)(3)).

A decision on whether to categorize a violation resulting in a misadministration at Severity Level III or IV must consider both the consequences and the isolated or programmatic nature of the violation. If the misadministration was caused by an isolated violation and there were only insubstantial or transient medical consequences, then the violation would be categorized at Severity Level IV (see the table below for examples of consequences). For example, a misadministration of 50 microcuries of sodium iodine I-131 caused by a one-time failure of an authorized user to prepare a written directive prior to the administration would be considered an isolated error of limited consequences. However, if the medical consequences were not limited, or if the violation appeared to be programmatic, then the violation would be categorized at Severity Level III.

EXAMPLES OF MISADMINISTRATION RESULTING IN:

Substantial Chronic Residual Consequence	Insubstantial or Transient Consequence
Chronic hypothyroid or athyroid function.	Transient hypothyroid function.
Small bowel adhesions with obstruction following radiation of abdomen.	Small bowel irritability and diarrhea that subsides without obstruction.
Chronic skin ulceration with severe disfiguring scarring.	Transient skin erythema.
Radiation pneumonitis with fibrosis and dyspnea following radiation of lung.	Transient pneumonitis with no residual ventilatory impairment.
Hypertension and/or chronic renal failure following radiation of kidney.	Transient reduction of renal function with full recovery within a few months after full recovery within a few months after radiation of kidney.
Chronic suppression of immunological response with increased susceptibility to whole body radiation >2Gy.	Transient decrease of platelets and lymphocytes following acute whole body radiation >0.5Gy and <1.75Gy.

To further contrast "isolated" vs. "programmatic": an isolated failure to follow a QMP applies in cases where an isolated error, mistake, or omission occurs in following an established QMP procedure. To be "isolated," the failure must represent a single occurrence as opposed to repetitive or multiple failures in the QMP procedure for that specific objective.

Enforcement actions categorized at Severity Level IV that involve an isolated failure to meet or implement a quality management objective and that result in a misadministration must be coordinated with the Director, OE.

8.6.5 Actions Involving Radiation Safety Officers (RSOs)

Example C.8 in Supplement VI of the Enforcement Policy provides an example of a Severity Level III violation involving "a failure to receive required NRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance."

The following guidance provides additional clarification on when it may be appropriate to consider the lack of an RSO or replacement of an RSO with an unqualified individual as a Severity Level III violation.

a. For some small materials licensees, there are no special qualification requirements or duties for the RSO position because of the limited types and quantities of material authorized on the license. At this type of licensee, a violation involving a change of RSO without receiving required NRC approval or an absent RSO is more appropriately categorized at Severity Level IV, unless other concurrent violations indicate the existence of a programmatic breakdown.

b. For these types of failures at all other materials licensees, the following guidance applies:

    1. If the RSO leaves the facility and no RSO is appointed, a Severity Level III violation is appropriate.

    2. If the RSO leaves the facility and the individual assigned as a replacement RSO is not qualified under applicable NRC criteria, a Severity Level III violation is appropriate.

    3. If the RSO leaves the facility and the individual assigned as a replacement RSO is qualified under the applicable NRC criteria, but the license has not been amended to name the new RSO, a Severity Level IV violation is appropriate.

8.6.6 Information Copies to Outside Organizations

In an effort to improve coordination between the NRC and the Department of Veterans Affairs (VA), and thereby improve the VA's management of nuclear medicine departments in its hospitals, the following office is to be sent a copy of every inspection report, Confirmatory Action letter, Notice of Violation, or order that is issued concerning a VA facility:

Department of Veterans Affairs (115HP/NRL)
ATTN: Director, National Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

Similarly, the following office is to be sent a copy of every inspection report, Confirmatory Action letter, Notice of Violation, or order that is issued concerning an individual radiographer:

American Society for Nondestructive Testing, Inc.
ATTN: Technical Services Manager
1711 Arlingate Lane
P.O. Box 28518
Columbus, OH 43228-0518

8.6.7 Possession of Material Without a License

This section has been reserved for future guidance on the issue of possession of material without a license.

8.6.8 Severity Level For Failure To Report A Misadministration

The Enforcement Policy, Example VI.C.5, indicates that failure to report a misadministration is normally categorized at Severity Level III.

a. 10 CFR 35.33 requires that misadministrations be reported to the NRC. When there is a failure to report a misadministration to the NRC, the following considerations apply:

   1. If no report has been made to NRC at the time that NRC becomes aware of the misadministration, the violation normally should be categorized at Severity Level III.

   2. If the report to NRC is late or incomplete, but is nonetheless the vehicle by which NRC becomes aware of the misadministration, the violation may be categorized at Severity Level IV *provided* that the late or incomplete nature of the report did not substantially diminish the NRC's ability to determine the significant facts of the misadministration once the NRC became aware of it.

b. 10 CFR 35.33 also requires that misadministrations be reported to: (1) the referring physician and (2) either the patient, or the patient's responsible relative or guardian. An exception in 10 CFR 35.33(a)(3) provides that the patient need not be notified if the referring physician informs the licensee that, based on medical judgement, telling the patient would be harmful. Pursuant to 10 CFR 35.33(a)(2), the term "patient" means both the patient and the patient's responsible relative or guardian. Therefore, a report to the patient is required unless the referring physician informs the licensee that, based on medical judgement, telling the patient would be harmful; and, in that case, a report to the patient's responsible relative or guardian is required unless the referring physician also informs the licensee that, based on medical judgement, telling the patient's responsible relative or guardian would be harmful.

   When there is a failure to report a misadministration to: (1) the referring physician or (2) the patient or the patient's responsible relative or guardian, the following considerations apply:

   1. If no report has been made to the referring physician, the violation normally should be categorized at Severity Level III. (The regulation does not specify that the report to the referring physician needs to be in writing; therefore, an oral report to the referring physician is sufficient.)

2. If neither an oral nor a written report has been made to the patient and the referring physician did not invoke the exception in 10 CFR 35.33(a)(3) as it applies to the patient, the violation normally should be categorized at Severity Level III.

3. If neither an oral nor a written report has been made to the patient because the referring physician invoked the exception in 10 CFR 35.33(a)(3) as it applies to the patient, one next must consider whether an oral or a written report was made to the patient's responsible relative or guardian. If there was also neither an oral nor a written report to the patient's responsible relative or guardian and the referring physician did not invoke the exception in 10 CFR 35.33(a)(3) as it applies to the patient's responsible relative or guardian, the violation normally should be categorized at Severity Level III.

4. If the licensee made an oral report to the patient or the patient's responsible relative or guardian (whichever is required pursuant to 10 CFR 35.33(a)(3)), but failed to make a written report as required, the violation may be categorized at Severity Level IV *provided* that the licensee promptly provides the written report once the matter is brought to the licensee's attention.

8.6.9 Guidance for Dispositioning Violations of the Clarification of Decommissioning Funding Assurance Rule

On July 26, 1995, the NRC issued a rulemaking on "Clarification of Decommissioning Funding Requirements" for materials licenses, (Clarification Rule, 60 FR 38235). The Clarification Rule requires that adequate financial assurance for decommissioning be in place during licensed operations, and be updated when the licensee decides to cease operations and begin decommissioning. The rule was meant to address those licensees who have been in timely renewal since the promulgation of the earlier Decommissioning Rule (53 FR 24018, June 27, 1988), or who have ceased operations without having adequate decommissioning funding arrangements in place. Licensees were required to provide adequate financial assurance for decommissioning by November 24, 1995, the effective date of the clarification rule.

In these cases, violations are normally identified during records reviews conducted to determine compliance with the Clarification Rule, and enforcement action should be taken if the licensee is currently not in compliance with the requirements of the Clarification Rule. The staff will provide the licensee with a letter indicating that an apparent violation has been identified as a result of a records review. Standard Form 1-IV, “Cover Letter Transmitting an Apparent Violation of a Decommissioning Requirement as a Result of a Records Review and Requesting Response,” should be used. In addition to sending the letter, the Region should contact the licensee's management by telephone to assure that the licensee has an opportunity to ask questions in order to fully understand the apparent violation. As stated in the standard letter format, the licensee can request a predecisional enforcement conference within 7 days or can provide a written response within 30 days.

Since an inspection report is not issued for a violation identified during a records review, the letter needs to identify clearly and document the specific apparent violation. The language used in the letter to identify and document the apparent violation may be adapted from the standard citations for 10 CFR 30.35 and 30.36. Although the text of these standard citations focuses on violations of Part 30, the text can be adapted for violations of the identical regulation in Part 40, 70, or 72.

The Enforcement Policy provides that violations involving significant failure to meet decommissioning requirements should be categorized at Severity Level III. See Enforcement Policy, Supplement VI, Example C.9). However, if the licensee responds within 30 days, provides an acceptable plan for meeting the decommissioning financial assurance requirements, and fully implements the plan according to an agreed-upon schedule, the violation then may be treated by issuing an NOV at Severity Level IV.[3] In this case, where the NOV is not issued until the corrective action is completed, a response to the NOV normally would not be required.

If the licensee is not responsive, does not provide an acceptable plan for meeting the decommissioning financial requirements, or is not implementing the plan according to an agreed-upon schedule, escalated enforcement action in the form of an NOV, civil penalty and/or Order is appropriate. These enforcement decisions will be made on a case-by-case basis. This guidance may be expanded or modified as further experience is gained.

In processing these cases, an EA number is to be obtained, prior to issuing the letter (Form 1-IV), using the standard EA Request and Enforcement Strategy form (Figure 3-4). Following the licensee's response, the determination of the severity level and sanction, if appropriate, is to be discussed on the weekly OE panel for the respective region. Appropriate regional and Division of Waste Management staff will participate in weekly OE panels involving escalated enforcement action in response to clarification rule violations.

In the event an application for renewal of a license is outstanding under these circumstances, the staff may deny the license renewal application and require decontamination and decommissioning. In addition to the normal Commission notification for Orders and Civil Penalties, the staff in accordance with NMSS policy, should notify the Commission of denials of license renewal applications in the weekly highlights.

As the staff considers escalated enforcement action, it should also consider, on a case-by-case basis, matters such as the licensee's financial status, the types and levels of contamination at the site, and the steps needed to ensure protection of the public health and safety if the licensee should declare bankruptcy, abandon the site, or both. The staff will analyze options for ensuring that the needed remediation steps are accomplished.

8.6.10 Guidance for Dispositioning Violations of the Timeliness in Decommissioning of Material Facilities Rule

This Section provides enforcement guidance for violations that are identified during inspections or records reviews conducted to determine compliance with the rulemaking on "Timeliness in Decommissioning of Material Facilities" for materials licensees (Timeliness Rule, 59 FR 36026-36040, July 15, 1994).

a. **Failure to Notify NRC pursuant to 10 CFR 30.36(d):** A failure to notify NRC pursuant to 10 CFR 30.36(d) should be dispositioned as a Severity Level IV violation provided that the failure is not willful and there are no other decommissioning violations for which escalated enforcement action

[3] Corrective action is not considered in determining the severity level (see Section 3.8 of the Enforcement Manual). In this case, categorization at Severity Level IV is warranted where the violation does not represent a <u>significant</u> failure to meet decommissioning requirements and therefore does not meet the criteria in Example VI.C.11. The significance of a violation is increased if the licensee has notice of the violation but is either unwilling or unable to achieve compliance.

may be taken. Use standard citation 30-36a. If the licensee is not responsive to the Notice of Violation, the issue should be paneled with OE to determine a further course of action.

If the failure to notify may be willful or if there are additional decommissioning violations for which escalated enforcement action may be taken, refer to paragraph b, below.

Note: Licensees are not required to notify NRC when a decision is made to permanently cease principal activities in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements. Also, Licensees are not required to notify NRC when no principal activities have been conducted for a period of 24 months in any separate building or outdoor area unless the separate building or outdoor area contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

b. **Processing Other Violations:** Section 8.6.11 discusses dispositioning violations of the Clarification of Decommissioning Funding Assurance Rule (Clarification Rule, 60 FR 38235, July 26, 1995). Violations of the Timeliness Rule are similar. Therefore, for violations of the Timeliness Rule that may involve escalated enforcement action, the guidance in Section 8.6.11 should be followed for contacting the licensee, providing notice of the apparent violation(s) in a letter to the licensee, and paneling the enforcement sanction with OE. Appropriate Regional and NMSS waste management staff should participate during the panel.

   Standard Citations for violations of the Timeliness Rule are available, See Appendix C. Standard Form 1-IV should be used for violations involving decommissioning timeliness. If the violation was identified as a result of an inspection, as opposed to a records review, the cover letter should be modified accordingly. For appropriate phrases to refer to an inspection, as opposed to a records review, see Standard Form 1-I.

c. **Compliance Dates:** The Timeliness Rule amended 10 CFR Parts 30, 40, 70, and 72, and established definitive criteria for timely decommissioning upon termination of operations. The Timeliness Rule establishes requirements for notifying the NRC of pending decommissioning actions and cessation in licensee operations, establishes requirements for when decommissioning plans need to be submitted, and establishes requirements for completing decommissioning activities. The regulations also allow licensees to request relief from the timing of requirements where justified. There are three general compliance dates associated with the Timeliness Rule for many licensees:

   1. August 15, 1996 - If principal activities ceased and written notification was made to NRC prior to the effective date of the Timeliness Rule (August 15, 1994), then August 15, 1994 is considered to be the date for initiating the decommissioning process. Therefore, for these licensees, the decommissioning process should have been completed by August 15, 1996.

   2. September 15, 1996 - If principal activities ceased prior to the effective date of the Timeliness Rule, but no written notification was submitted to the NRC, then the 24 month period of inactivity is considered to begin on August 15, 1994. Written requests from licensees under section 30.36(f) to delay the decommissioning process set forth in section 30.36(d) should have been submitted to the NRC within 30 days of August 15, 1996, which is September 15, 1996.

   3. October 15, 1996 - If principal activities ceased prior to the effective date of the Timeliness Rule, but no written notification was submitted to the NRC, then the 24 month period of inactivity is considered to begin on August 15, 1994; therefore the licensee should have provided written notification to the NRC within 60 days of August 15, 1996, which is October 15, 1996.

The Timeliness Rule should be consulted to determine additional compliance requirements for certain specific situations.

d. **Storage Only Licenses:** There are two different types of licenses where the authorized activity is "storage only." The Timeliness Rule applies differently depending on the type of "storage only" license, as follows:

1. In the first type, storage historically was not a principal activity authorized by the license; however, the license has been amended to authorize "storage only" as a result of some difficulty regarding the transfer or disposal of the material. Storage under these circumstances is not a "principal activity" as defined in 10 CFR 30.4. Therefore, the requirements to notify NRC and undertake decommissioning in 10 CFR 30.36(d)(2)-(4) are not triggered, because there is no principal activity to cease. For these licensees, decommissioning issues should be addressed when the license comes up for renewal. As always, concerns about such licensees also may be addressed through Demands for Information, Confirmatory Action Letters, Orders, etc. Such concerns, which may involve insolvency, lack of security and control, etc., should be discussed on the weekly OE panel for the respective region. The waste management staff in NMSS will participate.

2. In the second type, storage of material historically has been the principal activity conducted by the licensee, who did not engage in an activity that produced or used the material in storage. In such cases, storage should be treated as the principal activity under the license. Thus, the notification and decommissioning requirements in 10 CFR 30.36(d)(2)-(4) would apply, but would be triggered only if the licensee ceases storage (i.e., transfers the material).

Questions concerning an NRC position on the Timeliness Rule should be referred to the waste management staff in NMSS.

8.6.11 Severity Levels of Violations at Fuel Facilities

The examples in the Supplements that are applicable to fuel facilities are based on differentiation among violations by relating the loss of criticality safety control(s) to the availability (or likely availability) of a sufficient amount of fissile material for a nuclear criticality accident. Also provided are examples for events that involve chemical processes integral to licensed activities, whether or not radioactive material is released.

In Supplement VI, the term "system" has the same meaning as in Supplement I (i.e., it includes administrative and managerial control systems, as well as physical systems).

Example VI.A.6, concerning significant injury or loss of life to site personnel, addresses a very significant regulatory concern, because in addition to the radiation, contamination and releases defined in VI.A.1. of the Supplement, the NRC is concerned about the actual impact of any occurrence from a portion of a licensed fuel cycle activity, including chemical processes, that has been reviewed and approved as part of the NRC licensing process.

Example VI.B.4 indicates that the absence of all the criticality safety controls for a single anticipated or unanticipated nuclear criticality scenario is a very significant safety concern when the availability of fissile material makes a nuclear criticality accident possible.

Example VI.B.5 indicates that events which do not involve actual significant injuries or loss of life, but reasonably could have, had circumstances been different, are considered very significant safety concerns that do not amount to a Severity Level I threshold specified in Example VI.A.5.

As to Example VI.C.8 addressing changes of significance, consider also the "lack of a nuclear criticality specialist or replacement of a nuclear criticality specialist with an unqualified individual." This highlights the importance that the NRC places on the nuclear criticality specialist's position in a licensee's organization because this key position is responsible for conducting NCS evaluations and final reviews of changes or modifications to licensed processes. The failure to staff this position with an individual meeting the qualifications specified in the license could result in inadequate safety evaluations.

In considering whether a violation should be viewed as a significant regulatory concern and categorized at Severity Level III, example VI.C.16, provides examples that should be used as guidance that the absence of all but one criticality safety control for a single anticipated or unanticipated nuclear criticality scenario is a significant regulatory concern when a critical mass is present, or is reasonably expected to be present. Although a nuclear criticality accident was not possible, the loss of the remaining control could result in such a possibility.

Example VI.C.4 reflects the view that more than minor release of toxic material caused by the failure to comply with NRC regulations, including licensee procedures established to comply with license conditions, is a significant regulatory concern because, if not adequately corrected, it could have serious consequences to the public and licensee employees.

In considering whether a violation should be categorized at Severity Level IV, example VI.D.8 indicates that the absence of one or more criticality safety controls for a single anticipated or unanticipated nuclear criticality scenario is a regulatory concern of lesser significance when a critical mass is not but could have been present.

8.7 Miscellaneous Matters

Guidance on the miscellaneous issues addressed in Supplement VII of the Enforcement Policy is given in Chapter 7 of this Manual. See Section 7.4 for guidance concerning fitness-for-duty issues, Section 7.7 for guidance concerning employee discrimination, Section 7.8 for guidance concerning material false statements and completeness and accuracy of information, and Section 7.9 for guidance concerning enforcement actions against non-licensees (10 CFR Part 21 notification failures).

8.8 Emergency Preparedness

This section provides specific guidance concerning enforcement practices for emergency preparedness issues. Normally emergency preparedness findings are evaluated through the SDP and enforcement actions are taken based on the SDP outcome. 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.

8.8.1 10 CFR 50.54 Deficiency Grace Period

The significant provision of the Commission's regulations in this area is 10 CFR 50.54(s)(2)(ii), which provides a 4-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. 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. It 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. Thus, 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).

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. If plans were in place and capable of implementation, but a licensee itself failed to implement the plans either during a drill or an actual emergency, no grace period should be necessary to remedy the deficiency. In short, if the plans are adequate and capable of implementation, but there is a deficiency in the licensee's execution of the plan, then a grace period is not applicable. The Statements of Consideration supports this view. In the Statements of Consideration 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.

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. In addition, the EDO is to be notified before establishing the grace period and should concur on the enforcement action. 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.