
NRC Enforcement Policy

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PREFACE

The U.S. Nuclear Regulatory Commission (referred to as the NRC, Commission, or Agency) Enforcement Policy sets forth the general principles governing the NRC's enforcement program and the Commission's expectations regarding the process to be used by the NRC to assess and disposition violations of NRC requirements. However, this is a policy statement and not a regulation. The Commission may deviate from this statement of policy as appropriate under the circumstances of a particular case. The Policy also describes how organizations and individuals subject to NRC enforcement actions can provide input to the process. A glossary is provided which defines specific terms or words as they are used in the context of this Policy. The NRC Enforcement Manual contains specific processes and guidance for implementing this Policy. The guidance provided in the Enforcement Manual has been written to be consistent with this Enforcement Policy. The Enforcement Manual appears on the NRC's public Web site, <http://www.nrc.gov> (select **Public Meetings and Involvement**, then **Enforcement**, then **Guidance**, then **Enforcement Manual** or select **Electronic Reading Room, ADAMS Documents**, and search **ADAMS** using accession number **ML102630150**).

A compilation of the statutes and materials pertaining to current nuclear regulatory legislation can be found on the NRC webpage.

Changes to the NRC Enforcement Policy since it was first published with links to a summary of each change and the *Federal Register* notice for each change are maintained on the NRC Office of Enforcement (OE) webpage.

1.0 INTRODUCTION

The mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.

The following are some of the activities that the NRC performs as part of its mission:

- a. establishing requirements and guidance addressing the possession and use of source, byproduct, and special nuclear material
- b. licensing applicants to use source, byproduct, and special nuclear material and construct and operate licensed facilities in accordance with NRC requirements and specific license conditions
- c. promoting the transparency and openness of the NRC's enforcement program for all stakeholders

Oversight of licensed activities ensures that licensees are complying with NRC requirements and license conditions. Enforcement is an important part of the NRC's oversight activities.

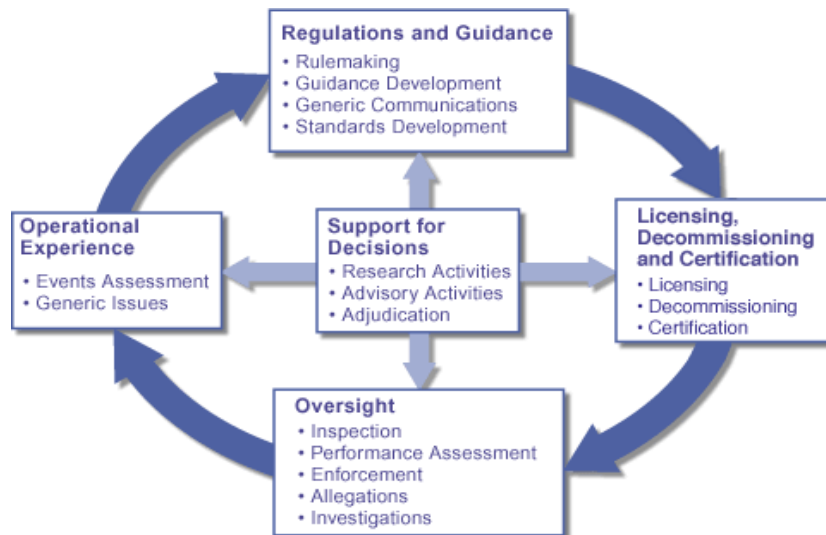


Figure 1. How the NRC Regulates

1.1 Purpose

The NRC Enforcement Policy supports the NRC's mission to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment. Adequate protection is presumptively assured by compliance with NRC requirements. Compliance with NRC requirements, including regulations, technical specifications, license conditions, and Orders, provides reasonable assurance to the NRC and the public that safety and security are being maintained. The application of this Policy ensures that associated enforcement actions properly reflect the safety or security significance of such violations. Consistent with this objective, the Enforcement Policy endeavors to do the following:

- a. Deter noncompliance by emphasizing the importance of compliance with NRC requirements.
- b. Encourage prompt identification and prompt comprehensive correction of violations of NRC requirements.

1.2 Applicability

The Enforcement Policy applies to all NRC licensees and applicants, to various categories of nonlicensees, and to individual employees of licensed and nonlicensed entities involved in NRC-regulated activities. These include, but are not limited to the following:

- a. organizations and individuals holding NRC licenses
- b. license applicants
- c. contractors and subcontractors to NRC licensees
- d. holders of and applicants for various NRC approvals, including, but not limited to:
 - 1. NRC certificates of compliance
 - 2. early site permits
 - 3. standard design certifications
 - 4. quality assurance (QA) program approvals
 - 5. certifications
 - 6. limited work authorizations (LWA)
 - 7. construction authorizations
 - 8. other permits and forms of NRC approval
- e. vendors supplying safety-related components to NRC licensees
- f. employees of any of the above

Not all NRC requirements apply to all of the categories listed above; however, the Agency will use the Enforcement Policy, as appropriate, to address violations of NRC requirements.

It is NRC policy to hold licensees, certificate holders, and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may cite the licensee, certificate holder, or applicant for violations committed by its employees, contractors, or vendors and their employees.

The NRC may use the term “licensee” in this Policy to generally refer not only to licensees, but also to certificate holders and applicants.

1.3 Statutory Authority

The NRC derives its principal authority to license and regulate the civilian use of nuclear materials from two statutes: (1) the [Atomic Energy Act \(AEA\) of 1954](#), as amended, which provides broad authority to license and regulate the civilian use of nuclear materials, and (2) the [Energy Reorganization Act \(ERA\) of 1974](#), as amended, which established the Agency and its major offices. The [Administrative Dispute Resolution Act of 1996 \(ADRA\)](#), 5 U.S.C. §§ 571-584, provides the statutory framework for the Federal Government to use alternative dispute resolution (ADR).

1.4 Regulatory Framework

The NRC’s enforcement program is governed by its regulations. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2, “Agency Rules of Practice and Procedure,” Subpart B, “Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties,” describes the formal procedures that the NRC uses to implement its enforcement authority.

1.5 Adequate Protection Standard

Adequate protection of the public health and safety and assurance of the common defense and security and protection of the environment are the NRC’s fundamental regulatory objectives. Compliance with NRC requirements plays a critical role in giving the NRC confidence that safety and security are being maintained. While adequate protection is presumptively assured by compliance with NRC requirements, circumstances may arise where new information reveals that an unforeseen hazard or security issue or security event exists or that a substantially greater potential exists for a known hazard to occur. In such situations, the NRC has the statutory authority to require action by licensees, their employees and contractors, and certificate holders above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety, and to ensure security of materials.

The NRC also has the authority to exercise discretion to permit continued operations—despite the existence of a noncompliance—where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When noncompliance with NRC requirements occurs, the NRC must evaluate the degree of risk posed by that noncompliance to determine whether immediate action is required. If the NRC determines that the noncompliance itself is of such safety significance that adequate protection is no longer provided, or that the noncompliance was caused by a failure of licensee controls so significant that it calls into question the licensee’s ability to ensure adequate protection, the NRC may demand immediate action, up to and including a shutdown or

suspension of licensed activities. Based on the NRC's evaluation of noncompliance, the appropriate action could include refraining from taking any action, taking specific enforcement action including the use of civil penalties, issuing Orders, or providing input to other regulatory actions or assessments, such as increased NRC oversight of a licensee's activities. Since some requirements are more important to safety than others, the NRC endeavors to use a risk-informed approach when applying NRC resources to the oversight of licensed activities, including enforcement activities.

1.6 Responsibilities

The Executive Director for Operations (EDO) and the principal enforcement officers of the NRC, the Deputy Executive Director for Reactor and Preparedness Programs (DEDR) and the Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration and Human Capital (DEDM), have been delegated the authority to approve or issue all escalated enforcement actions. The DEDM is responsible to the EDO for NRC enforcement programs. The Director, OE, with some limitations, is delegated the authority by the DEDM to approve, sign, and issue all enforcement actions and to oversee and implement the NRC enforcement program.¹

Subject to the oversight and direction of the Director, OE, and with the approval of the DEDM, where necessary, the regional offices normally issue notices of violation (NOVs) and proposed civil penalties. Subject to the same oversight as the regional offices, the Directors of the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of New Reactors (NRO), and the Office of Nuclear Security and Incident Response (NSIR) may also approve, sign, and issue certain enforcement actions as delegated by the Director, OE. The Director, OE, has delegated authority to the Directors of NRR, NMSS, NRO, and NSIR to issue Orders not related to specific violations of NRC requirements (i.e., nonenforcement-related Orders.) The Chief Financial Officer has been delegated the authority to issue Orders where licensees violate Commission regulations by nonpayment of license and inspection fees. (See NRC Enforcement Manual for a discussion of delegation of enforcement authority.)

2.0 NRC ENFORCEMENT PROCESS

The NRC's enforcement process has the following basic steps.

- a. First, violations must be identified.
- b. Next, the NRC must assess the severity or significance of the violation.
- c. Finally, the NRC must disposition the violation.

Throughout the process, an organization or individual subject to an NRC enforcement action has multiple opportunities to provide input.

¹ See NRC Enforcement Manual for additional information regarding the authority delegated to the Director, OE.

2.1 Identification of Violations

The enforcement process begins with the identification of violations, either through NRC inspections or investigations, a licensee report, or substantiation of an allegation.

All violations are subject to consideration for civil enforcement action; some violations may also be considered for criminal prosecution by the U.S. Department of Justice. After a potential violation is identified, it is assessed in accordance with this Policy. The NRC's enforcement assessment process is fact driven, performance based, and, when appropriate and possible, risk informed. The NRC reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level appropriate to the safety or security significance of the particular violation.

2.2 Assessment of Violations

After a violation is identified, the NRC assesses its severity or significance (both actual and potential). Under traditional enforcement, the severity level (SL) assigned to the violation generally reflects the assessment of the significance of a violation. For most violations committed by power reactor licensees, the significance of a violation is assessed using the Reactor Oversight Process (ROP) or the Construction Reactor Oversight Process (cROP), as discussed below in Section 2.2.3, "Assessment of Violations Identified Under the ROP or cROP." All other violations at power reactors or power reactor facilities under construction will be assessed using traditional enforcement as described in Section 2.2.4, "Using Traditional Enforcement to Disposition Violations Identified at Power Reactors." Violations identified at facilities that are not subject to an ROP or cROP are assessed using traditional enforcement.

2.2.1 Factors Affecting Assessment of Violations

In determining the appropriate enforcement response to a violation, the NRC considers the four specific factors discussed below. Whenever possible, the NRC uses risk information in assessing the safety or security significance of violations and assigning severity levels. A higher severity level may be warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance. Duration of the violation is also an appropriate consideration in assessing the significance of the violation.

- a. Whether the violation resulted in actual safety or security consequences. In evaluating actual consequences, the NRC considers issues such as whether the violation resulted in the onsite or offsite releases of radiation or radiation exposures exceeding 10 CFR Part 20, "Standards for Protection Against Radiation," regulatory limits, onsite or offsite chemical hazard exposures resulting from licensed or certified activities, accidental criticality, core damage, loss of significant safety barriers, loss of control of radioactive material or radiological emergencies, any violations during an actual General Emergency that prevents offsite response organizations from implementing protective actions (under their emergency plans) to protect public health and safety, or whether the security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an act of radiological sabotage occurred.

- b. Whether the violation had potential safety or security consequences. In evaluating potential consequences, the NRC considers whether the violation created a credible accident, security failure, or exposure scenario that could potentially have significant actual consequences. For facilities under construction, the NRC considers the actual or potential impact of the violation on the quality of construction and its resulting effect on the safety and security of the facility.
- c. Whether the violation impacted the ability of the NRC to perform its regulatory oversight function. The NRC considers the safety and security implications of noncompliances that may affect the NRC's ability to carry out its statutory mission. These types of violations include failures to provide complete and accurate information; failures to receive prior NRC approval for changes in licensed activities, when required; failures to notify the NRC of required changes in licensed activities, when required; failures to perform 10 CFR 50.59, "Changes, Tests and Experiments," and similar analyses; failures to maintain an up-to-date and accurate FSAR; and failures to comply with reporting requirements, 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 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 significant to safety or security. 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 reason why the failure occurred given their position and training, and whether the failure invalidates the licensing basis.

Unless otherwise categorized in the violation examples contained in this Policy (i.e., Section 6.0), the severity level of a violation involving the failure to make a required report to the NRC will depend on 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. The NRC will not normally cite a licensee 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. On the other hand, the Agency will normally cite a licensee for a failure to report a condition or event if the licensee knew of the information to be reported and did not recognize that it was required to make a report.

- d. Whether the violation involved willfulness. Willful violations are of particular concern because the NRC's regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. The Commission cannot tolerate willful violations. Therefore, a violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness. Violations with willful aspects will typically be considered for escalated enforcement (i.e., SL I, II, or III). The term "willfulness" as used in this Policy refers to conduct involving either a careless disregard for requirements or a deliberate violation of requirements or falsification of information. In determining the significance of a violation involving willfulness, the NRC will consider such factors as the position, training,

experience level, and responsibilities of the person involved in the violation (e.g., licensee official or nonsupervisory 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 the significance assessment will depend 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 more than minor. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances, such that the action reflects the seriousness of the violation, thereby creating a deterrent effect within the licensee's organization.

2.2.2 Traditional Enforcement

Under its traditional enforcement process, the NRC assesses significance by assigning a severity level to all violations by those subject to the NRC's enforcement authority as defined in Section 1.2, "Applicability of the Enforcement Policy," and to some violations by power reactor licensees. However, the Agency assesses most violations by power reactor licensees under the ROP or cROP using the significance determination process (SDP) (see Section 2.2.3). (Section 6.0 of this Policy provides examples of SL I, II, III, and IV violations in 15 activity areas. These examples are not intended to be exhaustive or controlling).

Recognizing that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion must be exercised in determining the severity levels of the violations and the appropriate enforcement sanctions. This judgment and discretion include the decision to issue an NOV, or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of policy and the significance of the violations, as well as the surrounding circumstances.

Severity level designations reflect different degrees of significance depending on the activity area in which the severity level is designated. For example, the immediacy of any hazard to the public associated with SL I in reactor operations is not directly comparable to that associated with SL I violations in facility construction.

- a. SL I violations are those that resulted in or could have resulted in serious safety or security consequences (e.g., violations that created the substantial potential for serious safety or security consequences or violations that involved systems failing when actually called on to prevent or mitigate a serious safety or security event).
- b. SL II violations are those that resulted in or could have resulted in significant safety or security consequences (e.g., violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serious safety or security event).
- c. SL III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).

- d. SL IV violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences).
- e. Minor Violations are those that are less significant than a SL IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations must be corrected.

2.2.3 Assessment of Violations Identified Under the ROP or cROP

The assessment, disposition, and subsequent NRC action related to inspection findings identified at operating power reactors are determined by the ROP, as described in NRC Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program," and IMC 0612, "Power Reactor Inspection Reports." The assessment, disposition, and subsequent NRC action related to inspection findings identified at power reactors under construction are determined by the cROP, as described in IMC 2505, "Periodic Assessment of Construction Inspection Program Results" and in IMC 0613, "Power Reactor Construction Inspection Reports."

Inspection findings identified through the ROP are assessed for significance using the SDP described in IMC 0609, "Significance Determination Process." Inspection findings identified through the cROP are assessed for significance using the SDP described in IMC 2519, "Construction Significance Determination Process." The SDPs use risk insights, where possible, to assist the NRC staff in determining the significance of inspection findings identified within the ROP or cROP. Inspection findings processed through the SDP, including associated violations, are documented in inspection reports and are assigned one of the following colors, depending on their significance.

- a. red—inspection findings with high safety or security significance
- b. yellow—inspection findings with substantial safety or security significance
- c. white—inspection findings with low-to-moderate safety or security significance
- d. green—inspection findings with very low safety or security significance

With the exceptions noted below in Section 2.2.4, violations associated with ROP or cROP inspection findings are not normally assigned severity levels, nor are they normally subject to civil penalties, although civil penalties are considered for any violation that involves actual consequences.

2.2.4 Using Traditional Enforcement to Disposition Violations Identified at Power Reactors

Some aspects of violations at power reactors cannot be addressed solely through the SDP. In these cases, violations must be addressed separately from any associated ROP or cROP findings (when findings are present). Accordingly, these violations are assigned severity levels

and can be considered for civil penalties in accordance with this Policy while the significance of the associated ROP or cROP finding (when present) must be dispositioned in accordance with the SDP. In determining the severity level assigned to such violations, the NRC will consider information in this Policy and the violation examples in Section 6.0 of this Policy, as well as SDP-related information, when available. Typically, the types of violations dispositioned using traditional enforcement include the following:

- a. violations that resulted in actual safety or security consequences (as described in Section 2.2.1.a)
- b. violations that may impact the ability of the NRC to perform its regulatory oversight function (as described in 2.2.1.c)
- c. violations involving willfulness (as described in Section 2.2.1.d)
- d. violations not associated with ROP or cROP findings

2.2.5 Export and Import of Nuclear Equipment and Material

The NRC will normally take enforcement action for violations of the Agency's export and import requirements in 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material," for radioactive material and equipment within the scope of the NRC's export and import licensing authority (10 CFR 110.8, 110.9, and 110.9a) for (1) completeness and accuracy of information, (2) reporting and recordkeeping requirements (10 CFR 110.23, 110.26, 110.50, and 110.54), and (3) adherence to general and specific licensing requirements (10 CFR 110.20 - 110.27 and 10 CFR 110.50).

2.2.6 Construction

In accordance with 10 CFR 50.10, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under 10 CFR Part 50, a combined license under 10 CFR Part 52, an early site permit authorizing the activities under 10 CFR 50.10(d), or a limited work authorization under 10 CFR 50.10(d). In an effort to preclude unnecessary regulatory burden on 10 CFR Part 52 combined license holders while maintaining safety, the Changes during Construction (CdC) Preliminary Amendment Request (PAR) process was developed in Interim Staff Guidance (ISG)-025 "Interim Staff Guidance on Changes During Construction Under 10 CFR Part 52." The license condition providing the option for a PAR as detailed in ISG-025 allows the licensee to request to make physical changes to the plant that are consistent with the scope of the associated license amendment request (LAR). The NRC staff may issue a No-Objection Letter with or without specific limitations, in response to the PAR. Enforcement actions will not be taken for construction pursuant to a PAR No-Objection Letter that is outside of the current licensing basis (CLB) while the corresponding LAR is under review as long as the construction is consistent with the associated LAR and the No-Objection Letter (the latter of which may contain limitations on construction activities). The PAR No-Objection Letter authorization is strictly conditioned on the licensee's commitment to return the plant to its CLB if the requested LAR is

subsequently denied or withdrawn. Failure to timely restore the CLB may be subject to separate enforcement, such as an order, a civil penalty, or both.

In accordance with 10 CFR 70.23(a)(7) and 10 CFR 40.32(e), commencement of construction before the NRC finishes its environmental review of license or amendment applications for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, uranium enrichment facility construction and operation, or uranium milling is grounds for denial to possess and use licensed material in the plant or facility. Additionally, in accordance with 10 CFR 70.23(b), failure to obtain Commission approval for the construction of the principal structures, systems, and components of a plutonium processing and fuel fabrication plant before the commencement of such construction may also be grounds for denial of a license to possess and use byproduct, source, or special nuclear material in the plant or facility.

2.3 Disposition of Violations

This section describes the various ways that the NRC can disposition violations.

2.3.1 Minor Violation

Violations of minor safety or security concern generally do not warrant enforcement action or documentation in inspection reports but must be corrected. Examples of minor violations can be found in the NRC Enforcement Manual, IMC 0612, Appendix E, "Examples of Minor Issues," IMC 0613, Appendix E, "Examples of Minor Construction Issues," and IMC 0617, Appendix E, "Minor Examples of Vendor and Quality Assurance Implementation Findings." Provisions for documenting minor violations can be found in the NRC Enforcement Manual, IMC 0610, IMC 0612, IMC 0613, IMC 0616, and IMC 0617.

2.3.2 Noncited Violation

If a licensee or nonlicensee has implemented a corrective action program that is determined to be adequate by the NRC,² the NRC will normally disposition SL IV violations and violations associated with green ROP or cROP findings as noncited violations (NCVs) if all the criteria in Paragraph 2.3.2.a. are met.

For licensees and nonlicensees that are not credited by the NRC as having adequate corrective action programs, the NRC will normally disposition SL IV violations and violations associated with green ROP or cROP findings as NCVs if all of the criteria in Paragraph 2.3.2.b. are met. If the SL IV violation or violation associated with a Green ROP or cROP finding was identified by the NRC, the NRC will normally issue a Notice of Violation.

Inspection reports or inspection records document NCVs and briefly describe the corrective action the licensee or nonlicensee has taken or plans to take, if known. Licensees and nonlicensees are not required to provide written responses to NCVs; however, they may provide a written response if they disagree with the NRC's description of the NCV or dispute the validity of the NCV.

² The NRC may credit a formal corrective action program that has been inspected and found to meet regulatory guidance, industry standards, or both.

- a. Licensees and Nonlicensees with a credited Corrective Action Program³
1. The licensee or nonlicensee must place the violation into a corrective action program to restore compliance and address recurrence.
 2. The licensee or nonlicensee must restore compliance (or demonstrate objective evidence of plans to restore compliance) within a reasonable period of time (i.e., in a timeframe commensurate with the significance of the violation) after a violation is identified.
 3. For traditional enforcement, the violation must either not be repetitive⁴ as a result of inadequate corrective action, or, if repetitive, the repetitive violation must not have been identified by the NRC. This criterion does not apply to violations associated with green ROP or cROP findings.
 4. The violation must not be willful. Notwithstanding willfulness, an NCV may still be appropriate in the following circumstances:
 - (a) The licensee or nonlicensee identified the violation and promptly provided the information concerning the violation, if not required to be reported, to appropriate NRC personnel, such as a resident inspector or regional branch chief.
 - (b) The violation involved the acts of an individual in a low-level position within the licensee's or nonlicensee's organization (and not a licensee or nonlicensee official as defined in Section 7.0, "Glossary").
 - (c) 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.
 - (d) The licensee or nonlicensee took significant remedial action commensurate with the circumstances. This action demonstrated the seriousness of the violation to other employees and contractors, thereby creating a deterrent effect within the licensee's or nonlicensee's organization.

The approval of the Director, OE, is required to disposition willful violations as NCVs.

³ The NRC will credit a formal corrective action program that has been inspected and found to meet regulatory guidance, industry standards, or both.

⁴ A violation is considered "repetitive" if it could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation. In addition, a violation is considered "repetitive" if a previous licensee finding occurred within the past 2 years of the inspection at issue, or the period between the last two inspections, whichever is longer.

b. All Other Licensees and Nonlicensees

1. The licensee or nonlicensee identified the violation.⁵
2. The licensee or nonlicensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence.
3. The violation is not repetitive as a result of inadequate corrective action.
4. The violation is not willful. Notwithstanding willfulness, an NCV may still be appropriate if it meets the criteria in Section 2.3.2.a.4 above.

The approval of the Director, OE, is required to disposition willful violations as NCVs.

2.3.3 Notice of Violation

A Notice of Violation (NOV) ([see 10 CFR 2.201](#), “Notice of Violation”) is a written notice setting forth one or more violations of a legally binding requirement and normally requires the recipient to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken by the licensee or other person and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. The NRC may waive all or portions of a written response to the extent that relevant information has already been provided to the NRC in writing or documented in an NRC inspection report or inspection record. The NRC may require responses to NOV's to be under oath; however, normally, responses under oath will be considered necessary only for SL I, II, or III violations; violations assessed using an SDP as white, yellow, or red; or violations of NRC Orders. A civil penalty may be issued in conjunction with an NOV.

2.3.4 Civil Penalty

A civil penalty ([see 10 CFR 2.205](#), “Civil Penalties”) is a monetary penalty that the NRC may impose for violations of (1) certain specified licensing provisions of the AEA or supplementary NRC rules or Orders, (2) any requirement for which a license may be revoked, (3) reporting requirements under Section 206 of the ERA, or (4) any NRC rule adopted under Section 147 of the AEA with respect to safeguards information. Based on the circumstances of a specific case, the NRC may increase a civil penalty where application of the guidance in this Policy would normally result in a zero penalty or a base civil penalty, to ensure that the proposed civil penalty reflects the safety significance of the case. The NRC's policy of imposing graduated civil penalties generally takes into account the gravity of the violation as the primary consideration and the ability to pay as a secondary consideration. Thus, operations involving greater nuclear

⁵ An NOV is warranted when a licensee or nonlicensee 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 or nonlicensee demonstrated initiative in identifying the violation's root cause.

material inventories, significantly higher consequences resulting from a release or exposure to radioactive material and consequences to the public and workers receive higher civil penalties. Regarding the secondary factor of the ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be so severe that it adversely affects a licensee's ability to safely conduct licensed activities or puts a licensee out of business (Orders, rather than civil penalties, are used when the NRC's intent is to suspend or terminate licensed activities).

Civil penalties are considered for all SL I, II, and III violations. The civil penalty assessment process described in this section and depicted in Figure 2 should be followed to determine the appropriateness of a civil penalty for any escalated enforcement action. Notwithstanding the outcome of the normal civil penalty assessment process, discretion, as discussed in this section and in Section 3.6, "Use of Discretion in Determining the Amount of a Civil Penalty," may be exercised by either escalating or mitigating the amount of the civil penalty.

Violations assessed under an SDP normally are not considered for civil penalties. However, civil penalties are considered for violations associated with inspection findings evaluated through an SDP that involve actual consequences.

The NRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit for each day the violation continues (i.e., daily civil penalties). The NRC may exercise this discretion when a licensee was aware of a violation of at least moderate significance (i.e., at least a SL III) and had a clear opportunity to prevent, identify, and correct the violation but failed to do so.

In evaluating whether daily civil penalties are appropriate, the NRC will consider such factors as whether the violation resulted in actual consequences to public health and safety or to the common defense and security, the safety significance of the violation, whether the violation was repetitive because of inadequate corrective actions, the degree of management culpability in allowing the violation to continue or in not precluding it, the responsiveness of the licensee once the violation and its significance were identified and understood, whether the continuing violation was willful, and the duration of the violation. These evaluation factors are not necessarily of equal significance; therefore, for each case, the NRC will weigh the relative importance of each contributing factor, as well as any extenuating circumstances, to determine whether it is appropriate to use daily civil penalties.

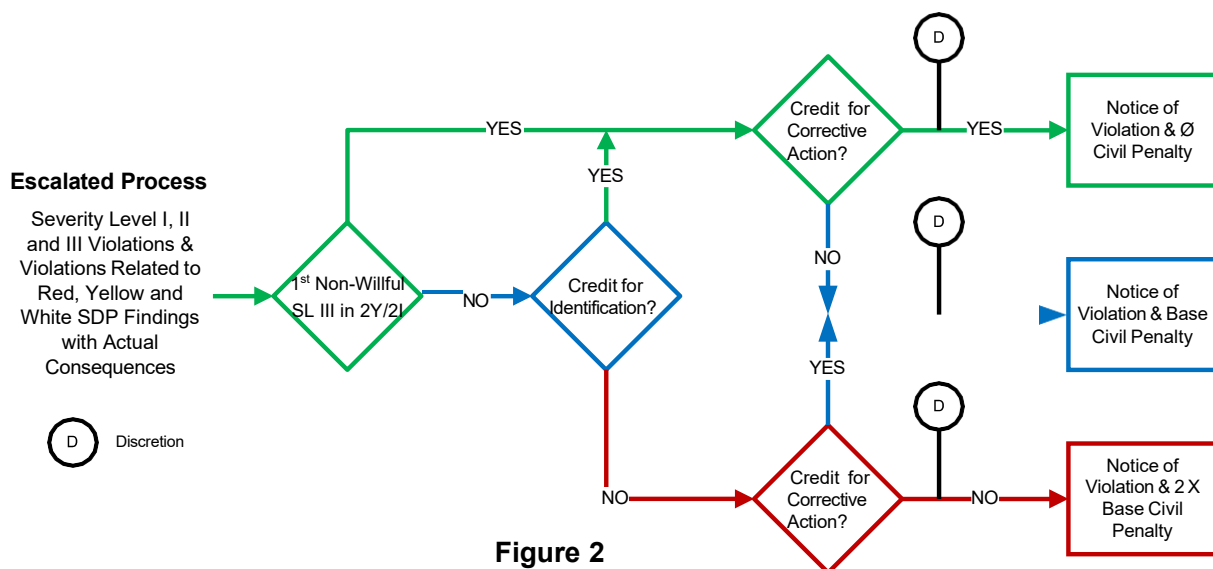
When the NRC determines that the use of daily civil penalties is appropriate as part of an enforcement action, the Agency will assess a base civil penalty for the first day of the violation in accordance with the civil penalty assessment process discussed in this section and Section 8.0, "Table of Base Civil Penalties," of the Policy. Then, to determine the total civil penalty for the continuing violation, the NRC will supplement the base civil penalty determination with a daily civil penalty for some or all of the days the violation continues. The NRC will determine the amount of the daily civil penalty on a case-by-case basis after considering the factors noted in the preceding paragraph and any relevant past precedent for similar violations. The daily civil penalty may be less than the maximum statutory daily limit in effect at the time of the violation.

The NRC considers civil penalties for violations associated with loss of regulated material (i.e., the NRC's lost source policy). The loss of NRC-regulated material is a significant regulatory and security concern because of the potential unauthorized possession or use of the material and because of the potential for overexposure to members of the public from its misuse. Such violations may include but are not limited to the loss, abandonment, improper transfer, or improper disposal of a device, source, or other form of regulated material. Notwithstanding the normal civil penalty assessment process, in cases where a licensee has lost its regulated radioactive material, the NRC may exercise discretion and impose a civil penalty. However, the Agency may mitigate or escalate a civil penalty amount based on the merits of a specific case. When appropriate, the NRC may consider, for example, information on the estimated or actual cost of authorized disposal and the actual consequences of the material remaining out of the control of the licensee, as well as any effect on radiation workers or the environment. Normally, the NRC will not apply the lost source policy to generally licensed devices that are not required to be registered in accordance with 10 CFR 31.5(c)(13)(i). The NRC will continue to apply the normal Enforcement Policy in those cases where licensees have lost control of regulated material.

For cases involving the willful failure to either file for reciprocity or obtain an NRC specific license, the NRC will normally consider a civil penalty to deter noncompliance for economic benefit. Therefore, notwithstanding the normal civil penalty assessment process, in cases where there is any indication (e.g., statements by company employees regarding the nonpayment of fees, previous violations of the requirement including those not issued by the NRC, or previous filings without a significant change in management) that the violation was committed for economic gain, the NRC may exercise discretion and impose a civil penalty. The resulting civil penalty will normally be no more than 3 times the base civil penalty; however, the agency may mitigate or escalate the amount based on the merits of a specific case.

The Commission recognizes that violations occur in a variety of activities and have varying impacts; therefore, the civil penalty tables in Section 8.0 of this Policy contain graduated sanctions based on the severity level of the violation. The tables present the base civil penalty (i.e., normal civil penalty, for any severity level violation for each type of licensee before consideration of factors to either escalate or use discretion to increase or decrease those amounts). The civil penalty amounts applied should be those in effect at the time of the violation.

The flow chart (Figure 2) presented below is a graphic representation of the civil penalty assessment process and should be used in conjunction with the narrative in this section.



The civil penalty assessment process considers four decision points. Although each of these decision 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 a base civil penalty escalated by 100 percent. The four decision points are the following:

- a. Did the licensee have any previous escalated enforcement action (regardless of the activity area) within the past 2 years of the inspection at issue, or the period between the last two inspections, whichever is longer? When the NRC determines that a nonwillful SL III violation or problem has occurred, and the licensee has not had any previous escalated actions (regardless of the activity area) during the past 2 years or two inspections, whichever period is longer, the NRC will consider whether the licensee's corrective action for the present violation or problem is reasonably prompt and comprehensive (see the discussion under Section 2.3.4.c, below). Using 2 years as the basis for assessment is expected to cover most situations, but considering a slightly longer or shorter period may be warranted based on the circumstances of a particular case. For a licensee-identified violation or an event, the starting point of this period is when the licensee becomes aware that a problem or violation exists that requires corrective action. For an NRC-identified violation, the starting point is when the NRC put the licensee on notice of the need to take corrective action for the previous violation, which could be during the inspection, at the inspection exit meeting, or as part of post inspection communication with the licensee. The 2 year period typically ends on the date of the second violation.

- b. Should the licensee be given credit for actions related to identification of the violation? A stated purpose of this Policy is to encourage prompt identification of violations of NRC requirements. While the decision regarding credit for identification can become complicated, the overarching consideration is whether the NRC should give credit for a licensee's efforts to identify the violation. It is the responsibility of the licensee to bring information on efforts to identify the violation to the attention of the NRC. The NRC will not undertake an inquiry to obtain information on whether identification credit is warranted.
1. The civil penalty assessment should normally consider the factor of identification, in addition to corrective action (see the discussion in Section 2.3.4.c, below). In these circumstances, the NRC should consider whether the licensee should be given credit for actions related to identification when any of the following conditions exist:
- (a) the violation is a SL I or II
 - (b) the violation is a willful SL III
 - (c) the licensee has been issued at least one other escalated action during the past 2 years or 2 inspections, whichever is longer.

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 the following:

- (a) whether the problem requiring corrective action was identified by the NRC, identified by the licensee, or revealed through an event
- (b) whether prior opportunities existed to identify the problem requiring corrective action, and if so, the age and number of those opportunities
- (c) 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
- (d) 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
- (e) 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

- (f) for NRC-identified issues, whether the licensee should have identified the issue (and taken action) earlier
 - (g) for cases in which the NRC identified 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
2. 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 by the licensee before the problem results 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 (i.e., the problem is self-revealing), the decision as to 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’s 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. Even if the problem 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 discovering the root cause and associated violations, or simply because no prior opportunities, for example, 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 as to 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 may include a similar previous violation, NRC or industry notices, internal audits, or readily observable trends.

If the NRC identified the violation but concludes that, under the circumstances, the licensee could not have reasonably identified the problem earlier, the matter would be treated as licensee identified for purposes of assessing the civil penalty.

- (d) **Mixed Identification**—For “mixed” identification situations (i.e., where multiple violations exist, some identified by the NRC and some by the licensee, 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's 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 licensee had dismissed the NRC's analysis or was pursuing it in parallel.

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 to take the necessary comprehensive action. In this case, the decision as to whether to give the 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 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. A missed opportunity 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 act to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, the NRC will consider, 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. A missed opportunity to identify is normally not applied where the licensee appropriately considered the information available to it and took, or planned to take, reasonable action within a reasonable time.

In some situations, the missed opportunity is a violation in itself. In these cases, unless the missed opportunity is a SL III violation in itself, the missed opportunity violation may be grouped with the other violations into a single SL III “problem.” However, if the missed opportunity is the only violation, then it should not normally be counted twice (i.e., counting it as both a violation and a missed opportunity constitutes “double counting”), unless the number of opportunities missed was particularly significant.

The timing of the missed opportunity should also be considered. While a rigid timeframe is unnecessary, for consistency in implementation, 2 years should generally be considered as the period reflecting relatively current performance.

3. 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, depending 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 an NOV with either a base civil penalty or a base civil penalty escalated by 100 percent, depending on the quality of corrective action.

- c. Were the licensee’s corrective actions prompt and comprehensive?

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, security, 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 the issuance of at least a base civil penalty.

In assessing this factor, the NRC will consider 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 on the specific violation or broadly on the general area of concern).

Normally, the judgment of the adequacy of corrective actions will hinge on whether the NRC had to act to focus the licensee's evaluative and corrective process to obtain comprehensive corrective action. This will normally be determined 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 receive 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 effective 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.

The NRC, in considering the comprehensiveness of the corrective action, will consider whether the licensee applied the corrective actions to all its similarly licensed operations that could be susceptible to the same failure (for those licensees having more than one facility or location). When the NRC, at the time of the 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.

Corrective action for violations involving discrimination should normally be considered comprehensive only if the licensee takes prompt, comprehensive corrective action that (1) appropriately addresses the broader environment for raising safety concerns in the workplace and (2) provides a remedy for the particular discrimination at issue.

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.

In response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee makes a prompt decision on operability and does either of the following:

1. Makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as-found condition
 2. Promptly initiates corrective action consistent with Criterion XVI of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," if the licensee intends to restore the facility or procedure to the final safety analysis report (FSAR) description
- d. In view of the circumstances of the violation, should the NRC exercise enforcement discretion to either escalate or mitigate the amount of the civil penalty?

As discussed in Section 3.6, "Use of Discretion in Determining the Amount of a Civil Penalty," discretion may be exercised by either escalating or mitigating the amount of the civil penalty determined after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects all relevant circumstances of the particular case. However, in no instance will a civil penalty for any one violation exceed the statutory daily limit.

2.3.5 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 other action as may be proper (see [10 CFR 2.202](#), "Orders"). Orders may be issued in lieu of, or in addition to, civil penalties, as appropriate, for SL I, II, and III violations. Unless a separate response is warranted pursuant to 10 CFR 2.201, the NRC does not need to issue an NOV in addition to the Order when the NOV is based on violations described in the Order. Orders may be made immediately effective, without prior opportunity for a hearing, whenever the NRC determines that the public health, safety, interest, or common defense and security so requires, or if the violation or conduct causing the violation is willful. In such cases, the Order may provide, for stated reasons, that the proposed action be immediately effective pending further action. Otherwise, the Agency grants a prior opportunity for a hearing on the Order.

The NRC may also issue Orders to nonlicensees, including contractors and subcontractors, holders of NRC approvals (e.g., certificates of compliance, early site permits, standard design certifications, or applicants for any such approvals), and to employees of any of the foregoing and to licensed individuals, such as licensed reactor operators, and nonlicensed individuals.

A more detailed discussion of Orders is available in the Enforcement Manual.

2.3.6 Demand for Information

The Commission may also issue a demand for information (DFI) (see [10 CFR 2.204](#), "Demand for Information") to determine whether an Order under 10 CFR 2.202 should be issued or whether other action should be taken.

2.3.7 Administrative Actions

The NRC also uses administrative actions, such as confirmatory action letters, notices of deviation, and notices of nonconformance, to supplement its enforcement program. These administrative actions are explained in the Enforcement Manual and defined in the glossary of this Policy. The NRC expects licensees and other persons subject to the Commission's jurisdiction to adhere to any obligations and commitments resulting from administrative actions and will consider issuing additional Orders, as needed, to ensure compliance.

2.3.8 Reopening Closed Enforcement Actions

Under special circumstances (e.g., when the NRC receives significant new information indicating that an enforcement sanction was incorrectly applied), the Agency may consider, on a case-by-case basis, reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record.

Special circumstances include, but are not limited to, situations where (1) persons provided incomplete or inaccurate information that would have been considered material to the NRC's disposition of a case, (2) information was deliberately withheld or obscured, or (3) the licensee made errors in calculations that would not have normally been reviewed by the NRC. Special circumstances do not normally include the discovery of additional information that was reasonably available to the NRC at the time the Agency made its initial enforcement decision unless the Commission determines that action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

2.3.9 Enforcement Guidance Memoranda

Enforcement guidance memoranda (EGM) are used to provide the NRC staff with temporary enforcement guidance, including, in some instances, enforcement discretion, when the criteria specified in the EGM are met. EGM normally describe the situation that has occurred that requires the use of such guidance, as well as the length of time the EGM will be in effect. For a list of current EGM, see [Appendix A](#) of the NRC Enforcement Manual.

2.3.10 Commission Notification and Consultation on Enforcement Actions

Certain enforcement actions require either advance written notification to the Commission or advance consultation with and approval by the Commission depending on the nature of the proposed sanction. Specific enforcement actions requiring prior Commission notification and consultation include, but are not limited to, the following:

- a. Enforcement Actions Requiring Written Notification to the Commission:
 1. All enforcement actions involving civil penalties or Orders
 2. All notices of enforcement discretion involving natural events, such as severe weather conditions

3. The first time that discretion is exercised for a plant that meets the criteria of Section 3.1, "Violations Identified during Extended Shutdowns or Work Stoppages"
 4. Where appropriate, based on the uniqueness or significance of the issue, when discretion is exercised for violations that meet the criteria of Section 3.5, "Violations Involving Special Circumstances"
- b. Enforcement Actions Requiring Advance Consultation with the Commission:
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 against the potential radiological or other hazards associated with continued operation
 2. Proposals 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 A of Section 8.0 for that class of licensee
 3. Any proposed enforcement action that involves a SL I violation
 4. Any action that the EDO believes warrants Commission involvement
 5. Any proposed enforcement case involving an Office of Investigations (OI) report where the NRC staff (other than the OI staff) does not arrive at the same conclusions as those in the OI report concerning issues of intent if the Director, OI, concludes that Commission consultation is warranted
 6. Any proposed enforcement action on which the Commission asks to be consulted
 7. Any proposals to use discretion to impose a daily civil penalty

2.3.11 Inaccurate and Incomplete Information

A violation of the regulations involving the submittal of incomplete or inaccurate information can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee or applicant normally will be categorized based on the guidance herein, in Section 2.2, "Assessment of Violations," and in Section 6.9, "Inaccurate and Incomplete Information or Failure To Make a Required Report."

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 a licensee or applicant official concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, the Commission may consider factors such 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 before 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 inaccurate or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

In the absence of 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 or applicant official (e.g., information to support a Notice of Enforcement Discretion). However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee or applicant official or others on behalf of a licensee or applicant, if a record was made of the oral information and provided to the licensee or applicant, thereby permitting an opportunity to correct the oral information. An example of such a situation would be a case in which the licensee or applicant had available a transcript of the communication or meeting summary containing the error and did not subsequently correct the error in a timely manner.

When a licensee or applicant has corrected inaccurate or incomplete information, the decision to issue an enforcement action for the initial inaccurate or incomplete information normally will depend on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the NRC or the licensee or applicant identified the problem with the communication, and whether the NRC relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee or applicant before the NRC relies on the information, or before the NRC raises a question about the information, no enforcement action will be taken for the initial 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 even if the information is corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or an advance in technology, a citation normally would not be appropriate if, when the new information became available or the advance in technology was made, the initial submittal was corrected. The failure to correct inaccurate or incomplete information that the licensee or applicant does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of 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 or applicant 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 a licensee or applicant recognizes that information not corrected is significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's or applicant's actions in not correcting or providing information raise questions about

the licensee's or applicant's commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. Enforcement determinations are made on a case-by-case basis, taking into consideration the issues described in this section.

2.3.12 Reporting of Defects and Noncompliance

Licensees and entities that supply products or services for use in nuclear activities are subject to certain requirements designed to ensure that products or services that could affect safety meet regulatory standards. Through procurement contracts with licensees or their contractors, suppliers may be required to have quality assurance programs that meet applicable quality assurance requirements (e.g., 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," or 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," Subpart H, "Quality Assurance"). Contractors supplying basic components or services to licensees or their contractors are subject to the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," for reporting defects and failures to comply associated with a substantial safety hazard. Contractors constructing or modifying 10 CFR Part 50 construction permit holder or 10 CFR Part 52 licensee facilities, up to the 52.103(g) finding, are subject to the additional requirements of 10 CFR 50.55(e) for reporting of defects and failures to comply associated with a substantial safety hazard, and any significant breakdown in the quality assurance program that could cause a defect in basic components when contractually imposed.

When inspectors determine that violations of NRC requirements (e.g., 10 CFR Part 50, Appendix B) have occurred that could adversely affect the quality of a safety-significant product or service, the NRC will typically take enforcement action. NOVs and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements. The NRC may also issue NOVs to contractors and vendors who violate 10 CFR Part 21 and may also issue NOVs for other violations such as those resulting from deliberate misconduct. Civil penalties may be imposed against individual directors or responsible officers of a contractor organization who deliberately fail to provide the notice required by 10 CFR 21.21(d)(1). The NRC may issue NOVs or orders to nonlicensees who are subject to the specific requirements of 10 CFR Part 71 and 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste." 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.

2.4 Participation in the Enforcement Process

Before making a final enforcement decision in cases where the NRC is considering taking escalated enforcement action (i.e., a SL III or higher NOV or a greater-than-green ROP or cROP finding), the NRC will typically offer the organization or individual subject to the enforcement action a conference with the NRC to present facts relevant to the assessment and disposition of the apparent violations. The NRC may also request a conference if additional information is needed to make a determination relevant to the assessment and disposition of the apparent violations (e.g., whether violations occurred, the severity level of the violations,

willfulness of any violations, and whether credit should be given for corrective actions or self-identification). The conference is normally held at an NRC regional office and is normally open to public observation except when the proposed enforcement action involves discussions of classified or Safeguards Information, an enforcement action against an individual, proprietary information, or other sensitive, nonpublic information. In addition, licensees, nonlicensees, and individuals can be offered ADR (see Section 2.4.3, "Alternative Dispute Resolution").

2.4.1 Predecisional Enforcement Conference

A predecisional enforcement conference (PEC) is a conference held with a licensee for violations assessed using traditional enforcement. (The term "licensee," as used in Section 2.4.1, is applied broadly and includes NRC licensees, applicants, licensed and nonlicensed individuals, contractors, vendors, and other persons.) The purpose of the PEC is to obtain information from the licensee to assist the NRC in determining whether an enforcement action is necessary and, if so, what the appropriate enforcement action is. The PEC focuses on areas such as (1) a common understanding of the facts, root causes, and missed opportunities associated with the apparent violation and (2) a common understanding of the corrective actions taken or planned. If held, a PEC is normally the final step in the NRC's fact-finding process before making an enforcement decision.

When the NRC determines that there is a violation for which escalated enforcement action appears warranted, the Agency normally offers the licensee the opportunity to attend a PEC or provide a written response to the apparent violation, or both, before the NRC makes an enforcement decision. If the NRC concludes that it has sufficient information to make an informed enforcement decision involving a licensee, the NRC will notify the licensee that a PEC does not appear to be necessary, and unless the licensee specifically requests a PEC, one will not be held. The NRC may specifically request a PEC if it needs additional information before making a final enforcement decision. If the NRC does not request a PEC or if the licensee does not accept the NRC's offer to attend a PEC, the licensee may choose to respond in writing to a documented apparent violation (including its root causes and a description of planned or implemented corrective actions) before the NRC takes enforcement action. To the extent practicable, the NRC will consider the licensee's response before taking enforcement action.

A more detailed discussion of PECs is available in the Enforcement Manual.

2.4.2 Regulatory Conference

A regulatory conference is conducted, in lieu of a PEC, for power reactor inspection findings assessed using an SDP. For reactor inspection findings that are preliminarily assessed as greater than green, the licensee will normally be given an opportunity to meet with the NRC to exchange information related to that assessment. Because the significance assessment typically requires a determination as to whether violations occurred, a subsequent PEC is not normally required.

2.4.3 Alternative Dispute Resolution

The ADRA authorizes and encourages the use of ADR procedures by Federal agencies. ADR refers to a variety of processes that emphasize creative, cooperative approaches to handling

conflicts in lieu of adversarial procedures. Mediation is the form of ADR typically used by the NRC. The use of ADR in the NRC's enforcement program is available for cases involving discrimination and other wrongdoing as well as escalated nonwillful (traditional) enforcement cases, with the potential for civil penalties (not including violations associated with findings assessed through the ROP or cROP).

ADR may also be used for discrimination violations based solely on a finding by the U.S. Department of Labor (DOL); however, the NRC will not negotiate the DOL finding. Individuals within the Commission's jurisdiction may also be offered ADR. ADR complements, and works in conjunction with, the traditional NRC enforcement process. ADR may be offered (1) before a PEC, (2) after the initial enforcement action is taken (i.e., an NOV or proposed imposition of a civil penalty), or (3) with the imposition of a civil penalty and prior to a hearing request. Use of the ADR program is voluntary for all parties, including the NRC; any participant may end the process at any time. Mediation activities are kept confidential in accordance with 5 U.S.C. § 574; however, the terms of the settlement agreement are normally formalized in a Confirmatory Order, which is published in the *Federal Register*. Normally, there is also a press release providing information about the settlement agreement.

In some circumstances, it may not be appropriate for the NRC to engage in ADR (e.g., the U.S. Department of Justice has substantial involvement in the case, cases in which the subject matter is such that a Confirmatory Order detailing the terms of a settlement agreement cannot be made public, or other particularly egregious cases in which the public interest is not served by engaging in ADR). The approval of the Director, OE, is required in those cases where the staff proposes not to offer ADR.

Additional information concerning the NRC's ADR program is available in the NRC Enforcement Manual and on the NRC Web site.

In addition, an individual and his or her employer (or former employer) can use ADR to resolve discrimination complaints (under Section 211 of the ERA) before the initiation of investigative activities by OI (i.e., pre-investigation ADR, commonly referred to as "early ADR") (see NRC Management Directive 8.8, "Management of Allegations") or a licensee-sponsored ADR program that is similar in nature to the NRC's early ADR program. If the parties reach a settlement agreement using early ADR or licensee-sponsored ADR, the NRC subsequently reviews the agreement to ensure that it does not include any provisions in violation of the NRC's "Employee Protection" regulations. If no such restrictive provisions exist, the NRC will not investigate the discrimination complaint or take enforcement action.

3.0 USE OF ENFORCEMENT DISCRETION

The NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority. The exercise of discretion allows the NRC to determine what actions should be taken in a particular case, notwithstanding the guidance contained in this statement of policy. After considering the general tenets of this Policy and the safety and security significance of a violation and its surrounding circumstances, judgment and discretion may be exercised in determining the severity levels of violations and the appropriate enforcement sanctions to be taken.

3.1 Violations Identified during Extended Shutdowns or Work Stoppages

Notwithstanding the outcome of the normal NOV and civil penalty assessment processes, the NRC may reduce or refrain from issuing an NOV or a proposed civil penalty for a SL II, III, or IV violation that is identified after one of the following:

- a. The NRC has taken significant enforcement action based on a major safety event contributing to an extended shutdown of an operating nuclear reactor or a material licensee (or a work stoppage at a construction site).
- b. 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 materials cases) and meets all of the following criteria:
 - 1. The violation was either identified by the licensee as a result of a comprehensive program for violation identification and correction developed in response to the shutdown or work stoppage or identified as a result of an employee or contractor concern identified to the licensee through its internal processes.
 - 2. The violation was based on activities of the licensee before the events leading to the shutdown.
 - 3. The violation would not be categorized at SL I.
 - 4. The violation was not willful.
 - 5. The licensee's decision to restart the plant from the shutdown or work stoppage requires NRC coordination and/or action.
- c. Notwithstanding the discretion criterion described above in 3.1.b.4, enforcement discretion for violations involving willfulness may still be appropriate under the specific circumstances of a case. However, the Director, OE, must approve the exercise of such discretion when a willful violation is involved.

3.2 Violations Involving Old Design Issues

For operating facilities, the NRC may exercise discretion to refrain from proposing a civil penalty for a SL II or III violation involving a past problem, such as in engineering, design, or installation, if the violation is documented in an inspection report (or inspection records for some material cases) that describes the corrective action and it meets all of the following criteria:

- a. It was identified by the licensee as a result of a 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).

- c. It was unlikely to be identified (after the violation occurred) by efforts such as normal surveillances or routinely scheduled QA activities.

The NRC may refrain from issuing an NOV for a SL II, III, or IV violation that meets the above criteria, provided that the violation was caused by conduct that is not reasonably linked to the licensee's present performance (normally, violations that are at least 3 years old or violations occurring during plant construction) and that there had not been prior notice so that the licensee could not have reasonably identified the violation earlier. This exercise of discretion is to encourage licensees to initiate efforts to identify and correct subtle violations that are not likely to be identified by routine efforts before degraded safety systems are called on to work.

3.3 Violations Identified Because of Previous Enforcement Action

The NRC may refrain from issuing an NOV or a proposed civil penalty for a SL II, III, or IV violation that is identified after the NRC has taken enforcement action, if the violation is identified by the licensee as part of the corrective action for the previous enforcement action and the violation has the same or similar root cause as the violation for which enforcement action was previously taken. Additionally, the new example must not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation and must be corrected, including immediate corrective action and long-term comprehensive corrective action to prevent recurrence, within a reasonable time following identification.

3.4 Violations Involving Certain Discrimination Issues

For violations of the NRC's employee protection regulations (e.g., 10 CFR 30.7, 50.7, and 52.5), the NRC may exercise discretion to mitigate enforcement sanctions and refrain from issuing a civil penalty or an NOV, or both, 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, if required, the overall work environment for raising safety concerns.

Similarly, the NRC may exercise discretion when a licensee settles a complaint filed with DOL under Section 211 of the ERA before DOL makes an initial finding of discrimination and, as necessary, addresses the overall work environment. Alternatively, if DOL makes a finding of discrimination, the licensee may choose to settle the case before the evidentiary hearing begins. In such cases, the NRC may exercise its discretion not to take enforcement action when the licensee has addressed the overall work environment for raising safety concerns and has publicized that a complaint of discrimination for engaging in protected activity was made to DOL, that the matter was settled to the satisfaction of the employee, and that, if the DOL area office found discrimination, the licensee has acted to positively reemphasize that discrimination will not be tolerated.

After the initiation of an OI investigation and subsequent substantiation of the discrimination complaint, the NRC may also exercise discretion (i.e., mitigate enforcement sanctions) in discrimination cases in which a licensee settles a matter promptly after a person comes to the NRC without going to DOL. The NRC would normally not exercise such discretion in cases in

which the licensee does not appropriately address the overall work environment or in cases that involve the following: allegations of discrimination as a result of providing information directly to the NRC, allegations of discrimination caused by a manager above first-line supervisor, allegations of discrimination where a history of findings of discrimination (by DOL or the NRC) or settlements suggests a programmatic rather than an isolated discrimination problem, or allegations of discrimination that appear particularly blatant or egregious.

3.5 Violations Involving Special Circumstances

Notwithstanding the outcome of the normal enforcement process, the NRC may reduce or refrain from issuing a civil penalty or an NOV for a SL II, III, or IV violation based on the merits of the case after considering the guidance in this statement of policy and such factors as the age of the violation, the significance of the violation, the clarity of the requirement and associated guidance, the appropriateness of the requirement, the overall sustained performance of the licensee, and other relevant circumstances, including any that may have changed since the violation occurred. This discretion is expected to be exercised only where application of the normal guidance in the Policy is unwarranted. In addition, the NRC may refrain from issuing enforcement action for violations resulting from matters not within a licensee's control, such as equipment failures that were not avoidable by reasonable licensee QA measures or management controls (e.g., reactor coolant system leakage that was not within the licensee's ability to detect during operation, but was identified at the first available opportunity or outage). Generally, however, licensees are held responsible for the acts of their employees and contractors. Accordingly, this Policy should not be construed to excuse personnel or contractor errors.

3.6 Use of Discretion in Determining the Amount of a Civil Penalty

Notwithstanding the outcome of the normal civil penalty assessment process addressed in Section 2.3.4, "Civil Penalty," the NRC may exercise discretion⁶ by either: (1) proposing a civil penalty where application of the civil penalty assessment factors would otherwise result in zero penalty, (2) escalating the amount of the resulting civil penalty to ensure that the proposed civil penalty appropriately reflects the significance of the issue, or (3) mitigating the amount based on merits of the case and the ability of the various classes of licensees to pay. In accordance with Section 2.3.10, "Commission Notification and Consultation on Enforcement Actions," of this Policy, the Commission must be notified of all enforcement actions involving civil penalties and must be consulted for any proposed civil penalty for a single violation or problem that is greater than 3 times the value in Tables A and B in Section 8.0 for the severity level violation being considered.

Civil penalty discretion should be considered for, but is not limited to, the following:

- a. violations or problems originally categorized at a SL I or II
- b. overexposures or the release of licensed material in excess of NRC limits

⁶ In the context of Section 3.6, "discretion" refers to the escalation or mitigation of an enforcement action or sanction. This differs from the typical use of the term "discretion" to indicate the NRC's choice to mitigate or not take enforcement action for an issue.

- c. particularly poor licensee performance
- d. situations when the licensee's previous enforcement history has been particularly poor, or when the current violation directly repeats an earlier violation
- e. willfulness, particularly instances where the licensee made a conscious decision to be in noncompliance with NRC requirements in order to obtain an economic benefit
- f. situations where the violation resulted in a substantial increase in risk, including cases in which the duration of the violation has contributed to the substantial increase in risk
- g. violations involving a Master Materials Licensee (MML)—Discretion not to issue a civil penalty may be used in cases where the MML's oversight program resolved the issue appropriately. In recognition of the scope, level of responsibility, and independence entrusted to MMLs, the NRC may use discretion to increase a civil penalty by multiples of the normal base civil penalty. This increase would normally be applied in cases where a programmatic failure occurred in the MML's oversight program.
- h. loss of control of regulated material
- i. for cases involving an individual or a licensee where a concern exists that the outcome from the proposed civil penalty may be overly punitive rather than deterrent.

3.7 Exercise of Discretion to Issue Orders

The NRC may exercise discretion, where necessary or desirable, by issuing Orders with or in lieu of civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations.

3.8 Notices of Enforcement Discretion for Operating Power Reactors and Gaseous Diffusion Plants⁷

The NRC may choose not to enforce the applicable technical specification (TS) limiting condition for operation (LCO) or other license conditions, in circumstances where compliance would involve an unnecessary plant transient or the performance of a test, inspection, or system realignment that may not be the most prudent action to take under the specific plant conditions, or unnecessary delays in plant startup, without a corresponding health and safety benefit. Similarly, for example, for a gaseous diffusion plant, circumstances may arise where compliance with a technical safety requirement or TS 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.

⁷ NOEDs will not be used at reactors during construction before the Commission's 10 CFR 52.103(g) or 10 CFR 50.57 finding, as applicable. However, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions or otherwise refrain from taking enforcement action within the Commission's statutory authority, as identified in Section 3.0 of this Enforcement Policy.

The NRC will issue a notice of enforcement discretion (NOED) only if the staff is clearly satisfied that the action is consistent with protecting the public health and safety or security. The NRC 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 staff shall inform the Commission expeditiously following the granting of a NOED in these situations.

Issuance of 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 has chosen to issue an NOED, enforcement action will normally be taken for the root causes, to the extent violations were involved, that led to the noncompliance for which enforcement discretion was used.

Additional guidance on the process for issuing an NOED is found on the NRC's web site.

3.9 Violations Involving Certain Construction Issues

a. Fuel Cycle Facilities

The NRC may choose to exercise discretion for fuel cycle facilities under construction (construction is defined in 10 CFR 40.4 for source material licensees and in 10 CFR 70.4 for special nuclear material licensees) based on the general enforcement discretion guidance contained in Section 3 of this Enforcement Policy.

b. Part 50 Construction Permit and LWA Holders

The NRC may exercise discretion for Construction Permit and LWA holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy.

c. COL Holders (Reactor Facilities)

The NRC may exercise discretion for COL holders during construction using the general enforcement discretion guidance in Section 3 of the Enforcement Policy, as applicable. Additionally, the NRC may reduce or refrain from issuing an NOV/NCV for a violation associated with an unplanned change that deviates from the licensing basis that is implemented during construction⁸ and that would otherwise require prior NRC approval (in the form of a license amendment) when all of the following criteria are met:

⁸ The NRC may issue an enforcement action, including consideration of willfulness, for the cause of these unplanned changes, such as a failure to implement appropriate work controls or quality control measures, or a failure to adhere to procedures, processes, instructions, or standards that implement NRC requirements. This enforcement may be appropriate for the actions that led to the changes during construction issue.

- The licensee identifies the unplanned changes implemented, which the staff would normally disposition as a Severity Level IV violation of NRC requirements.⁹
- The licensee submits the necessary information without delay to the NRC so that it can conduct a timely evaluation of the change as part of the license amendment review process, or submits information to the NRC stating that it will restore the current licensing basis.
- Either (1) the cause of the deviation was not within the licensee's control, such that the change was not avoidable by reasonable licensee quality assurance measures or management controls, or (2) the licensee placed the cause of the unplanned change in its corrective action program to ensure comprehensive corrective actions to address the cause of the change to preclude recurrence.

For similar issues not identified by the licensee, the NRC may refrain from issuing an NOV/NCV on a case-by-case basis depending upon the circumstances of the issue, such as whether the requirements were clearly understood or should have been understood at the time, the cause of the issue, and why the licensee did not identify the issue.

When the NRC determines that an unplanned change during construction associated with a violation of requirements meets the outlined criteria above and the licensee without delay submits the necessary information for NRC evaluation, the licensee's continued failure to meet the current licensing basis (CLB) will not be treated as a willful or continuing violation only while the licensee prepares the license amendment request and the NRC reviews the submittal. (Note: If the NRC subsequently denies a requested license amendment change, or if the NRC requires additional measures to be taken for the change to be considered acceptable, then a separate NOV or order may be issued to ensure appropriate corrective actions are taken, including restoring the configuration to the CLB).

3.10 Reactor Violations With No Performance Deficiencies

The NRC may exercise discretion for violations of NRC requirements by reactor licensees for which there are no associated performance deficiencies (e.g., a violation of a TS which is not a performance deficiency).

4.0 **ENFORCEMENT ACTIONS INVOLVING INDIVIDUALS**

Any individual may be subject to NRC enforcement action if the individual (1) deliberately causes or would have caused, if not detected, a licensee to be in violation of any regulation or Order, or any term, condition, or limitation of any license issued by the Commission related to NRC-licensed activities or (2) deliberately submits materially inaccurate or incomplete information to the NRC, a licensee, an applicant or a licensee, or a contractor or subcontractor

⁹ NRC-identified violations that result in a "use as built" determination or that result in an unplanned change (or both) will normally be dispositioned as a cited, noncited, or minor violation, whether or not the unplanned change issue is resolved by a subsequently approved license amendment.

of a licensee or applicant for a license (e.g., see “Deliberate Misconduct” regulations in 10 CFR 30.10, 10 CFR 50.5, 10 CFR 52.4, and 10 CFR 76.10).

The Agency will normally take enforcement actions against nonlicensed individuals only in cases involving deliberate misconduct by the nonlicensed individual, in cases involving a lack of reasonable assurance, as discussed below in Section 4.2, “Notices of Violation and Orders to Individuals,” and in cases in which an individual violates any requirement directly imposed on him or her (e.g., a violation of any rule adopted under Section 147, “Safeguards Information,” of the AEA). However, the NRC may take enforcement action against NRC-licensed reactor operators even if the violation does not involve deliberate misconduct, since operators licensed by the NRC are subject to all applicable Commission requirements (see 10 CFR 55.53(d)).

The NRC considers enforcement actions against individuals to be significant actions that will be closely evaluated and judiciously applied. Typically, the NRC will take an enforcement action involving an individual, either licensed or nonlicensed, only when the violation has actual or potential safety or security significance. NOV and Orders are examples of enforcement actions that may be issued to individuals. Enforcement actions issued to individuals will normally be placed on the NRC OE Web site. Generally, before taking enforcement action against an individual, the NRC will seek to gather information to determine whether an Order or other enforcement action should be issued. The Agency may gather such information by conducting a PEC, by requesting a written response from the individual, or by issuing a DFI. If the violation was deliberate, the individual may also be provided the opportunity to address the apparent violation during ADR. The exact nature of the opportunity to address the apparent violation will depend on the circumstances of the case, including the significance of the issue, the enforcement sanction that the NRC is contemplating, and whether the individual has already had an opportunity to respond to the apparent violation.

If the NRC discovers (through inspections or investigation-related material) potentially damaging or disqualifying information regarding an individual's trustworthiness and reliability, and the individual currently possesses Unescorted Access (UA) or is in the process of obtaining Unescorted Access Authorization (UAA), the NRC will consider, on a case-by-case basis, notifying the licensee that has granted, or is processing the UA or UAA of the information. This notification may occur in the preliminary or final determination stage of the enforcement process, as appropriate, with approval of the Director, OE. The NRC will strongly consider the degree of certainty associated with the information in making this decision. If the NRC makes such a notification, it nevertheless remains the licensee's responsibility to evaluate the information provided in accordance with its access authorization program to determine the appropriate actions regarding individual access authorizations. A licensee may reasonably reach a conclusion that the information provided by the NRC is not disqualifying under the circumstances (e.g., based on additional facts, based on a different assessment of the facts, or based upon the final resolution of the enforcement process).

Since it is NRC policy to hold licensees responsible for the acts of their employees and contractors, in most cases, the NRC will cite the licensee for violations committed by their employees and contractors. Violations with a significance that would typically warrant escalated enforcement action against the licensee may warrant an enforcement action against an individual (e.g., deliberately providing inaccurate or incomplete information or deliberate falsification of documents). Typically, the NRC will not take enforcement action against the

employee or contractor if failures of licensee management (e.g., improper training or inadequate procedures) are responsible for the individual's improper actions. In deciding whether to issue enforcement actions both to a licensee and a nonlicensed individual, the NRC will make decisions on a case-by-case basis.

4.1 Considerations in Determining Enforcement Actions Involving Individuals

The NRC recognizes that decisions regarding enforcement actions against individuals will have to be made on a case-by-case basis. The NRC may propose an enforcement action or refrain from taking an enforcement action after considering all the relevant circumstances of each case.

The primary factors considered by the NRC in considering whether to take action or what action to take are (1) the significance of the underlying violation or technical issue (not considered in discrimination cases) and (2) the individual's position within the organization (i.e., notwithstanding an individual's job title, consider the position of the individual within the licensee's organizational structure and the individual's responsibilities related to the oversight of licensed activities and to the use of licensed material).

Other factors include, but are not limited to, whether the violation was the result of deliberate misconduct (typically a prerequisite for taking action against a nonlicensed individual), the benefit to the wrongdoer (e.g., direct personal or corporate gain), the degree of management responsibility or culpability, and the attitude of the wrongdoer (e.g., admission of wrongdoing, acceptance of responsibility).

For Fitness-for-Duty (FFD) violations involving non-licensed individuals who violate drug and alcohol provisions of site FFD programs, which are explicitly described in 10 CFR 26.75, "Sanctions," the NRC will not typically consider FFD drug and alcohol-related violations for enforcement action unless there is an apparent deficiency in the licensee's FFD program to take the required sanctions against the individual(s) or deficiencies in implementation of the licensee FFD program.

4.2 Notices of Violation and Orders to Individuals

Although the NRC has the authority to issue NOV's to any individual who holds an NRC license and violates NRC requirements, regardless of whether willfulness, either deliberate misconduct or careless disregard, was involved, actions against licensed individuals for nonwillful violations are rare. In the case of a licensed operator's failure to meet applicable fitness-for-duty requirements (i.e., 10 CFR 55.53(j)), the NRC may issue an NOV to the individual, or an Order to suspend, modify, or revoke the individual's 10 CFR Part 55 operator's license. The Agency may also issue to licensed individuals Orders containing provisions that would modify or revoke the individual's license or 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).

The Commission may also take enforcement action (e.g., an Order or NOV) against nonlicensed individuals, including contractors and subcontractors and their employees, who knowingly provide components, equipment, or other goods or services that relate to a licensee's

activities subject to NRC regulations. However, the NRC will not normally issue an enforcement action against a nonlicensed individual unless the individual's actions were a result of deliberate misconduct. When needed to ensure adequate protection of public health and safety and the common defense and security or the public interest, the NRC may issue an Order to an unlicensed person, whether a firm or an individual, requiring (1) the removal of the person from all NRC-licensed activities for a specified period of time (normally, the period of suspension would not exceed 5 years) and (2) prior notice to the NRC before engaging in NRC-licensed activities. In addition, Orders to employers who are NRC licensees could require retraining, additional oversight, independent verification of activities performed by the individual, if the individual is to be involved in licensed activities, and to inform other persons or NRC licensees who make reference inquiries (e.g., employment reference inquiries) regarding the nonlicensed individual or firm, of the issuance of such an Order.

For either a licensed or nonlicensed individual, the initial determination of a period of prohibition from NRC-licensed activities is normally based on the significance of the underlying violation and the individual's level of responsibility within the organization. A high level of significance combined with a high degree of responsibility results in initially considering a 5-year prohibition period. Depending on the circumstances of the case, the NRC may consider either escalation (including a permanent ban from NRC-licensed activities in significant cases) or mitigation of the prohibition period.

In addition to the above, the NRC may take enforcement action against a licensee that may affect an individual, where the conduct of the individual calls into 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 (e.g., lying to the NRC), competence, fitness for duty, or other matters that may not necessarily be a violation of specific Commission requirements.

4.3 Civil Penalties to Individuals

Except for individuals subject to civil penalties under Section 206 of the ERA, as amended, the NRC will not normally impose a civil penalty against an individual. However, Section 234 of the AEA gives the Commission authority to impose civil penalties on "any person." Furthermore, any person, whether or not a licensee of the Commission, who violates any regulations adopted under Section 147, "Safeguards Information," of the AEA will be subject to the full range of enforcement sanctions, including civil penalties. Section 11s of the AEA broadly defines "person" to include individuals, a variety of organizations, and their representatives or agents.

The NRC may issue a civil penalty to any individual who deliberately releases Safeguards Information (SGI), including SGI-M, regardless of whether that individual is employed by a licensee. If an individual deliberately released or failed to properly control SGI after employment ends with a licensee, the NRC will typically consider individual enforcement actions, including civil penalties in accordance with this Policy, as described below.

The NRC will typically not issue a civil penalty to an individual for non-deliberate violations of SGI requirements if that individual's employer (a licensee, certificate holder,

applicant for a license or a certificate of compliance, or contractor) places the violation in its corrective action program and has taken, or plans to take, corrective actions to restore compliance. The NRC will consider, based on the circumstances of a case, the appropriateness of a civil penalty for non-deliberate releases of SGI by an individual in which the employer failed to take or plan to take corrective actions and for cases involving deliberate or non-deliberate releases of SGI by an individual after employment has ended with a licensee.

The NRC considers an individual's reasons and potential motivations for disclosing SGI and the willingness of the individual to correct or mitigate the release of information in determining if a civil penalty is to be issued and in determining the final civil penalty amount. The NRC typically reserves civil penalties for cases involving egregious violations and for individuals who refuse to correct or mitigate the release of information. Table A in Section 8.0 of this Policy lists the base civil penalty to individuals who release SGI. The intent of civil penalties to individuals is to serve as a deterrent; these penalties generally do not require a base civil penalty as high as that issued to a licensee or contractor. However, willful violations may support a civil penalty outside of the range listed in Section 8.0.

Section 6.13, "Information Security," of this Policy provides a risk-informed approach for assessing the significance of information security violations. Also, in determining the appropriate SL for the release of SGI, the NRC will consider the type of SGI information disclosed, its availability to the public, the damage or vulnerability that the information caused or may cause to the licensee that possessed ownership of the SGI, and the damage that the information caused or could cause to public health and safety. The NRC will also use SGI-related significance determination process (under the Reactor Oversight Process) information, when available, to inform the SL determination.

4.4 Confirmatory Orders to Individuals

Agreements with individuals reached as a result of the ADR process are normally formalized by the issuance of a Confirmatory Order. ADR is typically offered to individuals consistent with the process used for licensees (see Section 2.4.3 of this Policy).

5.0 PUBLIC AVAILABILITY OF INFORMATION REGARDING ENFORCEMENT ACTIONS

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," enforcement actions and licensees' responses are normally made publicly available for inspection. However, some security-related information and medical records, except if obtained pursuant to the Commission's regulations, will not be made available to the public. The NRC Office of Public Affairs is responsible for making final decisions as to whether press releases will be issued; however, such releases are normally issued for Orders and civil penalties at the same time that the Order or proposed imposition of the civil penalty is issued. Press releases may also be issued when a civil penalty is withdrawn or substantially mitigated. Press releases are not normally issued for NOVs that are not accompanied by Orders or proposed civil penalties, unless the issue or licensee involved is of some particular interest.

6.0 VIOLATION EXAMPLES

The violation examples in this Policy are intentionally broad in scope so as to serve as a set of guiding examples that are neither exhaustive nor controlling for making severity level determinations. Licensed activities are placed in the most appropriate activity area in light of the particular violation involved, including activities not directly covered by one of the listed areas. The violation examples are not intended to address every possible circumstance. However, when an enforcement case scenario very nearly achieves all or some of the criteria set forth in an example, the case should be considered to be at the severity level of that example. For example, when using the examples in Section 6.7, "Health Physics," if the circumstances of a case are such that one or more of the severity levels in an example were very nearly reached, and it was only fortuitous that the limit was not actually met or exceeded, then the severity level for the subject example would be applicable. Additionally, if the circumstances for a case do not squarely fit any particular violation example, a comparable example in the same activity area may be considered to determine the severity (e.g., the case for an industrial licensee presents a set of circumstances and considerations comparable to those for a medical example provided in Section 6.3, "Materials Operations;" hence, the severity level for the medical example can be applied).

Many examples are written to reflect the risks associated with the use of nuclear materials. However, violations during construction generally occur before the nuclear material and its associated risk are present. Therefore, the NRC will consider the lower risk significance of violations that occur during construction in the areas of emergency preparedness, reactor operator licensing, and security and may reduce the severity level for those violations from that indicated by the examples in those areas. In order to maintain consistent application, the staff must coordinate with the Office of Enforcement before applying this lower risk significance concept for violations that occur during construction.

6.1 Reactor Operations

a. *SL* / violations involve, for example:

1. A system¹⁰ that is part of the primary success path and which functions or actuates to mitigate a Design Basis Accident (DBA) or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier is unable to perform its licensing basis safety function¹¹ when actually called on to function;
2. An inadvertent or unplanned criticality; or
3. A technical specification safety limit is exceeded.

¹⁰ The term "system" as used in these violation examples includes administrative control systems, managerial control systems, as well as physical systems.

¹¹ "Licensing basis safety function" means the total safety function and is not directed toward a loss of redundancy. A loss of one subsystem does not defeat the intended safety function as long as the other subsystem is operable.

b. *SL II* violations involve, for example:

1. A system that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier would be unable to perform its licensing basis safety function had it been called upon to function.

c. *SL III* violations involve, for example:

1. A licensee fails to shut down the reactor or follow remedial actions permitted by a technical specification action requirement when a Limiting Condition for Operation (LCO) is not met (i.e., noncompliance with 10 CFR 50.36(c)(2)(i));
2. A system that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of or presents a challenge to the integrity of the fission product barrier not being able to perform its licensing basis safety function because it is not fully qualified (per the IMC 0326, "Operability Determinations & Functional Assessment for Conditions Adverse to Quality or Safety") (e.g., materials or components not environmentally qualified);
3. Changes in reactor parameters cause unanticipated reductions in margins to safety;
4. A licensee fails to adequately oversee contractors, which results in the use of safety-significant products or services that are defective or of indeterminate quality;
5. Equipment failures caused by inadequate or improper maintenance substantially complicate recovery from a plant transient;
6. A licensee fails to obtain prior Commission approval required by 10 CFR 50.59 for a change that has a consequence evaluated by the SDP as having low-to-moderate or greater safety significance (i.e., white, yellow, or red); or
7. A licensee fails to update the FSAR as required by 10 CFR 50.71(e), and the un-updated FSAR is used to perform a 10 CFR 50.59 evaluation for a change to the facility or procedures, implemented without Commission approval, that results in a condition evaluated as having low-to-moderate or greater safety significance (i.e., white, yellow, or red) by the SDP.

d. *SL IV* violations involve, for example:

1. A failure to comply with a technical specification action requirement demonstrates misapplication of the conventions in technical specifications Section 1.0, "Use and Application", or the allowances for LCO and surveillance requirement applicabilities in technical specifications Section 3.0;

2. Violations of 10 CFR 50.59 result in conditions evaluated as having very low safety significance (i.e., green) by the SDP;
3. A licensee fails to update the FSAR as required by 10 CFR 50.71(e) and the lack of up-to-date information has a material impact on safety or licensed activities; or
4. A licensee fails to adequately assess the risk of plant operations associated with implementation of a risk-informed technical specification allowance such that the allowance is implemented inappropriately.

6.2 Fuel Cycle Operations

This section provides examples in the area of fuel cycle operations for licensees with an integrated safety analysis (ISA) under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material,” and fuel cycle licensees without an ISA. The NRC will determine the appropriate severity level for a specific violation by using licensee ISAs and other applicable risk information.

a. *SL I* violations involve, for example:

1. Under 10 CFR Part 70, Subpart H, a high-consequence event occurs; or
2. For licensees not under 10 CFR Part 70, Subpart H, the occurrence of an event with a consequence commensurate with a 10 CFR Part 70, Subpart H, high-consequence event, as a result of licensed materials or hazardous chemicals produced from licensed materials.

b. *SL II* violations involve, for example:

1. Under 10 CFR Part 70, Subpart H, a high-consequence event is “not unlikely” based on a licensee’s ISA;
2. Under 10 CFR Part 70, Subpart H, an intermediate-consequence event occurs;
3. For licensees not under 10 CFR Part 70, Subpart H, a very substantial increase in the likelihood of a consequence commensurate with a Part 70 high-consequence event occurs; or
4. For licensees not under 10 CFR Part 70, Subpart H, an event with a consequence commensurate with a Part 70, Subpart H intermediate-consequence event occurs as the result of licensed materials or hazardous chemicals produced from licensed materials.

c. *SL III* violations involve, for example:

1. Under 10 CFR Part 70, Subpart H, a high-consequence event is “unlikely” based on a licensee’s ISA;
 2. Under 10 CFR Part 70, Subpart H, an intermediate-consequence event is “not unlikely” based on a licensee’s ISA;
 3. For licensees not under 10 CFR Part 70, Subpart H, a substantial increase in the likelihood of a consequence commensurate with a Part 70, Subpart H, high-consequence event occurs;
 4. For licensees not under 10 CFR Part 70, Subpart H, a significant increase in the likelihood of a consequence commensurate with a Part 70, Subpart H, intermediate-consequence event occurs;
 5. A significant failure to comply with the action statement for a technical safety requirement Limiting Condition for Operation (LCO) results in the appropriate action not being taken within the required time;
 6. Under 10 CFR 70.72, “Facility Changes and Change Process,” or 10 CFR 76.68, “Plant Changes,” a significant failure to adequately evaluate a change to the facility results in implementation of the change without a required license or certificate amendment;
 7. Under 10 CFR 70.24 or 10 CFR 76.89, both titled “Criticality Accident Requirements,” a criticality accident alarm system fails to provide either detection or annunciation coverage for a substantial time period during which operations involving handling or using fissile material occurred; or
 8. A licensee fails to meet or implement more than one emergency planning standard.
- d. *SL IV* violations involve, for example:
1. Under 10 CFR Part 70, Subpart H, a licensee fails to meet the requirements of 10 CFR 70.61, “Performance Requirements,” or Appendix A, “Reportable Safety Events,” to 10 CFR Part 70, and the failure does not result in a SL I, II, or III violation;
 2. A failure of safety systems or controls occurs such that an acceptable safety margin has not been maintained, and the failure does not result in a SL I, II, or III violation;
 3. A less significant failure to comply with the action statement for a technical safety requirement LCO occurs when the appropriate action was not taken within the required time;
 4. Under 10 CFR 70.72 or 10 CFR 76.68, a less significant failure to adequately evaluate a change to the facility results in implementation of the change without a

required license or certificate amendment. The failure does not result in a SL I, II, or III violation;

5. Under 10 CFR 70.24 or 10 CFR 76.89, a criticality accident alarm system fails to provide either detection or annunciation coverage of fissile material operations during a time period when fissile material was handled, used, or stored;
6. A licensee fails to meet or implement more than one emergency planning standard involving assessment or notification during an Alert emergency; or
7. A licensee fails to meet or implement any emergency planning standard or requirement not directly related to assessment and notification (e.g., emergency response training, emergency equipment maintenance).

6.3 Materials Operations

a. SL I violations involve, for example:

1. The loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, results in serious injury or loss of life;
2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function, and this results in serious injury or loss of life;
3. Failure to use a properly prepared written directive as required by 10 CFR 35.40, "Written Directives," or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," results in serious injury or loss of life; or
4. Failure to have or to follow written operating procedures as required by 10 CFR 36.53, "Operating and Emergency Procedures," results in a serious injury or loss of life.

b. SL II violations involve, for example:

1. The loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, results in the substantial potential for a significant injury or loss of life, whether or not radioactive material is released;
2. A system designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function;
3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's

procedures to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41, or a failure to train personnel in those procedures, results in a medical event; or

4. Failure to have or to follow written operating procedures as required by 10 CFR 36.53 results in a substantial potential (e.g., an event did not occur, but no barriers, neither procedural nor system, including interlocks, would have prevented it, and the event was not highly unlikely to occur) for a serious injury or death.
- c. *SL III* violations involve, for example:
1. A system designed to prevent or mitigate a serious safety event has one of the following characteristics:
 - (a) It is unable to perform its intended function under certain conditions (e.g., a safety system is not operable unless the required backup power is available), or
 - (b) It is outside design specifications to the extent that a detailed evaluation would be required to determine its operability;
 2. A programmatic failure occurs to implement written directives or procedures for administrations requiring a written directive, such as the following:
 - (a) A licensee's procedures fail to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41,
 - (b) A licensee fails to train personnel in procedures for administrations requiring a written directive,
 - (c) A nonisolated failure occurs to use and follow written directives or procedures for administrations requiring a written directive; or
 - (d) A licensee fails to have procedures or requirements for written directives or fails to have procedures for administrations that require written directives.
 3. Except as provided for in section 6.3.d.10 of the Policy, a licensee fails to secure a portable gauge as required by 10 CFR 30.34(i);
 4. A significant failure to implement the requirements of 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," during radiographic operations includes, but is not limited to, the following:
 - (a) During radiographic operations at a location other than a permanent radiographic installation, a licensee fails to have present a radiographer

- and at least one additional radiographer or qualified individual,
- (b) A licensee fails, during radiographic operations, to use radiographic equipment, radiation survey instruments, or personnel monitoring devices as required by 10 CFR Part 34, or
 - (c) During radiographic operations, a failure to stop work occurs, after a pocket dosimeter is found to have gone off-scale or after an electronic dosimeter reads greater than 200 millirem (mrem), and before a determination is made of the individual's actual radiation exposure;
5. An unqualified person conducts licensed activities. The unqualified person is characterized by either of the following:
- (a) lacking adequate qualifications, experience, or training to safely conduct activities, or
 - (b) lacking the required certification or training for positions such as radiographer; authorized user under 10 CFR Part 35, "Medical Use of Byproduct Material"; or irradiator operator under 10 CFR 36.51, "Training"
6. Licensed material is used on humans where such use is not authorized;
7. A licensee authorizes the release from its control of an individual who does not meet the release criteria in 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material;"
8. An individual without supervision operates an irradiator when the individual has not been trained as required by 10 CFR 36.51;
9. A programmatic failure occurs to have and follow written operating procedures as required by 10 CFR 36.53;
10. A programmatic failure occurs to perform inspection and maintenance checks as required by 10 CFR 36.61, "Inspection and Maintenance;"
11. A licensee fails to seek required NRC approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance, such as the following:
- (a) a change in ownership,
 - (b) a change in the location where licensed activities are being conducted or where licensed material is being stored,
 - (c) an increase in the quantity or type of radioactive material being processed or used that has radiological significance, or

- (d) a change in program status with regard to the RSO named on its license (e.g., licensee fails to have an RSO; licensee appoints an unqualified individual as RSO);
- 12. Failures occur involving decommissioning requirements, such as the following:
 - (a) a significant failure to meet decommissioning as required by regulation or license condition, or
 - (b) failure to meet required schedules without adequate justification
- d. *SL IV* violations involve, for example:
 - 1. A licensee fails to use a properly prepared written directive as required by 10 CFR 35.40, or fails to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures are characterized by all of the following:
 - (a) are isolated
 - (b) do not demonstrate programmatic weaknesses in implementation
 - (c) have limited consequences if a medical event is involved;
 - 2. A licensee fails to keep the records required by 10 CFR 35.2040, "Records of Written Directives," and 10 CFR 35.2041, "Records for Procedures for Administrations Requiring a Written Directive;"
 - 3. A licensee fails to implement procedures including, but not limited to, recordkeeping, surveys, and inventories;
 - 4. A licensee fails to comply with the U.S. Department of Transportation requirement to provide hazardous material (HAZMAT) employee training as required by 10 CFR 71.5(a);
 - 5. There is an isolated failure to have and to follow written operating procedures as required by 10 CFR 36.53;
 - 6. A licensee fails to document the required certification or training for positions such as radiographer, authorized user under 10 CFR Part 35, or irradiator operator under 10 CFR 36.51;
 - 7. A licensee fails to seek required NRC approval before the implementation of a change in ownership that results in little or no adverse impact on radiological or programmatic activities or on the NRC's ability to inspect licensed activities, such that the locations and types of activities are unaffected by the unauthorized license transfer;

8. A licensee fails to seek required NRC approval prior to replacement of the RSO, where the RSO was evaluated as qualified;
9. A licensee fails to seek NRC approval, when required, before changing the location where licensed activities are being conducted or where licensed material is being stored that has little or no radiological or programmatic significance, and all other safety and security requirements have been met; or
10. A licensee fails to secure a portable gauge as required by 10 CFR 30.34(i), whenever the gauge is not under the control and constant surveillance of the licensee, where one level of physical control existed and there was no actual loss of material, and that failure is not repetitive.

6.4 Licensed Reactor Operators

a. SL I violations involve, for example:

1. A licensed operator, or a senior operator actively performing the functions covered by that position, is involved in procedural errors that result in, or exacerbate the consequences of, an Alert or higher level emergency, and, at the time the procedural errors occurred, was determined to be either of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the licensee, or
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j), or
 - (c) unfit for duty as determined by a post event fatigue assessment required by 10 CFR 26.211(a)(3).

b. SL II violations involve, for example:

1. A licensed operator, or a senior operator actively performing the functions covered by that position, is involved in procedural errors, and, at the time the procedural error occurred, was determined to be any of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the facility licensee,
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j),
 - (c) in noncompliance with a condition stated on the individual's license, or
 - (d) unfit for duty as determined by a post event fatigue assessment required by 10 CFR 26.211(a)(3);

2. A deliberate compromise (see 10 CFR 55.49, "Integrity of Examinations and Tests") occurs of an application, test, or examination required by 10 CFR Part 55, "Operators' Licenses," or inaccurate or incomplete information is deliberately provided to the NRC and has any of the following effects:
 - (a) in the case of initial operator licensing, contributes to an individual being granted an operator or senior operator license, or
 - (b) in the case of operator requalification, contributes to an individual being permitted to continue to perform the functions of an operator or senior operator, or
 - (c) contributes to a medically unqualified individual performing the functions of a licensed operator or senior operator; or
 3. A licensed operator or senior operator, while within the protected area, is involved in the use, sale, or possession of illegal drugs or the consumption of alcoholic beverages.
- c. *SL III* violations involve, for example:
1. A licensed operator, or a senior operator actively performing the functions covered by that position, is determined to be any of the following:
 - (a) unfit for duty as a result of a confirmed positive test for drugs or alcohol at cutoff levels established by the licensee,
 - (b) under the influence of any prescription or over-the-counter drug as described in 10 CFR 55.53(j),
 - (c) in noncompliance with a condition stated on the individual's license, or
 - (d) unfit for duty as determined by a post event fatigue assessment required by 10 CFR 26.211(a)(3);
 2. A licensed operator, or a senior operator actively performing the functions covered by that position, is inattentive to duty;
 3. A licensed operator or senior operator is involved in the use, sale, or possession of illegal drugs;
 4. A nonwillful compromise (see 10 CFR 55.49, "Integrity of Examinations and Tests") of an application, test, or examination required by 10 CFR Part 55, or inaccurate or incomplete information inadvertently provided to the NRC, subsequently contributes to the NRC making an incorrect regulatory decision, such as the following:

- (a) in the case of initial operator licensing, contributes to an individual being granted an operator or senior operator license, or
 - (b) in the case of operator requalification, contributes to an individual being permitted to continue to perform the functions of an operator or senior operator, or
 - (c) contributes to a medically unqualified individual performing the functions of a licensed operator or senior operator.
- d. *SL IV* violations involve, for example:
 - 1. A nonwillful compromise (see 10 CFR 55.49) of an application, test, or examination required by 10 CFR Part 55. For example,
 - (a) cases of inaccurate or incomplete information inadvertently provided to the NRC that do not contribute to the NRC making an incorrect regulatory decision as a result of the originally submitted information; or
 - (b) an individual operator who did not meet the American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," Section 5, "Health Requirements and Disqualifying Conditions," as certified on NRC Form 396, "Certification of Medical Examination by Facility Licensee," required by 10 CFR 55.23, "Certification," but who did not perform the functions of a licensed operator or senior operator while having a disqualifying medical condition; or
 - (c) an individual operator who did not meet ANSI/ANS 3.4, Section 5, as certified on NRC Form 396, "Certification of Medical Examination by Facility Licensee," required by 10 CFR 55.23, due to an incomplete medical examination, but was subsequently found to meet the health requirements for licensing; or
 - (d) an individual operator who met ANSI/ANS 3.4, Section 5, as certified on NRC Form 396, required by 10 CFR 55.23, but failed to report a condition that would have required a license restriction to establish or maintain medical qualification based on having the undisclosed medical condition.

6.5 Facility Construction (10 CFR Parts 50 and 52 Licensees and Fuel Cycle Facilities)

- a. *SL I* violations involve, for example:
 - 1. A significant breakdown of a licensee's QA program that results in multiple structures, systems, or components being completed¹² in a manner such that

¹² The term "completed" as used in this example means completion of a construction activity,

they would not have satisfied their intended safety purpose.

b. *SL II* Violations involve, for example:

1. A significant breakdown occurs in the QA program, as exemplified by multiple deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). These deficiencies involve the licensee's failure to provide adequate oversight or take prompt corrective action and involve multiple examples of deficient construction or construction of unknown quality as the result of inadequate program implementation; or
2. Multiple structures, systems, or components are completed in a manner that would have an adverse impact on the safety of operations.

c. *SL III* violations involve, for example:

1. A breakdown occurs in a licensee's QA program for construction related to a single work activity (e.g., structural, piping, electrical, foundations). This significant deficiency involves the licensee's failure to provide adequate oversight or take prompt corrective action and entails multiple examples of deficient construction or construction of unknown quality as the result of inadequate program implementation;
2. A failure to confirm the design safety requirements of a structure, system, or component as the result of inadequate preoperational test program implementation;
3. Ineffective corrective actions result in multiple examples of recurring significant deficiencies associated with a single construction activity;
4. A licensee fails to obtain prior Commission approval required by 10 CFR 50.59 or 10 CFR 52.98 for a change that results in a condition evaluated as having low-to-moderate or greater safety significance; or
5. A licensee fails to update the FSAR as required by 10 CFR 50.71(e), and the FSAR is used to perform a 10 CFR 50.59 or 10 CFR 52.98 evaluation for a change to the facility or procedures, implemented without Commission approval, that results in a condition evaluated as having low-to-moderate or greater safety significance.

d. *SL IV* violations involve, for example:

1. A licensee fails to meet regulatory requirements, including one or more QA criteria that have more than minor safety or security significance;
2. A licensee fails to establish, maintain, or implement adequate controls over

including review and acceptance by the construction Quality Control or Quality Assurance organization.

procurement, construction, examination, or testing processes that are important to safety;

3. A licensee fails to adequately implement QA processes or procedures;
4. A licensee fails to maintain QA records to demonstrate the adequacy of construction;
5. A licensee fails to implement adequate 10 CFR Part 21 processes or procedures that have more than minor safety or security significance;
6. Violations of 10 CFR 50.59 or 10 CFR Part 52, Appendix A-D result in conditions evaluated as having very low safety significance; or
7. A licensee has failed to update the FSAR as required by 10 CFR 50.71(e) but the lack of up-to-date information has not resulted in any unacceptable change to the facility or procedures.

6.6 Emergency Preparedness

These examples are appropriate for violations at power reactor facilities for those violations that are dispositioned under traditional enforcement rather than under the ROP or cROP. For operating power reactors, the NRC treats participant performance deficiencies identified in emergency exercises under the ROP. This section also provides examples of violations in the area of emergency preparedness at nonpower reactor facilities.

a. *SL I* violations involve, for example:

1. During an actual General Emergency, a licensee fails to promptly do any of the following:
 - (a) correctly classify and declare the event,
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors," or 10 CFR Part 50, Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities") to responsible Federal, State, and local agencies, or
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

b. *SL II* violations involve, for example:

1. During an actual Site Area Emergency, a licensee fails to promptly do any of the following:

- (a) correctly classify and declare the event,
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, or 10 CFR 50, Appendix E) to responsible Federal, State, and local agencies, or
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);
 - 2. A licensee loses its ability to meet or implement any regulatory requirement related to assessment (other than emergency classification) or notification¹³ such that the required function would not be implemented during the response to an actual emergency; or
 - 3. An emergency action level (EAL) initiating condition (IC) has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event.¹⁴
- c. *SL III* violations involve, for example:
- 1. During an actual Alert emergency, a licensee fails to promptly do any of the following:
 - (a) correctly classify and declare the event,
 - (b) make required notifications (i.e., notifications required by the licensee's emergency plan, 10 CFR 50.72, or 10 CFR 50, Appendix E) to responsible Federal, State, and local agencies, or
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);
 - 2. A licensee's ability to meet or implement any regulatory requirement related to assessment (other than emergency classification) or notification is degraded such that the effectiveness of the emergency plan decreases. Although the regulatory requirement could be implemented during the response to an actual

¹³ As used in this example, "assessment" includes classification, assessment of the impact of a release of radioactivity, and the making of protective action recommendations; "notification" includes initial and follow-up notifications to offsite response organizations. For power reactors, this includes the risk-significant planning standards in 10 CFR 50.47(b)(4), (b)(5), (b)(9), and (b)(10). See Inspection Manual Chapter 0609, Appendix B, Emergency Preparedness Significance Determination Process, Section 5.0, for examples of conditions that may cause a required function not to be implemented or to be implemented in a degraded manner.

¹⁴ An EAL IC may be rendered ineffective by changes to facility procedures, systems, or equipment; errors in numeric thresholds; or any other cause that could result in an IC that should be declared not being declared in a timely and accurate manner following the change.

emergency, the implementation would be degraded (e.g., not fully effective, inappropriately delayed);

3. An EAL IC has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event, but because of redundant EALs for that IC, an appropriate declaration could be made but not within the 15-minute requirement;
 4. An EAL IC has been rendered ineffective such that any Site Area Emergency would not be declared for a particular off-normal event; or
 5. A licensee's ability to meet or implement any regulatory requirement *not* related to assessment or notification is lost such that the required function would not be implemented during the response to an actual emergency.
- d. *SL / V* violations involve, for example:
1. The licensee's ability to meet or implement any regulatory requirement *not* related to assessment or notification such that the effectiveness of the emergency plan decreases. Although the regulatory requirement could be implemented during the response to an actual emergency, the implementation would be degraded (e.g., not fully effective, inappropriately delayed);
 2. An EAL IC has been rendered ineffective such that any General Emergency would not be declared for a particular off-normal event, but because of redundant EALs for that IC, an appropriate declaration could be made in an accurate and timely manner;
 3. An EAL IC has been rendered ineffective such that any Site Area Emergency would not be declared for a particular off-normal event, but because of redundant EALs for that IC, an appropriate declaration could be made but not within the 15-minute requirement; or
 4. An EAL IC has been rendered ineffective such that any Alert Emergency or Notice of Unusual Event would not be declared for a particular off-normal event, or declared in a degraded manner for a particular off-normal event.

6.7 Health Physics

Personnel overexposures and associated violations incurred during a lifesaving or other emergency response effort will be treated on a case-by-case basis.

- a. *SL /* violations involve, for example:
1. An adult worker receives a radiation exposure during any year in excess of 25 rem (0.25 sievert (Sv)) total effective dose equivalent; 75 rem (0.75 Sv) to the lens of the eye; or 250 rem (2.5 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;

2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus of 2.5 rem (0.025 Sv) total effective dose equivalent;
 3. A minor worker (i.e., an individual less than 18 years of age) receives a radiation exposure during any year in excess of 2.5 rem (0.025 Sv) total effective dose equivalent; 7.5 rem (0.075 Sv) to the lens of the eye; or 25 rem (0.25 Sv) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
 4. A member of the public receives an annual exposure in excess of 1 rem (0.01 Sv) total effective dose equivalent;
 5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 50 times the limits for members of the public as stated in 10 CFR 20.1302(b)(2)(i); or
 6. Disposal of licensed material occurs in quantities or concentrations in excess of 10 times the limits of 10 CFR 20.2003, "Disposal by Release into Sanitary Sewerage."
- b. *SL II* Violations involve, for example:
1. An adult worker receives a radiation exposure during any year in excess of violations 10 rem (0.1 Sv) total effective dose equivalent; 30 rem (0.3 Sv) to the lens of the eye; or 100 rem (1.0 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
 2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 1.0 rem (0.01 Sv) total effective dose equivalent;
 3. A minor worker receives a radiation exposure during any year in excess of 1.0 rem (0.01 Sv) total effective dose equivalent; 3.0 rem (0.03 Sv) to the lens of the eye; or 10 rem (0.1 Sv) to the skin of the whole body, or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
 4. A member of the public receives an annual exposure in excess of 0.5 rem (5 millisieverts (mSv)) total effective dose equivalent;
 5. Release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 10 times the limits stated in 10 CFR 20.1302(b)(2)(i) (except when the Commission has approved operation up to 0.5 rem (5 mSv) per year under 10 CFR 20.1301(c)); or
 6. Disposal of licensed material occurs in quantities or concentrations in excess of 5 times the limits of 10 CFR 20.2003.

c. *SL III* Violations involve, for example:

1. An adult worker receives a radiation exposure during any year in excess of 5 rem (0.05 Sv) total effective dose equivalent; 15 rem (0.15 Sv) to the lens of the eye; or 50 rem (0.5 Sv) to the skin of the whole body or to the feet, ankles, hands, or forearms, or to any other organ or tissue;
2. A declared pregnant woman receives a radiation exposure over the gestation period of the embryo/fetus in excess of 0.5 rem (5 mSv) total effective dose equivalent (except when doses are in accordance with the provisions of 10 CFR 20.1208(d));
3. A minor worker receives a radiation exposure during any year in excess of 0.5 rem (5 mSv) total effective dose equivalent; 1.5 rem (0.015 Sv) to the lens of the eye; or 5 rem (0.05 Sv) to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 0.1 rem (1 mSv) total effective dose equivalent (except when operation up to 0.5 rem (5 mSv) per year under 10 CFR 20.1301(c));
5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of 2 times the effluent concentration limits referenced in 10 CFR 20.1302(b)(2)(i) (except when the Commission has approved operation up to 0.5 rem (5 mSv) per year under 10 CFR 20.1301(c));
6. A substantial potential exists for exposures or releases in excess of the applicable limits in 10 CFR 20.1001–20.2401, whether or not an exposure or release occurs;
7. Disposal of licensed material occurs in quantities or concentrations in excess of the regulatory limits of 10 CFR 20.2003;
8. A licensee releases, for unrestricted use, contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public exceeding the annual dose limits for members of the public;
9. A technically unqualified person conducts licensee activities; or
10. A violation involves failure to secure, or maintain surveillance over, licensed material in the following situations:
 - (a) involves licensed material in any aggregate quantity greater than 1,000 times the quantity specified in Appendix C, “Quantities of Licensed Material Requiring Labeling,” to 10 CFR Part 20, “Standards for Protection against Radiation,”
 - (b) involves licensed material in any aggregate quantity greater than 10 times

the quantity specified in Appendix C to 10 CFR Part 20, where the failure is accompanied by the absence of a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action), or

- (c) results in a substantial potential for exposures or releases in excess of the applicable limits in 10 CFR Part 20.

d. *SL IV* violations involve, for example:

1. Intakes exceed those specified in 10 CFR 20.1201(e) or the equivalent for 10 CFR 20.1207, "Occupational Dose Limits for Minors;"
2. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of the limits for members of the public as referenced in 10 CFR 20.1302(b)(2)(i) (except when the Commission has approved operation up to 0.5 rem (5 mSv) per year under 10 CFR 20.1301(c));
3. A radiation dose rate in an unrestricted or controlled area exceeds 0.002 rem (0.02 millisieverts) in any 1 hour (2 mrem/hour) or 50 mrem (0.5 mSv) in a year;
4. A licensee fails to conduct required leakage or contamination tests or to use properly calibrated equipment, although the failure does not contribute to an event;
5. Doses to a member of the public exceed any of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," as required by 10 CFR 20.1301(e); or
6. An isolated failure occurs to secure, or maintain surveillance over, licensed material in any aggregate quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20, provided that both of the following apply:
 - (a) The material is labeled as radioactive or located in an area posted as containing radioactive materials, and
 - (b) Such failure occurs despite a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action);

6.8 Transportation

Some transportation requirements apply to more than one licensee involved in the same activity (e.g., a shipper and a carrier). When such a violation occurs, the NRC will direct enforcement action against the responsible licensee or licensees.

a. *SL I* violations involve, for example:

1. Failure to meet transportation requirements results in loss of control of radioactive material with a breach in package integrity such that the material causes a radiation exposure to a member of the public in excess of the regulatory limits;
 2. Surface contamination exceeds 50 times the NRC limit; or
 3. External radiation levels exceed 10 times the NRC limit.
- b. *SL II* violations involve, for example:
1. Failure to meet transportation requirements results in loss of control of radioactive material with a breach in package integrity such that there is a clear potential for a member of the public to receive a radiation exposure in excess of the regulatory limits;
 2. Surface contamination exceeds 10 times, but not more than 50 times, the NRC limit;
 3. External radiation levels exceed 5 times, but not more than 10 times, the NRC limit; or
 4. A licensee fails to make required initial notifications associated with *SL I* or *II* violations.
- c. *SL III* violations involve, for example:
1. Surface contamination exceeds 5 times, but not more than 10 times, the NRC limit;
 2. External radiation exceeds 1 times, but not more than 5 times, the NRC limit;
 3. A violation involves labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result any of the following:
 - (a) a significant failure to identify the type, quantity, or form of material
 - (b) a failure of the carrier or recipient to exercise adequate controls
 - (c) a substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material
 4. A licensee fails to make required initial notification associated with *SL III* violations.
- d. *SL IV* Violations involve, for example:

1. A breach of package integrity occurs without external radiation levels exceeding the NRC limit or without contamination levels exceeding the NRC limits;
2. Surface contamination is in excess of, but is not more than 5 times, the NRC limit;
3. A licensee fails to register as an authorized user of an NRC-Certified Transport package;
4. A licensee fails to demonstrate that packages for special-form radioactive material meet applicable regulatory requirements; or
5. A licensee fails to demonstrate that U.S. Department of Transportation specifications are met for 7A Type A packages as required by 10 CFR 71.5, "Transportation of Licensed Material."

6.9 Inaccurate and Incomplete Information or Failure to Make a Required Report

a. *SL* / violations involve, for example:

1. A licensee official deliberately provides or maintains information known by the licensee official to be incomplete or inaccurate. If the information had been completely and accurately provided or maintained, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security;
 - (a) For example, deliberately incomplete or inaccurate information associated with an inspections, tests, analyses, and acceptance criteria (ITAAC) notification letter is submitted in accordance with 10 CFR 52.99, "Inspection during Construction." If the information had been complete and accurate, it would likely have caused the NRC to issue an Order halting a significant portion of construction activities;
2. A deliberate withholding of information or a deliberate failure to make a required report occurs. If the information had been provided or the report been made, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security;
3. A licensee official provides or maintains information with careless disregard of its completeness or accuracy. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security;

- (a) For example, a licensee official submits incomplete or inaccurate information associated with an ITAAC notification letter, in accordance with 10 CFR 52.99, with careless disregard for its completeness and accuracy. If this information had been complete and accurate, it would likely have caused the NRC to issue an Order halting a significant portion of construction activities;
 - 4. A withholding of information or a failure to make a required report occurs, with careless disregard of the underlying requirement. If the information had been provided or the report been made, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security; or
 - 5. A deliberate failure to notify the Commission as required by 10 CFR Part 21, "Reporting of Defects and Noncompliance."
- b. *SL II* violations involve, for example:
- 1. A licensee official deliberately provides or maintains information known by the licensee official to be incomplete or inaccurate. If the information had been completely and accurately provided or maintained, it would likely have caused the NRC to reconsider a regulatory position or undertake a substantial further inquiry;
 - (a) For example, a licensee official deliberately provides incomplete or inaccurate information associated with an ITAAC notification letter, submitted in accordance with 10 CFR 52.99. If this information had been complete and accurate, it would likely have caused the NRC to reject closure of that ITAAC;
 - 2. A licensee official provides or maintains information with careless disregard of its completeness or accuracy. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to reconsider a regulatory position or undertake a substantial further inquiry.
 - (a) For example, a licensee official provides incomplete or inaccurate information associated with an ITAAC notification letter, submitted in accordance with 10 CFR 52.99, with careless disregard for its completeness and accuracy. If this information had been complete and accurate, it would likely have caused the NRC to reject closure of that ITAAC;
 - 3. A deliberate withholding of information or a deliberate failure to make a required report occurs. If the information had been provided or the report been made, it would likely have resulted in reconsideration of a regulatory position or substantial further inquiry;

4. A withholding of information or a failure to make a required report occurs with careless disregard of the underlying requirement. If the information had been provided or the report been made, it would likely have resulted in reconsideration of a regulatory position or substantial further inquiry;
 5. Inaccurate or incomplete information is provided or maintained. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security;
 6. A withholding of information or a failure to make a required report occurs. If the information had been provided or the report been made, it would likely have caused the NRC to issue an Order requiring suspension or cessation of licensed activity or other immediate action to protect the public health and safety or common defense and security; or
 7. A licensee fails to make an immediate notification as required by 10 CFR 20.2202(a)(1) or (a)(2).
 8. A deliberate failure to notify the Commission as required by 10 CFR 50.55(e).
- c. *SL III* violations involve, for example:
1. Inaccurate or incomplete information is provided or maintained. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to reconsider a regulatory position or undertake a substantial further inquiry;
 - (a) For example, incomplete or inaccurate information associated with an ITAAC notification letter, submitted in accordance with 10 CFR 52.99, is submitted. If this information had been complete and accurate, it would likely have caused the NRC to reject closure of that ITAAC;
 2. A withholding of information or a failure to make a required report occurs. If this information had been provided or the report been made, it would likely have caused the NRC to reconsider a regulatory position or undertake a substantial further inquiry. The following are examples:
 - (a) failure to make a 24-hour notification required by 10 CFR 20.2202(b) or an immediate notification required by 10 CFR 20.2201(a)(1)(i);
 - (b) failure to make any report required by 10 CFR 73.71, "Reporting of Safeguards Events," or Appendix G, "Reportable Safeguards Events," to 10 CFR Part 73, "Physical Protection of Plants and Materials," or 10 CFR Part 26, "Fitness for Duty Programs";
 - (c) failure to submit an initial NRC Form 241, "Report of Proposed Activities

- in Non-Agreement States,” as required by 10 CFR 150.20, “Recognition of Agreement State Licenses”;
- (d) for materials licensees, failure to make an immediate or 24-hour report or notification when required; or
- (e) failure to make a report required by 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors,” or 10 CFR 50.73, “Licensee Event Report System,” associated with any SL III violation;
- 3. A programmatic failure to comply with 10 CFR 20.2207, “Reports of Transactions Involving Nationally Tracked Sources,” occurs;
- 4. A 10 CFR Part 50 licensee submits inaccurate or incomplete performance indicator (PI) data to the NRC. Accurate or complete information would have caused a PI to change from green to either yellow or red, white to either yellow or red, or yellow to red; or
- 5. A failure to provide the notice required by 10 CFR Part 21 or 10 CFR 50.55(e), for example:
 - (a) An inadequate review or failure to review such that, if an appropriate review had been made as required, a 10 CFR Part 21 or 10 CFR 50.55(e) report would have been required; or
 - (b) A withholding of information or a failure to make a required interim report by 10 CFR 21.21, “Notification of Failure to Comply or Existence of a Defect and Its Evaluation,” or 10 CFR 50.55(e) occurs with careless disregard.
- d. *SL IV* violations involve, for example:
 - 1. A licensee fails to make a required report that, had it been submitted, would have resulted in, for instance, increasing the inspection scope of the next regularly scheduled inspection;
 - 2. A licensee fails to make a timely written report as required by 10 CFR 20.2201(b), 20.2204, 20.2206, or 20.2207;
 - 3. A licensee fails to report an exceedance of the dose constraint established in 10 CFR 20.1101(d);
 - 4. A licensee fails to report indicators of programmatic weaknesses as required in 10 CFR 26.719(d);
 - 5. A licensee fails to make a report required by 10 CFR 76.120(d)(2), Appendix A to 10 CFR Part 70, or 10 CFR 70.50(c)(1);

6. A licensee fails to make a written event report, as required by 10 CFR 70.50(c)(1), Appendix A to 10 CFR Part 70, or 10 CFR 76.120(d)(2);
7. A materials licensee fails to provide or make a 15-day or 30-day written report or notification; fails to include all information required by regulation or license condition in a 15-day or 30-day report or notification; or is late making a report to the NRC required by 10 CFR 35.3045, "Report and Notification of a Medical Event," or 10 CFR 35.3047, "Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child," that does not impact the regulatory response by the NRC;
8. A licensee fails to make the 30-day notification required by 10 CFR 20.2201(a)(1)(ii) or 10 CFR 20.2203(a);
9. A licensee fails to make a report required by 10 CFR 50.72 or 10 CFR 50.73;
10. A failure to identify all applicable reporting codes on a Licensee Event Report that may impact the completeness or accuracy of other information (e.g., performance indicator data) submitted to the NRC;
11. A 10 CFR Part 50 licensee submits inaccurate or incomplete PI data to the NRC that would have caused a PI to change from green to white;
12. A licensee fails to make an interim report required by 10 CFR 21.21(a)(2) or under 10 CFR 50.55(e);
13. Failure to implement adequate 10 CFR Part 21 or 10 CFR 50.55(e) processes or procedures that has more than minor safety or security significance; or
14. A materials licensee fails to provide the NRC with a Form 241, where:
 - (a) the licensed activity is not of a type designated as NRC Priority 1, 2, or 3 inspection (as identified in Enclosure 1 of NRC Manual Chapter 2800); and
 - (b) the licensee has not previously violated the requirement; and
 - (c) the facts of the specific case would not have otherwise resulted in the NRC conducting an onsite inspection; and
 - (d) the circumstances of the case generally include either the failure to file an amended Form 241 for additional work locations of limited scope, or the failure to provide an initial Form 241 for work of very limited scope and single occurrence of a few days within NRC jurisdiction (e.g., portable radiological gauge use).

6.10 Discrimination

In certain cases, the severity level of a violation may be escalated based on unique escalating factors such as whether the adverse action was taken because the employee had contacted the NRC or whether the applicable NRC employee protection regulation (e.g., 10 CFR 50.7 or similar NRC employee protection regulations) was deliberately violated. Conversely, the severity level of a violation of an NRC employee protection regulation may be mitigated to a lower severity level based on factors unique to the specific facts and circumstances of the case.

a. *SL I* violations involve, for example:

1. An executive-level corporate manager (or equivalent) (which for this definition includes a site vice president) is the decisionmaker or plays a significant role in the adverse action decisionmaking process regardless of the severity of the adverse action, but with at least one of the following escalating factors:
 - (a) The adverse action against the employee had a widespread site impact on other employees' willingness to raise concerns, or
 - (b) The employer failed to take meaningful action to investigate and address the allegation of discrimination, if such allegation was first raised internally within the employer's processes addressing employee concerns; or
2. A mid- or a senior-level plant manager (or equivalent) or a corporate-level line manager (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively more adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., suspension without pay); and either a.1(a) or a.1(b) above is cited, or other unique factors are present.

b. *SL II* violations involve, for example:

1. An executive-level corporate manager (or equivalent) (which for this definition includes a site vice president) is the decisionmaker or plays a significant role in the adverse action decisionmaking process regardless of the severity of the adverse action but without an escalating factor present;
2. A mid- or senior-level plant manager (or equivalent) or a corporate-level line manager (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively more adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., suspension without pay); and no escalating factor is present;
3. A mid- or senior-level plant manager (or equivalent) or a corporate-level line manager (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively less adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., verbal counseling); and either a.1(a) or a.1(b) above is cited,

or other unique escalating factors are present; or

4. A lower level plant manager (or equivalent) or supervisor (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively more adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., suspension without pay); and either a.1(a) or a.1(b) above is cited, or other unique escalating factors are present.
- c. *SL III* violations involve, for example:
1. A mid- or senior-level plant manager (or equivalent) or a corporate-level line manager (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively less adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., verbal counseling); and no escalating factor is present;
 2. A lower level plant manager (or equivalent) or supervisor (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively more adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., suspension without pay); and no escalating factor is present; or
 3. A lower level plant manager (or equivalent) or supervisor (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively less adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., verbal counseling); and either a.1(a) or a.1(b) above is cited, or other unique escalating factor(s) are present.
- d. *SL IV* violations involve, for example:
1. A lower level plant manager (or equivalent) or supervisor (or equivalent) is the decisionmaker or plays a significant role in the adverse action decisionmaking process; the employment action is relatively less adverse to the employee's terms, conditions, compensation, or privileges of employment (e.g., verbal counseling); and no escalating factor is present.
- 6.11 Reactor, Independent Spent Fuel Storage Installation, Fuel Facility, and Special Nuclear Material Security
- a. *SL I* violations involve, for example:
1. The theft, diversion, or act of sabotage involves a formula quantity of special nuclear material (SNM), spent nuclear fuel or a very significant quantity of other radioactive material having the potential for substantial impact on the public; or
 2. Any failure of a licensee's security program as outlined in their security plan or

insider mitigation program results in an act of sabotage against one or more target sets or target set elements.

b. *SL II* violations involve, for example:

1. An act of radiological sabotage that results in the loss or destruction of a quantity of SNM of moderate strategic significance or a quantity of other radioactive material determined equally or similarly significant by the NRC;
2. The theft, diversion, or act of radiological sabotage involves a quantity of SNM of moderate strategic significance or a quantity of other radioactive material determined equally or similarly significant by the NRC, in which one or more attributes of the security program did not function as required;
3. A licensee fails to involve its reviewing official in developing an unescorted access authorization determination or determination of fitness for duty, following a for-cause action by a licensee that results in an individual's voluntary or involuntary loss of employment; or
4. A licensee fails to maintain the high assurance standard of 10 CFR 73.20 and 10 CFR 73.55.

c. *SL III* violations involve, for example:

1. An insider (e.g., licensee employee, licensee contractor or subcontractor) attempts an act of radiological sabotage to any radiological material;
2. The security or insider mitigation program has a failure, but the failure does not amount to a *SL I* or *SL II* violation that challenges the high assurance standard of 10 CFR 73.20, "General Performance Objective and Requirements," or 10 CFR 73.55, "Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors against Radiological Sabotage;"
3. A licensee fails to develop and maintain records concerning the denial of access, or fails to respond to inquiries concerning denials of access, so that, as a result of the failure, a person previously denied unescorted access or unescorted access authorization is improperly granted such access;
4. A licensee fails to ensure that a licensee-approved contractor or vendor access authorization program is operating in accordance with regulatory and licensee requirements;
5. A licensee fails to complete more than one of the requirements of an access authorization program before granting an individual unescorted access or unescorted access authorization;
6. An individual is assigned to a job task related to implementing the licensee's protective strategy without the person being qualified in accordance with

regulatory requirements;

7. A reviewing official relies on a deliberate falsification of information to make an unescorted access or unescorted access authorization determination;
 8. The safeguards or security systems designed or used to prevent, detect, or assess, and respond to the theft, loss, or diversion of strategic SNM, or significant quantities of other radioactive material, experiences a significant failure; or
 9. A licensee fails to conduct a search or conducts an inadequate search at any protected area access control point, and this failure results in the introduction of firearms, explosives, or incendiary devices or reasonable facsimiles thereof that could assist in committing radiological sabotage or theft or diversion of strategic SNM.
- d. *SL /V* violations involve, for example:
1. A failure of the licensee security or insider mitigation program, as outlined in a licensee's security plan, results in an attempted act of radiological sabotage against one or more target set elements; or
 2. A loss of SNM of low strategic significance or less significant quantities of other radioactive material was not detected within the time period specified in the security plan, other relevant document, or regulation; or
 3. A licensee fails to comply with an element of its material and accounting program that results in a fuel cycle facility procedure degradation regarding adequate detection or protection against loss, theft, or diversion of SNM.

6.12 Materials Security

- a. *SL /* violations involve, for example:
1. The theft, diversion, or sabotage of a Category 1 quantity of radioactive material results from the failure to establish or implement one or more requirements, such as the following:
 - (a) failure to control unescorted access to a Category 1 quantity of radioactive material so that only individuals deemed trustworthy and reliable and having job duties that require unescorted access to the radioactive material are granted such access;
 - (b) failure to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 quantity of radioactive material, including requesting assistance from the local law enforcement agency;

- (c) failure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material; or
- (d) failure to implement the Radioactive Material Quantities of Concern (RAM QC) requirements before shipping a consignment containing a Category 1 quantity of radioactive material.

b. *SL II* violations involve, for example:

1. The theft, diversion, or sabotage of a Category 2 quantity of radioactive material results from the failure to establish or implement one or more increased control requirements, such as the following:
 - (a) failure to control unescorted access to a Category 1 or Category 2¹⁵ quantity of radioactive material so that only individuals deemed trustworthy and reliable and having job duties that require unescorted access to the radioactive material are granted such access;
 - (b) failure to immediately respond (e.g., without undue delay in accordance with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material, including requesting assistance from the local law enforcement agency;
 - (c) shipping a consignment of a Category 2 quantity of radioactive material by a carrier, other than the licensee, without first verifying that the carrier uses a package tracking system, implements methods to ensure trustworthiness and reliability of drivers, maintains constant control and/or surveillance during transit, and has the capability for immediate communication to summon appropriate response or assistance;
 - (d) failure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material;
 - (e) failure to implement the RAM QC Additional Security Measures before shipping a consignment containing a Category 1 quantity of radioactive material; or
 - (f) failure to use a method to disable a vehicle or trailer, in or on which a Category 1 or Category 2 quantity of radioactive material is stored, when not under direct control and constant surveillance by the licensee.

c. *SL III* violations involve, for example:

1. A licensee fails to immediately respond (e.g., without undue delay in accordance

¹⁵ Violation examples 6.12. b. 1. (a), (b), and (f) recognize that a licensee may possess a total of either Category 1 or Category 2 quantity of radioactive material at the time of the subject incident, but only a Category 2 quantity was actually involved with theft, diversion, or sabotage. Hence, the severity level is determined by the category of material involved in the theft, diversion, or sabotage.

- with the licensee's prearranged plan) to an attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material, including a failure to request assistance from the local law enforcement agency, but the failure does not result in actual theft, sabotage, or diversion of radioactive material;
2. A licensee fails to determine the trustworthiness and reliability of individuals having unescorted access to radioactive material quantities of concern and devices;
 3. A licensee fails to verify that a carrier uses package tracking systems, implements methods that ensure trustworthiness and reliability of drivers, maintains constant control and/or surveillance during transit, and has the capability for immediate communication to summon appropriate response or assistance, before shipping a Category 2 quantity of radioactive material, per consignment, by the carrier;
 4. A licensee fails to provide enhanced monitoring during periods of source delivery and shipment of a Category 1 quantity of radioactive material;
 5. A licensee fails to initiate an investigation to determine the location of a shipment of licensed material containing a Category 2 quantity of radioactive material when the shipment does not arrive on or about the expected arrival time;
 6. A licensee fails to notify the NRC Operations Center promptly after initiating a response to any actual or attempted theft, diversion, or sabotage of sources or devices containing a Category 1 or Category 2 quantity of radioactive material;
 7. A licensee fails to implement the RAM QC before shipping a Category 1 quantity of radioactive material, per consignment;
 8. A licensee fails to use a method to disable a vehicle or trailer, in or on which a Category 1 or Category 2 quantity of radioactive material is stored, when not under direct control and constant surveillance by the licensee;
 9. A licensee fails to contact the local law enforcement agency and does not attempt to establish a prearranged response plan with the local law enforcement agency, or a programmatic failure occurs in the implementation of the plan;
 10. A licensee fails to establish a program to monitor and immediately detect, assess, and respond to unauthorized access to a Category 1 or Category 2 quantity of radioactive material, or a programmatic failure occurs during implementation;
 11. A licensee fails to have a dependable means to transmit information between and among the various components of the intrusion detection system or to summon the appropriate responder; or

12. A licensee fails to verify that a recipient licensee is authorized to possess the material being transferred.
- d. *SL IV* Violations involve, for example:
1. A licensee fails to document the basis for concluding that an individual was determined to be trustworthy and reliable for the purposes of granting unescorted access to a Category 1 or Category 2 quantity of radioactive material;
 2. A licensee fails to perform a complete and adequate trustworthiness and reliability determination for an individual, such that information relevant to access approval was not obtained or considered, but the individual would likely have been granted unescorted access if the required information had been obtained or considered;
 3. A licensee fails to limit approval for unescorted access with respect to a Category 1 or Category 2 quantity of radioactive material to individuals with job duties requiring unescorted access;
 4. A licensee fails to maintain a list of persons approved for unescorted access;
 5. A licensee fails to confirm receipt of transferred/shipped radioactive material;
 6. A licensee fails to document the prearranged plan with the local law enforcement agency or to update the prearranged plan when changes to the facility design or operation affect the potential vulnerability of sources;
 7. An isolated failure occurs in the as-designed operation of the dependable means to transmit information between and among the various components of the intrusion detection system or to summon the appropriate responder. This is a violation if caused by a failure of the licensee in the design, construction, operation, or maintenance of the system. (This example does not include isolated failures caused by means outside the licensee's control, such as service disruptions;)
 8. A licensee fails to contact the recipient or originator of a shipment to coordinate an expected arrival time for a shipment of a Category 2 quantity of radioactive material;
 9. An isolated failure occurs in implementing a portion of the licensee's program to monitor and immediately detect, assess, and respond to unauthorized access to a Category 1 or Category 2 quantity of licensed radioactive material, such that an opportunity exists for unauthorized and undetected access to the material, but the opportunity is neither easily nor likely to be exploitable; or
 10. A licensee fails to comply with an element of its procedure to provide enhanced monitoring during periods of source delivery and shipment of a Category 1

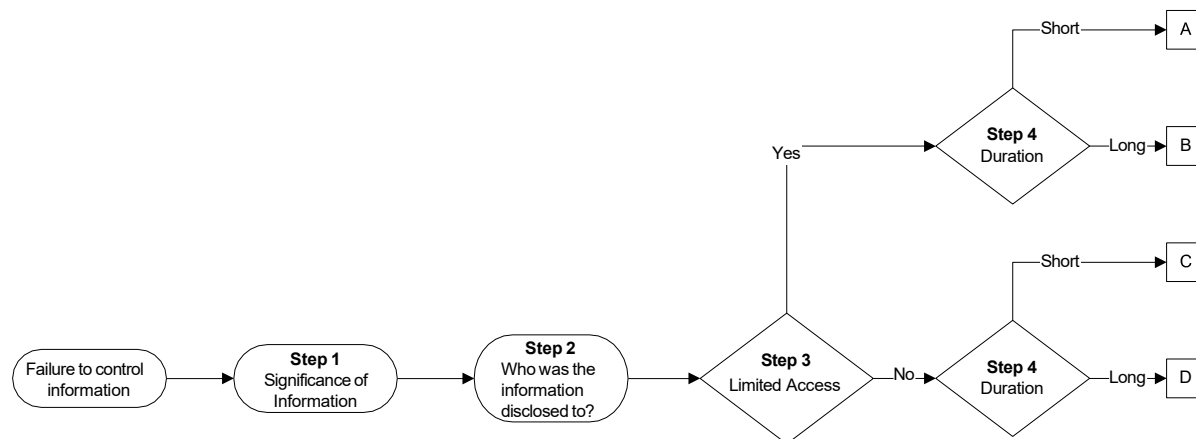
quantity of radioactive material, and this failure does not seriously degrade the enhanced monitoring capability.

6.13 Information Security

This section applies to information that is classified as SECRET or CONFIDENTIAL (National Security or Restricted Data), information that is designated Safeguards in accordance with the Atomic Energy Act of 1954, as amended, and information requiring protection under 10 CFR Part 37.¹⁶ This approach is a change from the traditional enforcement violation examples and will use a flow chart and table, along with defined terms to determine the potential severity.

Under this approach, once a noncompliance is identified, a four-step approach will be applied to determine the severity level of the violation. The four steps are: 1) based upon the provided criteria and the consideration of the totality of the information disclosed determine whether the event should be quantified as high significance, moderate significance, or low significance and 2) determine the extent of the disclosure. Upon completion of steps 1 and 2, determine the options at the intersection of the significance row and the disclosure column. Next, in step 3) determine the accessibility of the information by following the flow chart answering “Yes” or “No” to whether there was Limited Access to the information and in step 4 determine the duration of the noncompliance by answering “Short” or “Long” to find the designated letter, A, B, C, or D. Next use this letter within the previously determined intersection point from the conclusion of steps 1 and 2 to determine the severity level.

¹⁶ The violation examples in the NRC’s Enforcement Policy, including the risk-informed examples provided in this section, are neither exhaustive nor controlling for making severity level determinations. Although not expressly referenced in the examples provided in this section, the NRC’s Enforcement Policy is applicable to information security violations involving information that is classified as TOP SECRET.



Step 2 Disclosure		Disclosed to an individual deemed Trustworthy and Reliable				Unknown Disclosure				Confirmed to an Unauthorized Individual			
Step 1 Significance		A	B	C	D	A	B	C	D	A	B	C	D
	High	SL III	SL III	SL III	SL II	SL III	SL II	SL II	SL II	SL II	SL II	SL II	SL I
	Moderate	SL IV	SL III	SL III	SL III	SL IV	SL III	SL III	SL III	SL III	SL III	SL III	SL I
	Low	SL IV	SL IV	SL IV	SL III	SL IV	SL IV	SL IV	SL III	SL III	SL III	SL III	SL II

Step 1: Significance¹⁷ – Describes the decision point to determine the significance of the disclosure as it relates to national security and/or common defense and security.

High Significance: The totality of information disclosed provides a significant amount of information about a technology (i.e., key elements of a technology or system) or combinations of the following elements related to protective strategies: Response Strategy, Target Sets, Physical Security Plan, Contingency Plan or Integrated Response Plan. The information can be either SECRET or CONFIDENTIAL (National Security or Restricted Data) or Safeguards.

Moderate Significance: The totality of information disclosed provides limited information that may be useful to an adversary about technology information or physical security plan of a facility. The information can be either SECRET or CONFIDENTIAL (National Security or Restricted Data), Safeguards or information requiring protection under 10 CFR Part 37.

Low Significance: The totality of information disclosed, taken by itself, would not aid an adversary in gaining information about a technology or physical security plan of a facility. The information can be either SECRET or CONFIDENTIAL (National Security or Restricted Data), Safeguards, information requiring protection under 10 CFR Part 37.

¹⁷ The significance guidance provided in Step 1 is only applicable within the context of the NRC's Enforcement Policy and its application. The significance guidance is not intended to define the "harm" that an unauthorized disclosure of SECRET or CONFIDENTIAL information is reasonably expected to cause as those definitions are set forth in Executive Order 13526, "Classified National Security Information." Nothing in section 6.13 of the Enforcement Policy should be read to contradict the National Policy on classified information.

Step 2: Disclosure – Describes the decision point to determine if: a) the information was accessible to any individual(s) via hard copy format or electronic (e.g. computers) form, b) you can determine who the individual(s) are, and c) those individual(s) would meet the definition of Trustworthy and Reliable.

Trustworthy and Reliable (T&R): Are characteristics of an individual considered dependable in judgment, character, and performance, such that disclosure of Information to that individual does not constitute an unreasonable risk to the public health and safety or common defense and security. A determination of T&R for this purpose is based upon the results from a background investigation or background check in accordance with 10 CFR 37.5 or 10 CFR 73.2, respectively. To meet the T&R requirement, the individual must possess a T&R determination before the disclosure of the information, regardless of the “need to know” determination. Note: In accordance with 10 CFR 73.21 or 73.59, there are designated categories of individuals that are relieved from fingerprinting, identification and criminal history checks and other elements of background checks.

Unknown Disclosure: Instances when controlled information has been secured, protected, or marked improperly but there is no evidence that anyone has accessed the information while it was improperly handled.

Confirmed: Instances where a person who does not have authorization to access controlled information gains access to the information.

Electronic Media/Confirmed: For electronic media it is considered confirmed once the information is no longer on an approved network for that type of information.

Unauthorized Individual: A person who does not possess a T&R determination and a need to know.

Step 3: Limited Access – Describes the decision point to determine the amount of controls (e.g., doors, locks, barriers, firewalls, encryption levels) needed to enter or gain access to an area or computer system in order to obtain the disclosed security information.

Hard Copy Format: A location provides limited access if it meets all of the following conditions:

- a. the area was locked or had access control measures, and;
- b. individuals that frequented the area were part of a known population, and;
- c. records of personnel entry were maintained to the area via key control or key card access.

Electronic Media: A computer network provides limited access if it meets all of the following conditions:

- a. the information is stored in a location that is still within the licensee’s computer network’s firewall, and
- b. the licensee has some type of control system in place which delineates who can access the information.

Step 4: Duration – Describes the decision point in which a time period determination is made regarding the number of days the information was not controlled properly in accordance with the respective handling and storage requirements of the security information.

Long: Greater than or equal to 14 days from the date of infraction to discovery of the non-compliance.

Short: Less than 14 days from the date of infraction to discovery of the non-compliance.

6.14 Fitness for Duty¹⁸

a. SL I violations involve, for example:

1. A licensee fails to substantially implement or substantially maintain reasonable assurance of fitness-for-duty program performance in two or more subparts of 10 CFR Part 26.

b. SL II violations involve, for example:

1. A licensee fails to remove an individual from unescorted access status when this person has been involved in the sale, use, or possession of illegal drugs within the protected area, or a licensee fails to take action in the case of an on-duty misuse of alcohol, illegal drugs, prescription drugs, or over-the-counter medications or once the licensee identifies an individual that appears to be impaired or that their fitness is questionable, the licensee fails to take immediate actions to prevent the individual from performing the duties that require him or her to be subject to 10 CFR Part 26; or
2. A licensee fails to take action to meet a regulation or a licensee behavior observation program requirement when observed behavior within the protected area or credible information concerning the activities of an individual indicates impairment by any substance, legal or illegal, or mental or physical impairment from any cause, which adversely affects their ability to safely and competently perform their duties.

c. SL III violations involve, for example:

1. A licensee fails to take the required action for a person who has violated the licensee's Fitness-For-Duty Policy, in cases that do not amount to a SL II violation;
2. A licensee fails to ensure that a licensee-approved contractor's or vendor's fitness-for-duty program is operating in accordance with regulatory and licensee requirements;
3. A licensee fails to complete or maintain more than one of the requirements of a program for individuals listed in 10 CFR 26.4, "FFD Program Applicability to

¹⁸ See Section 6.4 for examples of fitness-for-duty violations specific to licensed reactor operators.

Categories of Individuals;”

4. A licensee fails to develop and maintain records concerning the denial of access or to respond to inquiries concerning denials of access so that, as a result of the failure, a person previously denied fitness-for-duty authorization is improperly granted such access;
 5. A licensee’s employee assistance program (EAP) staff fails to notify licensee management when the EAP staff is aware that an individual’s condition, based on information known at the time, may adversely affect the safety or security of the facility and the failure to notify did not result in a condition adverse to safety or security; or
 6. An individual covered by 10 CFR Part 26, Subpart I, involved in a human error that caused or contributed to an actual event or a potential degradation of the level of safety of the plant, who at the time the error occurred, was determined to be fatigued as a result of a fatigue assessment as defined in 10 CFR 26.211.
- d. SL IV violations involve, for example:
1. Failure to prepare, implement, and maintain written procedures that describe the methods to be used implementing the FFD policy;
 2. A licensee fails to take an action required by the licensee’s behavior observation program in cases that do not amount to a SL I, II, or III violation; or
 3. Failures to appropriately implement any of the requirements (e.g., work hours, waivers, self declarations, or fatigue assessment) of 10 CFR Part 26, Subpart I that do not result in an actual event or a degradation of a level of safety, but are more than minor in that they are not isolated or demonstrate programmatic weaknesses in implementation.

6.15 Export and Import Activities

Several of the following violation examples involve deliberateness or careless disregard. For those examples, the normal Enforcement Policy process for discretion to potentially escalate the severity level of the violation based on willfulness is not necessary.

- a. SL I violations involve, for example:
1. Deliberate misrepresentation of facts, with the knowledge of a licensee official, that led to the export of licensable and sensitive equipment or material in quantities of concern to a destination that, if represented accurately, would not have been authorized by the NRC (or other authority); or

2. Deliberate misrepresentation of facts that led to unauthorized individuals obtaining sensitive nuclear equipment or materials in quantities of concern.
- b. SL II violations involve, for example:
1. Failure to provide notice of 10 CFR Part 110, Appendix P, material import as required by 10 CFR 110.50 that, if the notice had been provided, would have prompted the NRC to take action to block the import;
 2. Misrepresentation of facts in careless disregard of requirements, with the knowledge of a licensee official, for the export or import of radioactive or byproduct materials, such as those involving the completeness or accuracy of the information that, if represented accurately, would not have been authorized by the NRC (or other authority); or
 3. Inaccurate or incomplete information provided or maintained that led to unauthorized individuals possessing radioactive materials. If this information had been completely and accurately provided or maintained, it would likely have caused the NRC to terminate or deny a license, to issue an Order requiring suspension or cessation of licensed activity, or to take action to block an export or import, to protect the public health and safety or common defense and security.
- c. SL III violations involve, for example:
1. Failure to submit timely notification of the import of 10 CFR part 110, Appendix P material, as required by 10 CFR 110.50, where, if this information had been provided, it would likely have caused the NRC to take further action or inquiry;
 2. Inaccurate or incomplete information on exports or imports of radioactive or byproduct materials such that, if the information had been represented accurately, it would likely have resulted in the NRC reconsidering the authorization of the activity, issuing a request for additional information (RAI), or conducting an inspection to resolve the matter;
 3. Export of byproduct material identified in 10 CFR part 110, Appendix P, to individuals or entities not authorized to receive such materials; or
 4. Failure to obtain a specific license before the export or import of any NRC licensable equipment, special nuclear material, and source or byproduct materials, when required.
- d. SL IV violations involve, for example:
1. Failure to submit timely reports as specified in 10 CFR 110.54;

2. Export or import of nuclear equipment or materials in excess of the limits specified in a specific license or license amendment, when such activity would have been authorized by the NRC (or other authority); or
3. Unauthorized export of foreign-obligated material or equipment in violation of 10 CFR 110.50(b)(3) requirements.

7.0 GLOSSARY

This glossary, while not exhaustive, contains many of the terms commonly used throughout the NRC enforcement process.

Activity Area refers to the area of NRC-licensed activity that a licensee (or other person) engages in (e.g., radiography, reactor operations).

Actual Consequences include such effects as actual, exposures to workers or members of the public exceeding regulatory limits (e.g., 10 CFR 20.1201, "Occupational Dose Limits for Adults" and 10 CFR 20.1301, "Dose Limits for Individual Members of the Public"), onsite or offsite releases of material exceeding regulatory or license limits, accidental criticality, core damage, loss of significant safety barriers, and loss of control of radioactive material.

Adverse Action is any action that may adversely impact the compensation, terms, conditions, or privileges of employment including but not limited to a failure to receive a routine annual pay increase or bonus; demotion or arbitrary downgrade of a position; transfer to a position that is recognized to have a lesser status or be less desirable (e.g., from a supervisory to nonsupervisory position); failure to promote; overall performance appraisal downgrade; verbal or written counseling, or other forms of constructive discipline.

Alternative Dispute Resolution (ADR) refers to a variety of processes that emphasize creative, cooperative approaches to handling conflicts in lieu of adversarial procedures. Mediation and arbitration are the most widely recognized processes. The NRC's ADR program uses mediation rather than arbitration (i.e., the parties develop mutually agreeable corrective actions rather than being obligated by an arbitrator's decision).

Apparent Violation is a situation or circumstance that does not appear to meet NRC requirements and for which the NRC staff has not made a final enforcement determination.

Careless Disregard refers to situations in which an individual acts with reckless indifference to at least one of three things: (1) the existence of a requirement, (2) the meaning of a requirement, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless proceeds to engage in conduct that the individual knows may cause a violation. Although aware that the action might cause a violation, the individual proceeds without first ascertaining whether a violation would occur.

Certificate Holder is any person or entity that has been issued a certificate by the NRC. Certificate holders include, but are not limited to, those issued certificates in accordance with the requirements of 10 CFR Parts 32, 71, or 76. For the purposes of this Policy, where not addressed specifically, Certificate Holders are typically handled the same as Licensees.

Civil Penalty is a monetary penalty that may be imposed for violations of (1) certain specified provisions of the AEA or supplementary NRC rules or Orders, (2) any requirements for which a license may be revoked, or (3) reporting requirements under Section 206 of the ERA.

Confirmatory Action Letter (CAL) is a letter confirming a licensee's, contractor's, or nonlicensee's (subject to NRC jurisdiction) voluntary agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

Confirmatory Order is an Order that confirms the commitments made by a license or individual to take certain actions. Before issuance of the Confirmatory Order, the licensee or individual and the NRC mutually agree on the terms of the Order.

Contractor, as used in this Policy, includes vendors who supply products or services to be used in an NRC-licensed facility or activity.

Corrective Action Program is a licensee's process for tracking, evaluating, and resolving deficiencies.

Deliberate Misconduct occurs when an individual voluntarily and intentionally (1) engages in conduct that the individual knows to be contrary to a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license or (2) provides materially inaccurate or incomplete information to a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license.

Demand for Information (DFI), as defined in 10 CFR 2.204, requires a licensee or other person subject to the jurisdiction of the Commission to respond with specific information for the purpose of enabling the NRC to determine whether an Order should be issued or whether other action should be taken.

Discrimination, as described in 10 CFR 50.7 (or similar provisions in 10 CFR Parts 30, 40, 52, 60, 61, 63, 70, 71, 72, and 76), is the taking of an adverse action against an employee because the employee engaged in certain protected activities.

Escalated Enforcement Actions include SL I, II, and III NOVs; NOVs associated with an inspection finding that the SDP evaluates as having low to moderate (white) or greater safety significance; civil penalties; NOVs to individuals; Orders to modify, suspend, or revoke NRC licenses or the authority to engage in NRC-licensed activities; and Orders issued to impose civil penalties.

Event, as used in this Policy, means (1) an occurrence 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 of a system to 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 discovers, 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 disclose an overexposure, the issue would be considered an event.

Fuel Cycle is the series of steps involved in supplying fuel for nuclear power reactors. It can include mining, milling, isotopic enrichment, fabrication of fuel elements, use in a reactor, chemical reprocessing to recover the fissionable material remaining in the spent fuel, reenrichment of the fuel material, refabrication into new fuel elements, waste disposal, storage, and transportation.

Impacts the NRC's Ability To Perform Its Regulatory Function refers to a situation that prevents the NRC from using appropriate regulatory tools to address a noncompliance because the Agency is unaware that the noncompliance exists (e.g., provision of inaccurate and incomplete information or failure to submit a required report).

Interim Enforcement Policies (IEPs) refers to a policy that is developed by the NRC staff and approved by the Commission for specific topics, typically for a finite period. Generally, IEPs grant the staff permission to refrain from taking enforcement action for generic issues which are not currently addressed in the Policy and are typically effective until such time that formal guidance is developed and implemented or other resolution to the generic issue. IEPs can be found in Section 9.0 of the Policy.

License Applicant, as used in this statement of policy, means any person who submits an application for review.

Licensee is any person or entity authorized to conduct activities under a license issued by the NRC. Licensees include, but are not limited to, facilities licensed under 10 CFR Parts 30-36, 39, 40, 50, 52, 60, 61, 63, 70 or 72. However, in most cases in the Policy the term is applied broadly to refer to any or all of entities listed in Section 1.2, "Applicability."

Licensee Official, as used in this statement of policy, in general, 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, the NRC will consider the individual's responsibilities relative to the oversight of licensed activities and the use of licensed material.

Licensed Reactor Operator, as used in this Policy, includes NRC licensed reactor operators (ROs) and NRC licensed senior reactor operators (SROs).

Lost Source Policy is the NRC's policy that a civil penalty may be issued for violations resulting in regulated material being out of the control of the licensee regardless of the use, license type, quantity, or type of regulated material (e.g., loss, abandonment, improper transfer, or improper disposal of regulated material).

Minor Violation is a violation that is less significant than a SL IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations must be corrected.

Noncited Violation (NCV) is a nonrecurring, typically nonwillful, SL IV violation or a violation associated with a Green ROP or cROP finding that is not subject to formal enforcement action if, for a reactor licensee, the licensee places the violation in a corrective action program to address recurrence and restores compliance within a reasonable period of time and, for all other

licensees, the licensee corrects or commits to correcting the violation within a reasonable period of time.

Nonescalated Enforcement Actions include NOVs that are dispositioned by the NRC as SL IV or minor violations.

Nonlicensee includes, but is not limited to, applicants, contractors, subcontractors, and vendors.

Notice of Deviation (NOD) is a written notice describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. An NOD requests that a licensee provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

Notice of Nonconformance (NON) is a written notice describing the failure of a licensee's contractor to meet commitments that have not been made legally binding requirements by the NRC (e.g., a commitment made in a procurement contract with a licensee or applicant as required by 10 CFR Part 50, Appendix B). (If the contractor deliberately fails to meet the terms of a procurement contract, the NRC may issue a violation under the Deliberate Misconduct Rule in 10 CFR 50.5.) NONs request that nonlicensees provide written explanations or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.

Notice of Violation (NOV) is a written notice setting forth one or more violations of a legally binding requirement (see 10 CFR 2.201).

Order is used to modify, suspend, or revoke a license, or to take other action against a licensee or other person subject to the jurisdiction of the Commission (see 10 CFR 2.202).

Potential Safety or Security Consequences include potential outcomes based on realistic and credible scenarios (i.e., the staff considers the likelihood that safety or security could have been negatively impacted under these scenarios).

Predecisional Enforcement Conference (PEC) is normally conducted with a licensee or individual before the NRC makes an enforcement decision when escalated enforcement action may warranted (i.e., SL I, II, or III violations, civil penalties, or Orders). The purpose of a PEC is to obtain information that will assist the NRC in determining the appropriate enforcement action, if any.

Regulatory Conference is conducted with a reactor licensee to discuss the significance of findings evaluated through the SDP, with or without associated violations. These meetings focus on the safety significance of the issues and not necessarily on the corrective actions associated with the issues. Because the significance assessment from the SDP determines whether escalated enforcement action will be taken, a subsequent PEC is not normally necessary.

Requirement, as used in this Policy, means a legally binding requirement such as a statute, regulation, license condition, technical specification, or Order.

Repetitive Violation is one that could reasonably be expected to have been prevented by a licensee's corrective action for the same, or a similar, previous violation or a previous licensee finding that occurred within the past 2 years of the current violation, or that occurred within the period covered by the last two inspections, whichever period is longer.

Risk Information is used wherever possible to develop realistic and credible scenarios to use when assessing the safety significance of a violation and assigning severity levels.

Severity Levels are used (1) to indicate the significance of a violation assessed under traditional enforcement and (2) to determine the appropriate enforcement action to be taken.

Significance, as used in this Policy for violations that do not involve application of the ROP or cROP, describes the seriousness of the violation. The significance of violations assessed under the ROP or cROP is determined by the SDP, described in IMC 0609 or IMC 2519 and related documents.

Substantial Potential for Overexposure describes a situation where it was fortuitous that the resulting radiation exposure did not exceed the dose limits of 10 CFR Part 20. The concern is not the significance of the resulting or potential exposure, but whether the licensee provided adequate controls over the situation, as required, to prevent exceedance of the 10 CFR Part 20 limits.

Traditional Enforcement, as used in this Policy, refers to the process for the disposition of violations of NRC requirements, including those that cannot be addressed only through the Operating Reactor Assessment Program. Traditional enforcement violations are assigned severity levels and typically include, but may not be limited to, those violations involving (1) actual safety and security consequences, (2) willfulness, (3) impeding the regulatory process, (4) discrimination, (5) violations not associated with ROP or cROP findings, (6) materials regulations, and (7) deliberate violations committed by individuals.

Violation is the failure to comply with a requirement.

Willful violations involve either a deliberate violation of NRC requirements or deliberately falsifying information, or careless disregard of NRC requirements or of the completeness and accuracy of information provided.

8.0 TABLE OF BASE CIVIL PENALTIES

TABLE A ¹⁹

a.	Power reactors, gaseous diffusion uranium enrichment plants, and high-level waste repository	\$350,000
b.	Fuel fabricators authorized to possess Category I or II quantities of SNM and uranium conversion facilities	\$175,000
c.	All other fuel fabricators, including facilities under construction, authorized to possess Category III quantities of SNM, industrial processors, ²⁰ independent spent fuel and monitored retrievable storage installations, mills, gas centrifuge and laser uranium enrichment facilities	\$87,500
d.	Test reactors, contractors, waste disposal licensees, industrial radiographers, and other large material users	\$35,000
e.	Research reactors, academic, medical, or other small material users ²¹	\$17,500
f.	Loss, abandonment, or improper transfer or disposal of regulated material, regardless of the use or type of licensee:	
	1. Sources or devices with a total activity greater than 3.7×10^4 MBq (1 Curie), excluding hydrogen-3 (tritium)	\$54,000
	2. Other sources or devices containing the materials and quantities listed in 10 CFR 31.5(c)(13)(i)	\$17,000
	3. Sources and devices not otherwise described above	\$7,000
g.	Individuals who release safeguards information	\$8,750

NOTE: In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), the civil penalty amounts apply to any penalties assessed on and after the date that the new amounts take effect; not from the date of the violation.

The maximum value in item a. of this Table is calculated by rounding the maximum civil penalty amount specified in 10 CFR 2.205 down to the nearest multiple of \$10,000. Although the 2015 Act does not mandate changes to the lesser civil penalty amounts, the other values are also changed to maintain the same proportional relationship between the penalties.

The values specified in this Table, with the exception of item f., are adjusted utilizing the philosophy described in Section 2.3.4, "Civil Penalty," of the NRC Enforcement Policy. The base civil penalty amounts in item f. have been determined to be approximately 3 times the average cost of disposal. For specific cases, the NRC may adjust these amounts to correspond to 3 times the estimated or actual cost of authorized disposal for the particular material in question. These values are adjusted periodically as necessary.

¹⁹ The NRC adjusts the amount specified in 10 CFR 2.205 on an annual basis pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The NRC may impose civil penalties in amounts greater than the values in this table (up to the statutory maximum) based on an increase to the amount specified in 10 CFR 2.205 as published in the *Federal Register*.

²⁰ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.

²¹ This applies to nonprofit institutions not otherwise categorized in this table, mobile nuclear services, nuclear pharmacies, and physician offices.

TABLE B

Severity Level	Base Civil Penalty Amount (Percent of amount listed in Table A)
I.....	100%
II	80%
III	50%

9.0 INTERIM ENFORCEMENT POLICIES

9.1 Enforcement Discretion for Certain Fire Protection Issues (10 CFR 50.48)

This section contains the interim Enforcement Policy that the NRC will follow to exercise enforcement discretion for certain noncompliances with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.48, “Fire Protection” (or fire protection license conditions), that are identified as a result of a licensee’s transition to the new risk-informed, performance-based fire protection approach included in 10 CFR 50.48(c) and for certain existing identified noncompliances that reasonably may be resolved by compliance with 10 CFR 50.48(c). Under 10 CFR 50.48(c), reactor licensees may voluntarily comply with the risk-informed, performance-based fire protection approaches in National Fire Protection Association Standard 805, “Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants” (NFPA 805), 2001 Edition (with limited exceptions stated in the rule language).

Enforcement discretion may apply to noncompliances identified during the licensee transition process. This timeframe starts on the date as specified in the licensee’s letter of intent to transition to 10 CFR 50.48(c) and ends (1) 3 years after that initial start date or (2) on the date as specified in the licensee’s commitment letter, as amended and approved by the NRC. If the licensee is unable to submit its license amendment request (LAR) within the timeframe stated above, it will lose its enforcement discretion. However, licensees with appropriate justification and staff approval may regain enforcement discretion once an acceptable²² LAR is submitted. If enforcement discretion is not granted, any identified noncompliances may be subject to enforcement action.

Once an acceptable LAR is submitted, enforcement discretion for previously identified noncompliances²³ and any newly identified noncompliances discovered either by the licensee or the NRC while the LAR is under review will continue to be in place until the NRC disposes the LAR.²⁴ If the NRC finds the amendment request unacceptable but gives the licensee an opportunity to provide supplemental information, the enforcement discretion will continue while the licensee prepares the supplemental information, provided that it submits the information within the timeframe stipulated by the staff. If the NRC finds the amendment acceptable after receipt of the supplemental information, enforcement discretion will continue until the NRC disposes the amendment. A licensee that submits an LAR that is not acceptably supplemented or an LAR that was initially characterized as unacceptable with no opportunity to provide supplemental information will lose its enforcement discretion. However, licensees with appropriate justification and NRC approval may regain enforcement discretion once an acceptable LAR is submitted. If enforcement discretion is not granted, any identified noncompliances may be subject to enforcement action.

²² The agency will use the Office of Nuclear Reactor Regulation’s (NRR) Office Instruction, LIC-109, “Acceptance Review Procedures,” to evaluate the LAR for acceptability.

²³ These are noncompliances that were previously granted enforcement discretion before submittal of the LAR.

²⁴ Noncompliances that are identified during the LAR review process and that are determined to be either associated with a finding of high safety significance or willful will be considered for potential enforcement action.

Once the NRC accepts an LAR for licensing review, the timeliness and quality of the responses to requests for additional information (RAI) will significantly affect the LAR review schedule. Licensees that do not respond in a timely fashion to staff RAIs or do not provide quality RAI responses may lose enforcement discretion.

If, after submitting the letter of intent to comply with 10 CFR 50.48(c) and before submitting the LAR, a licensee decides not to complete the transition to 10 CFR 50.48(c), the licensee must submit a letter stating its intent to retain its existing licensing basis and withdrawing its letter of intent to comply with 10 CFR 50.48(c). After the licensee's withdrawal from the transition process, the NRC, as a matter of practice, will not take enforcement action against any noncompliance that the licensee corrected during the transition process and will, on a case-by-case basis, consider refraining from taking action if reasonable and timely corrective actions are in progress (e.g., an exemption has been submitted for NRC review). The NRC will disposition noncompliances that the licensee has not corrected, and noncompliances that were identified after the date of the withdrawal letter, in accordance with normal enforcement practices.

a. Noncompliances Identified During the Licensee's Transition Process

Under this interim Enforcement Policy, the NRC will normally not take enforcement action for a violation of 10 CFR 50.48(b) (or the requirements in a fire protection license condition) involving a problem in an area such as engineering, design, implementing procedures, or installation if the violation is documented in an inspection report and meets all of the following criteria:

1. The licensee identified the violation as a result of a voluntary initiative to adopt the risk-informed, performance-based fire protection program under 10 CFR 50.48(c), or, if the NRC identified the violation, the NRC found it likely that the licensee would have identified the violation in light of the defined scope, thoroughness, and schedule of its transition to 10 CFR 50.48(c).
2. The licensee corrected the violation or will correct the violation after completing its transition to 10 CFR 50.48(c). Also, the licensee took immediate corrective action or compensatory measures or both within a reasonable time commensurate with the risk significance of the issue following identification; this action should involve expanding the initiative, as necessary, to identify other issues caused by similar root causes.
3. Routine licensee efforts, such as normal surveillance or quality assurance activities, were not likely to have previously identified the violation.
4. The violation was not willful.

The NRC may take enforcement action when the licensee has not met these conditions or when a violation that is associated with a finding of high safety significance is identified.

Although the NRC may exercise discretion for violations meeting the required criteria, if the licensee failed to make a required report to the agency, then it will normally issue a separate enforcement action for the licensee's failure to make the required report.

b. Existing Identified Noncompliances

In addition, the licensee may have existing identified noncompliances that could reasonably be corrected under 10 CFR 50.48(c). For these noncompliances, the NRC is providing enforcement discretion for the implementation of corrective actions until the licensee has made the transition to 10 CFR 50.48(c), provided that the noncompliances meet all of the following criteria:

1. The licensee has entered the noncompliance into its corrective action program and implemented appropriate compensatory measures.
2. The noncompliance is not associated with a finding that the Reactor Oversight Process significance determination process would evaluate as red, or otherwise it would not be categorized at Severity Level I.
3. The noncompliance was not willful.
4. The licensee submitted a letter of intent by December 31, 2005, stating its intent to transition to 10 CFR 50.48(c).

9.2 Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)

This section sets forth the interim policy that the NRC will use for medical event reporting violations under current 10 CFR 35.3045. Enforcement discretion will typically be exercised for reporting violations in the following scenarios, subject to criteria specified below, when the authorized treatment mode is permanent implant brachytherapy: (1) the licensee uses total source strength and exposure time for evaluating the existence of a treatment site medical event; or (2) the total absorbed dose to the treatment site equals or exceeds 120 percent of the prescribed dose. This policy does not provide regulatory relief from complying with any other aspect of §§ 35.41 or 35.3045, including the requirements related to the evaluation of dose to normal tissue.

The interim policy applies to violations that result from an otherwise appropriate use of total source strength and exposure time when determining the existence of a medical event and when the use of these values does not result in the misapplication of byproduct material by the licensee.

Specifically, under this interim Enforcement Policy, the NRC will normally not take enforcement action for using total source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose when evaluating whether a medical administration is a medical event under § 35.3045(a)(1) if the authorized treatment mode is permanent implant brachytherapy and all of the following criteria are met:

- a. The licensee's documented procedures required under § 35.41 specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons;
- b. The licensee entered both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time; and
- c. Per § 35.3045, the licensee timely reported the event based on that treatment site dose comparison, if applicable.

In addition, the NRC will normally not take enforcement action against a licensee for not submitting a medical event report when the permanent implant brachytherapy treatment site total dose equals or exceeds 120 percent of the prescribed dose. This enforcement discretion would only apply if: (1) the licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; (2) doses to normal tissues and structures did not exceed the regulatory dose limits for reporting medical events specified in current § 35.3045(a)(3); and (3) the total dose for the treatment site was expressed in the written directive as absorbed dose.

This discretion will not be exercised for licensees using source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose, since it is expected that the licensee has more control over delivery of the prescribed dose when using source strength and exposure time. However, this is not intended to limit the physician's current ability to make intraoperative adjustments in the quantity of source strength to be implanted based on

the conditions encountered during the surgical procedure and to document such adjustments in the portion of the written directive required after implantation but before completion of the procedure.

Licensees shall comply with all other requirements, as applicable, unless explicitly replaced or amended in this interim policy.

This interim policy will remain in place until the implementation date of a final rule associated with the medical event reporting requirements.

10.0 PAPERWORK REDUCTION ACT STATEMENT AND PUBLIC PROTECTION NOTIFICATION

Paperwork Reduction Act Statement

This policy statement contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval number 3150-0136. This policy statement references additional mandatory and voluntary information collections approved by OMB, approval numbers 3150-0002, 3150-0007, 3150-0008, 3150-0009, 3150-0010, 3150-0011, 3150-0013, 3150-0014, 3150-0016, 3150-0017, 3150-0018, 3150-0032, 3150-0035, 3150-0036, 3150-0104, 3150-0146, 3150-0151, 3150-0158, 3150-0195.

The burden to the public for the voluntary information collections approved under clearance number 3150-0136 is estimated to average 166 hours per NOED request and 40 hours per NFPA 805 letter of intent, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The information provided in a NOED request is needed for the NRC to determine if the exercise of enforcement discretion is clearly consistent with protecting the public health and safety. The information in a letter of intent to transition to NFPA 805 is needed to determine when the licensee's three years of enforcement discretion begins. Send comments regarding this burden estimate or any other aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0136), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.