

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-32223/94-02

License: 11-27398-01MD

Licensee: Nuclear Pharmacy of Idaho, Inc.
6053 Corporal Lane
Boise, Idaho 83702

Facility Name: Nuclear Pharmacy of Idaho, Inc.

Inspection At: Boise, Idaho

Inspection Conducted: May 16-17, 1994

Inspector: Mark R. Shaffer, Radiation Specialist
Nuclear Materials Inspection Branch

Approved: 
for Charles L. Cain, Acting Chief
Nuclear Materials Inspection Branch

6/3/94
Date

Inspection Summary

Areas Inspected: Special, unannounced inspection of licensed activities involving the use of byproduct material for the production, preparation, and distribution of radiopharmaceuticals.

The inspection was limited to a review of radiation levels present in unrestricted areas surrounding the licensee's facility and an evaluation of iodine-131 air effluent concentrations released by the licensee during calendar year 1993.

Results:

- Within the scope of this inspection, one apparent violation was identified. This violation relates to the failure of the licensee to maintain airborne effluent concentrations in unrestricted areas below the limits established in Table 2 of Appendix B to 10 CFR Part 20 as averaged over a year (Section 2).

Summary of Inspection Findings:

- Failure to comply with 10 CFR 20.106(a) which requires that airborne effluent concentrations of iodine-131 be maintained below the limits established in Table 2 of Appendix B to 10 CFR Part 20 as averaged over a year (Section 2).

Attachment:

- Persons Contacted and Exit Meeting

DETAILS

1 PROGRAM OVERVIEW (87100)

The licensee operates a nuclear pharmacy which prepares and distributes radiopharmaceuticals to medical licensees (hospitals and physicians). The NRC license for these operations was issued in September 1991. Licensed activities have been performed under the supervision of one authorized user who is also the licensee's Radiation Safety Officer (RSO). The majority of activity involved (1) the production of technetium-99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals and (2) the compounding and dispensing of iodine-131 therapy capsules.

Radiopharmaceutical distribution records revealed that the licensee prepared 50-60 unit doses each day. Approximately two iodine-131 therapy capsules were compounded per week, and the licensee received and processed approximately 8,700 millicuries of iodine-131 during calendar year 1993.

2 RADIATION SURVEYS, RECORDS, AND INDEPENDENT MEASUREMENTS (87100, 83822)

The licensee is required to perform surveys for effluent concentrations, removable contamination, and ambient radiation dose rates at intervals prescribed under the license and by NRC regulations.

2.1 Radiation Dose Rates

As a result of an NRC inspection conducted on February 3-4, 1994, a Notice of Violation (Notice) was issued to the licensee on April 4, 1994, regarding the failure to adequately evaluate radiation levels in unrestricted areas. During this inspection, NRC identified that the licensee had not measured the dose rates in areas immediately adjacent to the licensee's facility to demonstrate compliance with dose limits to individuals of the public. These areas consisted of offices where other businesses were located. (It should be noted that these unrestricted area offices were not residential quarters; therefore, due to occupancy times, doses received by members of the public could be reduced by an occupancy factor.)

In response to this Notice, the licensee performed radiation dose rate surveys within the neighboring offices (Building Nos. 6051 and 6055) on May 6, 1994. Records of these surveys indicated a maximum dose rate in adjacent offices to be 0.12 milliroentgens per hour (mR/hr) at the surface of the wall.

Additionally, at the request of the tenants occupying Building No. 6055, a representative from the State of Idaho, Department of Health and Welfare, Idaho National Engineering Laboratory (INEL) Oversight Program, also performed radiation dose rate measurements within the unrestricted areas located in Building 6055. In a letter dated May 9, 1994, INEL describes their independent measurements. This letter indicates that all measurements were at background radiation levels with the exception of one particular office. Within this office, INEL measured a maximum radiation dose rate of 1.3 mR/hr

at the surface of the wall. Background radiation was measured to be 0.015 mR/hr.

An NRC inspection was conducted to perform additional independent measurements to verify the licensee's level of compliance regarding dose limits to individual members of the public. The inspector performed surveys of the ambient dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to verify compliance. 10 CFR 20.1301 limits, in part, the total effective dose equivalent to individual members of the public from licensed operations to 0.1 rem in a year. Additionally, the dose in any unrestricted area from external sources must not exceed 2 millirems in any one hour.

Within Building No. 6051, the highest dose rate measured by the inspector was 0.2 mR/hr at the surface of the wall immediately adjacent to an area where the licensee stored iodine-131 and strontium-89 waste for decay. The dose rate at 30 centimeters from this point was measured to be 0.09 mR/hr. Background radiation was measured to be approximately 0.01 mR/hr. Although this dose rate demonstrates compliance regarding 2 millirems in any one hour, the inspector noted that if an individual were continually present in this area, and if the exposure rates were consistent, the dose limit of 0.1 rem in a year could be exceeded. However, the dose rates in this area vary significantly depending upon the quantity of radioactive waste material present at a given time. In this regard, in an effort to demonstrate compliance with the yearly limit of exposure to individual members of the public, on May 6, 1994, the licensee placed a thermoluminescent dosimeter (TLD) in this area to evaluate accumulated exposure over a specified period of time, and thereby take into account the multiple conditions that exist which vary exposure rates. Additionally, prior to the conclusion of the inspection, the RSO informed the inspector of the licensee's intent to place additional shielding in this area, and to relocate some of the waste which was contributing to the dose rate. The licensee expects to reduce exposure rates to background levels within this area.

Because the exposure levels measured by the inspector were ones which existed only during the first 5 months of the calendar year, and because the licensee's increased shielding is expected to reduce exposure levels to essentially background radiation, it appears unlikely that an individual of the public would receive a total effective dose equivalent in excess of 0.1 rem in a year as a result of the licensee's operations.

Within Building No. 6055, the location of the highest exposure rate measured by the inspector was within an office immediately adjacent to the licensee's technetium-99m preparation area. The inspector measured 1.2 mR/hr at the surface of the wall and at a height of approximately 6 feet from the floor. (Thus, this measurement was similar to the one obtained by the INEL official.) The dose rate at 30 centimeters from this point was measured to be 0.35 mR/hr. Background radiation was measured to be approximately 0.01 mR/hr. However, it was noted that these measurements were taken during afternoon hours when radiopharmaceuticals were not being prepared. The dose rate was attributed to

a storage container ("red needle bucket") containing syringes contaminated with technetium-99m. Due to the rapid decay of technetium-99m, it was noted that dose rates within this area would vary greatly depending upon the time of day and the day of the week. Furthermore, the licensee's workload (amount of doses prepared) during a given day would significantly affect the accumulated dose one might receive in any 1 hour. Therefore, to further assess the average dose rates in this area, the inspector performed additional surveys during the licensee's peak working hours (5:00 a.m. - 7:00 a.m.) and compared dose rate measurements with a set of simulated work conditions.

With a vial containing approximately 400 millicuries of technetium-99m left out of its leaded vial shield, the inspector measured a maximum dose rate in unrestricted areas to be 13 mR/hr. This dose rate was measured at approximately the same location as described above. The dose rate at 30 centimeters from this point was measured to be 9 mR/hr. With a syringe containing approximately 40 millicuries of technetium-99m left out of its leaded syringe shield, the inspector measured a maximum dose rate of 4 mR/hr. The dose rate at 30 centimeters from this point was measured to be 2 mR/hr. Although both conditions yielded dose rates greater than 2 mR/hr, these were conditions that were expected to exist for only seconds of time during any given hour (i.e., a vial and/or syringe is only unshielded during brief periods when the dose is assayed in a dose calibrator).

In this regard, in an effort to demonstrate compliance with the yearly limit of exposure to individuals of the public, on May 6, 1994, the licensee placed a TLD in this area to evaluate accumulated exposure over a specified period of time, and thereby take into account the multiple conditions that exist which vary exposure rates. Additionally, prior to the conclusion of this inspection, the licensee installed additional lead shielding surrounding the radiopharmaceutical preparation area to further reduce dose rates in unrestricted areas. Measurements taken after the installation of the shielding indicate dose rates which were essentially background radiation.

Therefore, because the exposure levels measured by the inspector were ones which existed only during the first 5 months of the calendar year, and because the licensee's increased shielding is expected to reduce exposure levels to essentially background radiation, it appears unlikely that an individual of the public would receive a total effective dose equivalent in excess of 0.1 rem in a year as a result of the licensee's operations.

Again, it should be noted that factors relating to occupancy times and distances from the wall by members of the public would significantly further reduce exposure estimates.

2.2 Effluent Concentrations

Also evaluated during this inspection was the licensee's air effluent concentrations of iodine-131 released to the environment during calendar year 1993. To demonstrate compliance with 10 CFR 20.106, Radioactivity in effluents to unrestricted areas, the licensee acquired air samples weekly to

measure the quantity of iodine-131 being release to the atmosphere. Table II of Appendix B to 10 CFR Part 20 limits the release of iodine-131 in air, in an unrestricted area, to a maximum of 1×10^{-10} microcuries per milliliter of air. Concentrations may be averaged over a period not greater than 1 year.

As noted in Section 1, the licensee handles millicurie quantities of unsealed radioiodine (iodine-131 sodium iodide solution) for compounding therapy capsules. The process is performed in a fume hood located in the licensee's hot lab. The hood is equipped with an activated charcoal filter to reduce air concentrations of iodine-131 prior to release to the atmosphere.

Using the data collected from weekly air samples, the licensee divided the total amount of iodine-131 released year to date, by the total air volume released through the hood's stack year to date, to calculate the total amount of iodine-131 released. The data were logged on the licensee's worksheet titled, "Year-to-Date Iodine-131 Released Air Concentrations." A review of these worksheets indicated that the licensee had exceeded the maximum allowable air concentration limits during 1993. The licensee's calculations, dated December 31, 1993, indicate an average release to unrestricted areas for 1993 to be 2.7×10^{-10} microcuries per milliliter of air. Further review of the licensee's sampling method suggests that the calculations may have underestimated the total quantity actually released during 1993.

The inspector noted that the licensee's weekly calculations did not account for the decay of iodine-131 prior to the sample collection, nor did the calculations consider the collection efficiency of the sample media used (4.7 centimeter impregnated carbon filter). The Notice to the licensee dated April 4, 1994, related to the licensee's failure to evaluate these effluents and compare them with the annual limit. It further suggested the potential to exceed air concentration limits during 1994. Based upon the licensee's records documenting air concentrations of iodine-131 released to an unrestricted area during 1993, this was identified as an apparent violation of 10 CFR 20.106(a) which requires, in part, that the licensee not release to an unrestricted area radioactive material in annual average concentrations which exceed the limits specified in Table II of Appendix B to 10 CFR Part 20 (1×10^{-10} microcuries per milliliter of air for soluble iodine-131). It should be noted that the concentration limit in revised Part 20 has been changed to 2×10^{-10} microcuries per milliliter of air for soluble iodine-131. This expanded limit was effective as of January 1, 1994.

Also responding to NRC's Notice, the licensee employed the services of a consultant physicist to assist in evaluating air effluents. The consultant's report, dated May 16, 1994, discusses similar concerns regarding the licensee's methods of calculating air concentrations (sampling efficiency and corrections for decay). Therefore, the consultant performed calculations using Environmental Protection Agency (EPA) approved methods outlined in 40 CFR 61, Appendix D. When the EPA methods were used to estimate the source term, and with the carbon filters being taken into account, the concentration of iodine-131 in the stack effluent was estimated to be 5×10^{-10} microcuries per milliliter of air for 1993. This method assumes the stack's point of

release (located on the roof of the licensee's facility) to be the unrestricted area. Since the licensee does not control access to the roof, this assumption would be valid.

The inspector did note that following NRC's inspection in February 1994, the licensee has purchased a glove box equipped with a three-layer activated charcoal bed, to be used in conjunction with the licensee's fume hood, to reduce effluent releases. At the time of this inspection, the glove box had not been installed but was expected to be within several days. The installation of these filters is expected to bring the licensee into compliance with 10 CFR 20.

ATTACHMENT

1 PERSONS CONTACTED

1.1 Licensee Personnel

- *Kay Gregorio, Pharmacist Assistant
- *Ned Gregorio, Radiation Safety Officer
- Bob Santos, Courier/Pharmacist Assistant

1.2 NRC Personnel

- Charles L. Cain, Acting Chief, Nuclear Materials Inspection Branch
- *Mark R. Shaffer, Radiation Specialist

1.3 Other Individuals Contacted

- SGT Crista Buchman, National Guard Liaison
- +Richard Cade, Director, Idaho Department of Law Enforcement
- Glenn Ford, Chief, Bureau of Narcotics, Idaho Department of Law Enforcement
- +William Hladik III, Consultant Physicist
- John Lewis, Assistant Deputy Director, Idaho Department of Law Enforcement
- Monte MacConnell, Deputy Director, Idaho Department of Law Enforcement
- Ronda Morton, Office Secretary, Bureau of Narcotics,
Idaho Department of Law Enforcement
- Steven Oberg, Ph.D., INEL Oversight Program
- Ed Rankin, Special Agent-In-Charge, Bureau of Narcotics,
Idaho Department of Law Enforcement
- +David Salmon, Health Physics Northwest
- Don VanCleave, Special Agent, Bureau of Narcotics,
Idaho Department of Law Enforcement
- Roy Weston, Office Accountant, Bureau of Narcotics,
Idaho Department of Law Enforcement

*Indicates those present during exit meeting on May 17, 1994.

+Indicates those contacted by phone only.

2 EXIT MEETINGS

A preliminary site exit briefing was conducted on May 17, 1994, with those individuals identified in Section 1.

Additionally, a formal exit briefing was conducted telephonically between the licensee's Radiation Safety Officer and Messrs. Charles L. Cain and Mark R. Shaffer on May 26, 1994, to review the specific findings as presented in the report.

APPENDIX B

PROPOSED ENFORCEMENT CONFERENCE AGENDA

NUCLEAR PHARMACY OF IDAHO, INC

July 1, 1994 - 9:00 a.m. (CDT)

- | | |
|---|----------------|
| I. INTRODUCTION AND PURPOSE | L. J. CALLAN |
| II. EXPLANATION OF ENFORCEMENT POLICY | G. F. SANBORN |
| III. NRC DISCUSSION OF APPARENT VIOLATIONS | C. L. CAIN |
| IV. LICENSEE COMMENTS AND RESPONSE/
CORRECTIVE ACTIONS | S. N. GREGORIO |
| V. CLOSING COMMENTS | S. J. COLLINS |

37 FR 15127

tion for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license, provided that the permit or license so issued contains the condition specified in § 50.55b of this chapter.

46 FR 55083

(f) Hearings on antitrust aspects will be conducted by a presiding officer, either an Administrative Law Judge or an atomic safety and licensing board comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom will have such technical or other qualifications as the Commission deems appropriate to the issues to be decided.

35 FR 39659

(g) When the Attorney General has advised that there may be adverse antitrust aspects and recommends that a hearing be held, the Attorney General or his designee may participate as a party in the proceedings.

45 FR 55083

(h) At the hearing, the presiding officer will give due consideration to the advice received from the Attorney General and to evidence pertaining to antitrust aspects received at the hearing.

(i) The presiding officer will, in the initial decision, make a finding as to whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act. If the presiding officer finds that such a situation would be created or maintained, it will consider, in determining whether the permit or license should be issued or continued, such other factors as it deems necessary to protect the public interest, including the need for power in the affected area. The certainty of contravening the antitrust laws or the policies clearly underlying these laws is not intended to be implicit in this standard; nor is mere possibility of inconsistency. The finding will be based on reasonable probability of contravention of the antitrust laws or the policies clearly underlying these laws. The presiding officer will conclude whether, in its judgment, it is reasonably probable that the activities under the license would, when the license is issued or thereafter, be inconsistent with any of the antitrust laws or the policies clearly underlying these laws.

(j) On the basis of the findings in the proceeding on the antitrust aspect of the application, the presiding officer may (i) authorize the issuance of the permit or license after favorable consideration of matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, at the hearing described in sections I-VIII of this appendix; (ii) authorize the continuation of a permit or license already issued; (iii) direct the denial of the application for the permit or license, or the revocation of a permit or license already issued; or (iv) authorize the issuance of a permit or license subject to appropriate conditions, and subject to favorable consideration of matters of radiological health and safety and common defense matters raised under the National Environmental Policy Act of 1969 at the hearing described in sections I-VIII of this appendix.

➤ Appendix B to Part 2
[Reserved 58 FR 46610.]

Appendix C — General Statement of Policy and Procedure for NRC Enforcement Actions

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58 FR 14308

Preface

The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions, and of the presiding officers and the Commission in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety, the common defense and security, and the environment.¹ This statement of general policy and procedure is published in the Code of Federal Regulations to provide widespread dissemination of the Commission's Enforcement Policy. However, this is a policy statement and not a regulation. The Commission may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

I. Introduction and Purpose

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by:

- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
- Deterring future violations and occurrences of conditions adverse to quality; and
- Encouraging improvement of licensee and vendor² performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees, vendors, contractors, and employees of any of them, who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects.³ Each enforcement action is dependent on the circumstances of the

¹ Antitrust enforcement matters will be dealt with on a case-by-case basis.

² The term "vendor" as used in this policy means a supplier of products or services to be used in an NRC-licensed facility or activity.

³ This policy primarily addresses the activities of NRC licensees. Therefore, the term "licensee" is used throughout the policy. However, in those cases where the NRC determines that it is appropriate to take enforcement action against a non-licensee or individual, the guidance in this policy will be used, as applicable. Specific guidance regarding enforcement action against individuals and non-licensees is addressed in Sections VIII and X respectively.

case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

II. Statutory Authority and Procedural Framework

A. Statutory Authority

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Section 186 authorizes NRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's failure to build or operate a facility in accordance with the terms of the permit or license, and for violation of an NRC regulation). Section 234 authorizes NRC to impose civil penalties not to exceed \$100,000 per violation per day for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. In addition to the enumerated provisions in section 234, sections 84 and 147 authorize the imposition of civil penalties for violations of regulations implementing those provisions. Section 232 authorizes NRC to seek injunctive or other equitable relief for violation of regulatory requirements.

Section 206 of the Energy Reorganization Act authorizes NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

Chapter 18 of the Atomic Energy Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of the Act and regulations or orders issued under sections 65, 161(b), 161(i), or 161(o) of the Act. Section 223 provides that criminal penalties may be imposed on certain individuals employed by firms constructing or supplying basic components of any utilization facility if the individual knowingly and willfully

violates NRC requirements such that a basic component could be significantly impaired. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the Atomic Energy Act are referred to the Department of Justice for appropriate action.

B. Procedural Framework

Subpart B of 10 CFR part 2 of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the civil penalty process is initiated by issuing a Notice of Violation and Proposed Imposition of a Civil Penalty. The licensee or other person is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the response, the civil penalty may be mitigated, remitted, or imposed. An opportunity is provided for a hearing if a civil penalty is imposed. If a civil penalty is not paid following a hearing or if a hearing is not requested, the matter may be referred to the U.S. Department of Justice to institute a civil action in District Court.

The procedure for issuing an order to institute a proceeding 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 is set forth in 10 CFR 2.202. The licensee or any other person adversely affected by the order may request a hearing. The NRC is authorized to make orders immediately effective if required to protect the public health, safety, or interest, or if the violation is willful. Section 2.204 sets out the procedures for issuing a Demand for Information (Demand) to a licensee or other person subject to the Commissioner's jurisdiction for the purpose of determining whether an order or other enforcement action should be issued. The Demand does not provide hearing rights, as only information is being sought. A licensee must answer a Demand. An unlicensed person may answer a Demand by either providing the requested information or explaining why the Demand should not have been issued.

III. Responsibilities

The Executive Director for Operations (EDO) and the principal enforcement officers of the NRC, the Deputy Executive Director for Nuclear Material Safety Safeguards and Operations Support (DEDS) and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research (DEDR), have been delegated the authority to approve or issue all escalated enforcement actions.* The DEDS is responsible to the EDO for the NRC enforcement programs. The Office of Enforcement (OE) exercises oversight of and implements the NRC enforcement programs. The Director, OE, acts for the Deputy Executive Directors in enforcement matters in their absence or as delegated. Subject to the oversight and direction of OE, and with the approval of the appropriate Deputy Executive Director, where necessary, the regional offices normally issue Notices of Violation and proposed civil penalties. However, subject to the same oversight as the regional offices, the Office of Nuclear Reactor Regulation (NRR) issues Notices of Violation and proposed civil penalties to vendors and suppliers and the Office of Nuclear Material Safety and Safeguards (NMSS) issues Notices of Violation and proposed civil penalties to certificate holders and to fuel cycle facilities for violations involving material control and accounting. Escalated enforcement actions are normally coordinated with the appropriate offices by the OE. Enforcement orders are normally issued by a Deputy Executive Director or the Director, OE. However, orders may also be issued by the EDO, especially those involving the more significant matters. The Directors of NRR and NMSS have also been delegated authority to issue orders, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions not associated with compliance issues. The Director, Office of the Controller, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license and inspection fees.

* The term "escalated enforcement action" as used in this policy means a Notice of Violation for any Severity Level I, II, or III violation; a civil penalty for any Severity Level I, II, III, or IV violation; and any order based upon a violation.

In recognition 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, including the decision to issue a Notice of Violation, 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 technical significance of the violations and the surrounding circumstances.

Unless Commission consultation or notification is required by this policy, the staff may depart, where warranted in the public's interest, from this policy with the approval of the appropriate Deputy Executive Director and consultation with the EDO as warranted. (See also Section VII, "Exercise of Discretion.")

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will also be provided notice in those cases where discretion is exercised and discussed in Section VII E.6. In addition, the Commission will be consulted prior to taking action in the following situations (unless the urgency of the situation dictates immediate action):

- (1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation;
- (2) Proposals to impose civil penalties in amounts greater than 3 times the Severity Level I values shown in Table 1A;
- (3) Any proposed enforcement action that involves a Severity Level I violation;
- (4) Any enforcement action that involves a finding of a material false statement;
- (5) Exercising discretion for matters meeting the criteria of Section VII.A.1 for Commission consultation;
- (6) Refraining from taking enforcement action for matters meeting the criteria of Section VII.B.3;
- (7) Any proposed enforcement action that involves the issuance of a civil penalty or order to an unlicensed individual or a civil penalty to a licensed reactor operator;

(8) Any action the EDO believes warrants Commission involvement;

(9) Any enforcement case involving an Office of Investigation (OI) report where NRC staff (other than OI staff) does not arrive at the same conclusions as those in the OI report concerning issues of intent.

(10) Any proposed enforcement action on which the Commission asks to be consulted.

IV. Severity of Violations

Regulatory requirements⁴ have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation, including both the technical significance and the regulatory significance is evaluated as the first step in the enforcement process.

Consequently, violations are normally categorized in terms of five levels of severity to show their relative importance within each of the following eight activity areas:

- I. Reactor Operations;
- II. Facility Construction;
- III. Safeguards;
- IV. Health Physics;
- V. Transportation;
- VI. Fuel Cycle and Materials Operations;
- VII. Miscellaneous Matters; and
- VIII. Emergency Preparedness.

Licensed activities will be placed in the activity area most suitable in light of the particular violation involved including activities not directly covered by one of the above listed areas, e.g., export license activities. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant regulatory concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

⁴ The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Reactor Operations is not directly comparable to that associated with Severity Level I violations in Facility Construction.

Supplements I through VIII provide examples and serve as guidance in determining the appropriate severity level for violations in each of the eight activity areas. However, the examples are neither exhaustive nor controlling. In addition, these examples do not create new requirements. Each is designed to illustrate the significance that the NRC places on a particular type of violation of NRC requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

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 best suited to the significance of the particular violation. In some cases, special circumstances may warrant an adjustment to the severity level categorization.

A. Aggregation of Violations

A group of violations may be evaluated in the aggregate and assigned a single, increased severity level, thereby resulting in a Severity Level III problem, if the violations have the same underlying cause or programmatic deficiencies, or the violations contributed to or were unavoidable consequences of the underlying problem. Normally, Severity Level I and II violations are not aggregated into a higher severity level.

The purpose of aggregating violations is to focus the licensee's attention on the fundamental underlying causes for which enforcement action appears warranted and to reflect the fact that several violations with a common cause may be more significant collectively than individually and may therefore, warrant a more substantial enforcement action. In addition, a civil penalty for multiple occurrences of a violation with the same root cause may be subject to escalation of the base civil penalty. (See Section VI.B.2.(e))

B. Repetitive Violations

The severity level of a Severity Level V or IV violation may be increased to Severity Level IV or III respectively, if the violation can be considered a repetitive violation.⁶ The purpose of escalating the severity level of a repetitive violation is to acknowledge the added significance of the situation based on the licensee's failure to implement effective corrective action for the previous violation. The decision to escalate the severity level of a repetitive violation will depend on the circumstances, such as, but not limited to, the number of times the violation has occurred, the similarity of the violations and their root causes, the adequacy of previous corrective actions, the period of time between the violations, and the significance of the violations. (Civil penalties may also be proposed for repetitive Severity Level IV violations as discussed in Section VI.B.)

C. Willful Violations

Willful violations are by definition of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. Willful violations cannot be tolerated by either the Commission or a licensee. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances such that it demonstrates the seriousness of the violation thereby creating a deterrent effect within the licensee's organization. While removal of the person is not necessarily required, substantial disciplinary action is expected.

⁶ The term "repetitive violation" or "similar violation" as used in this policy statement means a violation that reasonably could have been prevented by a licensee's corrective action for a previous violation normally occurring (1) within the past two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer.

Therefore, the severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the NRC. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official⁷ or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, the severity level of a willful severity level V violation will be increased to at least a severity level IV.

(D) Violations of Reporting Requirements

The NRC expects licensees to provide complete, accurate, and timely information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the

circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

V. Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the NRC will normally provide an opportunity for an enforcement conference with the licensee, vendor, or other person prior to taking enforcement action. Although enforcement conferences are not normally held for Severity Level IV violations, they may be scheduled if increased management attention is warranted e.g., if the violations are repetitive. The purpose of the enforcement conference is to (1) discuss the violations or nonconformances, their significance, the reason for their occurrence, including the apparent root causes, and the licensee's or vendor's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information that will help the NRC determine the appropriate enforcement action.

During the enforcement conference, the licensee, vendor, or other person will be given an opportunity to provide information consistent with the purpose of the conference, including an explanation to the NRC of the immediate corrective actions (if any) that were taken following identification of the potential violation or nonconformance and the long term comprehensive actions that were taken or will be taken to prevent recurrence. Licensees, vendors, or other persons will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be open to the public.

When needed to protect the public health and safety or common defense and security, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In these cases, an enforcement conference may be held after the escalated enforcement action is taken.

VI. Enforcement Actions

This section describes the enforcement sanctions available to the NRC and specifies the conditions under which each may be used. The basic sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative mechanisms such as Notices of Nonconformance, Notices of Deviation, Confirmatory Action Letters, letters of reprimand, and Demands for Information are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. Usually, whenever a violation of NRC requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, a Notice of Violation or a Notice of Nonconformance is the normal enforcement action.

⁷ The term "licensee official" as used in this policy statement means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license. Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

A. Notice of Violation

A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) corrective steps that have been taken and the results achieved; (3) corrective steps that will be taken to prevent recurrence; and (4) the date when full compliance will be achieved. The NRC may require responses to Notices of Violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

The NRC uses the Notice of Violation as the usual method for formalizing the existence of a violation. Issuance of a Notice of Violation is normally the only enforcement action taken, except in cases where the criteria for issuance of civil penalties and orders, as set forth in Sections VI.B and VI.C, respectively, are met. However, special circumstances regarding the violation findings may warrant discretion being exercised such that the NRC refrains from issuing a Notice of Violation. (See Section VII.B, "Mitigation of Enforcement Sanctions.") In addition, licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of (1) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders; (2) any requirement for which a license may be revoked; or (3) reporting requirements under section 206 of the Energy Reorganization Act. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations both by the involved licensee as well as by other licensees conducting similar activities.

Civil penalties are proposed (absent mitigating circumstances) for Severity Level I, II, and III violations, and may be proposed for repetitive Severity Level IV violations or for any willful violation. In addition, civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act.

1. Base Civil Penalty

The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, materials, and vendor programs. (Civil penalties issued to individuals are determined on a case-by-case basis.) The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of 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 puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of the penalties take into account a licensee's "ability to pay." In determining the amount of civil penalties for licensees for whom the tables do not reflect the ability to pay, the NRC will consider as necessary an increase or decrease on a case-by-case basis. Normally, if a licensee can demonstrate financial hardship, the NRC will consider payments over time, including interest, rather than reducing the amount of the civil penalty. However, where a licensee claims financial hardship, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

2. Civil Penalty Adjustment Factors

In an effort to recognize and encourage good performance, deter poor performance, and emphasize violations of particular regulatory concern, the NRC reviews each proposed civil penalty on its own merits and, after considering all relevant circumstances, may adjust the base civil penalties shown in Table 1A and 1B for Severity Level I, II, and III violations based on an assessment of the following civil penalty adjustment factors. Civil penalties for Severity Level IV violations are normally proposed at the base values identified in the tables without assessing the civil penalty adjustment factors.

While management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of management involvement may not be used to mitigate a civil penalty. Allowing mitigation in the latter case could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

(a) *Identification.* The purposes of this factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance. Therefore, the base civil penalty shown in Tables 1A and 1B may be mitigated up to 50% when a licensee identifies a violation and escalated up to 50% if the NRC identifies a violation. The base civil penalty may also be mitigated up to 25% when a licensee identifies a violation resulting from a self-disclosing event* where the licensee demonstrates initiative in identifying the root cause of the violation. In addition, the base civil penalty may also be mitigated where warranted if a licensee identifies a violation as a result of its review of a generic notification. While mitigation under this factor is appropriate for a licensee identified violation that was not reported to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make the required report.

* The term "self-disclosing event" as used in this policy statement means an event that is readily obvious by human observation or mechanical instrumentation such as a spill of liquid, an open door (required to be closed), an overexposure documented in a dosimetry report, an annunciator alarm, or a reactor trip.

(b) *Corrective action.* The purposes of this factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of similar violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be either mitigated or escalated by as much as 50% depending on the promptness and extensiveness of the licensee's corrective action. In assessing this factor, consideration will be given to, among other things, the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the degree of licensee initiative (i.e., whether NRC involvement was required before acceptable action was taken), the adequacy of the licensee's root cause analysis for the violation, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). Notwithstanding good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, mitigation of the civil penalty based on this factor will not normally be considered and escalation may be considered to address the licensee's failure.

(c) *Licensee performance.* The purpose of this factor is to recognize and encourage good or improving licensee performance and to recognize and deter poor or declining performance. Therefore, the base civil penalty shown in Tables 1A and 1B may be mitigated by as much as 100% if the current violation is an isolated failure that is inconsistent with a licensee's outstandingly good prior performance. The base civil penalty may also be escalated by as much as 100% if the current violation is reflective of the licensee's poor or declining prior performance. Neither mitigation nor escalation may be appropriate based on

this factor where a licensee's poor prior performance appears to clearly be improving. Prior performance, as used in this policy statement, refers to the licensee's performance normally (1) within the last two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer, in assessing the licensee's prior performance. Consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as Systematic Assessment of Licensee Performance (SALP) evaluations for power reactors, and the licensee's prior enforcement history overall and in the area of concern, including escalated and non-escalated enforcement actions and any enforcement actions that the NRC exercised discretion and refrained from issuing in accordance with Section VII.B. Notwithstanding good prior performance, mitigation of the civil penalty based on this factor is not normally warranted where the current violation reflects a substantial decline in performance that has occurred over the time since the last NRC inspection. In addition, this factor should not be applied for those cases where the licensee has not been in existence long enough to establish a prior performance or inspection history. Similarly, mitigation based on this factor is not normally appropriate where the area of concern has not been previously inspected, unless overall performance is good.

(d) *Prior opportunity to identify.* The purpose of this factor is to encourage licensees to take effective action in response to opportunities to identify or prevent problems or violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% for cases where the licensee should have identified the violation sooner as a result of prior opportunities, such as (1) through normal surveillances, audits, or quality assurance (QA) activities; (2) through prior notice (i.e., specific NRC or industry

notification; or (3) through other reasonable indication of a potential problem or violation, such as observations of employees and contractors, and had failed to take effective corrective steps. Prior notification may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, consideration will be given to, among other things, the opportunities available to discover the violation, the ease of discovery, the similarity between the violation and the notification, the period of time between when the violation occurred and when the notification was issued, the action taken (or planned) by the licensee in response to the notification, and the level of management review that the notification received (or should have received). Escalation of the civil penalty based solely on prior notification is normally not warranted where the licensee appropriately reviewed the notification for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

(e) *Multiple occurrences.* The purpose of this factor is to reflect the added significance resulting from multiple occurrences of the violation. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% where multiple examples of a particular violation are identified during the inspection period. Escalation of the civil penalty based on this factor will normally be considered only when there are multiple examples of Severity Level I, II, or III violations with the same root causes. Alternatively, separate civil penalties may be imposed for each violation.

(f) *Duration.* The purpose of this factor is to recognize the added significance associated with those violations (or the impact of those violations) that continue

or remain uncorrected for more than one day. Therefore, whether or not a licensee is aware or clearly should have been aware of a violation, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% to reflect the added technical and/or regulatory significance resulting from the violation or the impact of it remaining uncorrected for more than one day. This factor should normally be applied in cases involving particularly safety significant violations or where a significant regulatory message is warranted. In lieu of escalating the civil penalty based on this factor, the NRC may impose daily civil penalties for violations that continue for more than one day. (See Section VII.A.3. "Daily Civil Penalties.")

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The civil penalty adjustment factors presented in paragraphs (a) through (f) are additive. However, in no instance will a civil penalty for any one violation exceed \$100,000 per day.

Notwithstanding the application of the civil penalty adjustment factors, a civil penalty will normally be proposed in an amount of at least 50% of the base value in Tables 1A and 1B for Severity Level I and II violations involving overexposures, release of radioactive material, or loss of radioactive material to emphasize to the licensee the seriousness with which the NRC views these events and the importance of conducting licensed activities in a manner to avoid these violations. In considering mitigation for these cases,

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normally the only adjustment factors that will be considered to lower a base civil penalty will be identification and corrective action factors. In addition, as provided in Section VII, "Exercise of Discretion," discretion may be exercised by either escalating or mitigating the amount of the civil penalty arrived at after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects the NRC's concern regarding the violation at issue and that it conveys the appropriate message to the licensee.

TABLE 1A—BASE CIVIL PENALTIES

	Plant operations construction, health physics and EP	Safeguards	Transportation	
			Greater than Type A quantity	Type A quantity or less
a. Power reactors	\$100,000	\$100,000	\$100,000	\$5,000
b. Test reactors	10,000	10,000	10,000	2,000
c. Research reactors and critical facilities	5,000	5,000	5,000	1,000
d. Fuel fabricators and industrial processors ¹	25,000	20,000	25,000	5,000
e. Mills and Uranium conversion facilities	10,000	—	5,000	2,000
f. Industrial users of materials ² , and contractors and vendors	10,000	—	5,000	2,000
g. Waste disposal licensees	10,000	—	5,000	2,000
h. Academic or medical institutions ³	5,000	—	2,500	1,000
i. Independent spent fuel and monitored retrievable storage installations	25,000	20,000	25,000	5,000
j. Other material licensees	1,000	—	2,500	1,000

¹ Includes irradiated fuel, high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.

² Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.

³ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.

⁴ This amount refers to Category 1 licensees (as defined in 10 CFR 73.2). Licensed fuel fabricators not authorized to possess Category 1 material have a base penalty amount of \$50,000.

⁵ Includes industrial radiographers, nuclear pharmacies, and other industrial users.

⁶ This applies to nonprofit institutions not otherwise categorized under sections "a" through "g" in this table and mobile nuclear services.

TABLE 1 B—BASE CIVIL PENALTIES

Severity Level	Base Civil Penalty Amount	
	(Percent of amount listed in Table 1A)	
I	100	
II	80	
III	50	
IV	15	

C. 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 may also be issued in lieu of, or in addition to, civil penalties, as appropriate for Severity Level I, II, or III violations. Orders may be issued as follows:

- (1) License Modification orders are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.
 - (2) Suspension Orders may be used:
 - (a) To remove a threat to the public health and safety, common defense and security, or the environment;
 - (b) To stop facility construction when:
 - (i) Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component; or
 - (ii) The licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;
 - (c) When the licensee has not responded adequately to other enforcement action;
 - (d) When the licensee interferes with the conduct of an inspection or investigation; or
 - (e) For any reason not mentioned above for which license revocation is legally authorized.
- Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to

comply with requirements where such failure is not willful and adequate corrective action has been taken.

- (3) Revocation Orders may be used:
 - (a) When a licensee is unable or unwilling to comply with NRC requirements;
 - (b) When a licensee refuses to correct a violation;
 - (c) When licensee does not respond to a Notice of Violation where a response was required;
 - (d) When a licensee refuses to pay an applicable fee under the Commission's regulations; or
 - (e) For any other reason for which revocation is authorized under section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).
 - (4) Cease and Desist Orders may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.
 - (5) Orders to unlicensed persons, including vendors and contractors, and employees of any of them, are used when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities.
- Unless a separate response is warranted pursuant to 10 CFR 2.201, a Notice of Violation need not be issued where an order is based on violations described in the order. The violations described in an order need not be categorized by severity level.
- Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the NRC believes a basis could reasonably exist

for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show why the order should not be issued in the proposed manner by way of a Demand for Information. (See 10 CFR 2.204)

D. Related Administrative Actions

In addition to the formal enforcement mechanisms of Notices of Violation, civil penalties, and orders, the NRC also uses administrative mechanisms, such as Notices of Deviation, Notices of Nonconformance, Confirmatory Action Letters, letters of reprimand, and Demands for Information to supplement its enforcement program. The NRC expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met.

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

(2) Notices of Nonconformance are written notices describing vendor's failures to meet commitments which have not been made legally binding requirements by NRC. An example is a commitment made in a procurement contract with a licensee as required by 10 CFR part 50, appendix B. Notices of Nonconformances request non-licensees to 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.

(3) Confirmatory Action Letters (CALs) are letters confirming a licensee's or vendor's agreement to take

certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(4) Letters of reprimand are letters addressed to individuals subject to Commission jurisdiction identifying a significant deficiency in their performance of licensed activities.

(5) Demands for information are demands for information from licensees or other persons for the purpose of enabling NRC to determine whether an order or other enforcement action should be issued.

VII. Exercise of Discretion

Notwithstanding the normal guidance contained in this policy, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions within the Commission's statutory authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violation at issue and conveys the appropriate message to the licensee.

A. Escalation of Enforcement Sanctions

The NRC considers violations categorized at Severity Level I, II, or III

to be of significant regulatory concern. If the application of the normal guidance in this policy does not provide an appropriate sanction, or if particularly serious violations occur, such as in cases involving willfulness, repeated poor performance in an area of concern, or serious breakdowns in management controls, the NRC may apply its full enforcement authority where the action is warranted. NRC action may include (1) escalating civil penalties, (2) issuing appropriate orders, and (3) assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$100,000 per violation, per day.

(1) *Civil penalties.* Notwithstanding the outcome of the normal civil penalty assessment process (i.e., base civil penalty adjusted based on application of the civil penalty adjustment factors addressed in Section VI.B), with the approval of the appropriate Deputy Executive Director and consultation with the EDO as warranted, the NRC may exercise discretion by either proposing a civil penalty where application of the factors would otherwise result in zero penalty or by further escalating the amount of the

adjusted civil penalty to ensure that the proposed civil penalty reflects the NRC's concern regarding the violation at issue and that it conveys the appropriate message to the licensee. In addition to the approval of the appropriate Deputy Executive Director, consultation with the Commission is required if the deviation in the amount of the civil penalty proposed under this discretion from the amount of the civil penalty assessed under the normal process is more than two times the base civil penalty shown in Tables 1A and 1B.

(2) *Orders.* The NRC will, where necessary, issue orders in conjunction with civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations. Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. Enforcement sanctions will normally escalate for recurring similar violations.

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TABLE 2—EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
	1st	2nd	3rd
I	a - c	a - b - c	b
II	b	2 - b - c	3 - b - c
III	b	a - c	3 - c

Notes

- a. Civil penalty
- b. Suspension of affected operations until the Office Director is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements or modification of the license, as appropriate
- c. Consider issuing an order for modification, suspension, or revocation of the license, as appropriate, through use of a Demand for Information
- d. Further action, as appropriate

(3) *Daily civil penalties.* In order to recognize the added technical safety significance or regulatory significance for those cases where a very strong message is warranted for a significant violation that continues for more than one day, the NRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of \$100,000 for each day the violation continues. The NRC may exercise this discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

B. Mitigation of Enforcement Sanctions

Because the NRC wants to encourage and support licensee initiative for self identification and correction of problems, the NRC may exercise discretion and refrain from issuing a civil penalty and/or issuing a Notice of Violation under certain circumstances. In addition, while the NRC may exercise this discretion for violations meeting the required criteria where the licensee failed to make a required report to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make a required report. The circumstances under which this discretion may be exercised are as follows:

(1) *Severity Level V Violations.* The NRC may refrain from issuing a Notice of Violation for a Severity Level V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(b) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(c) It was not a willful violation.

(2) *Licensee Identified Severity Level IV and V Violations.* The NRC may refrain from issuing a Notice of Violation for a Severity Level IV or V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was identified by the licensee, including as a result of a self-disclosing event;

(b) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(c) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(d) It was not a willful violation or if it was a willful violation:

(i) The information concerning the violation, if not required to be reported, was promptly provided to appropriate NRC personnel, such as a resident inspector or regional section or branch chief;

(ii) The violation involved the acts of a low level individual (and not a licensee official as defined in section IV.C);

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

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

(3) *Violations Identified During Extended Shutdowns or Work Stoppages.* The NRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after (i) the NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee (or a work stoppage at a construction site), or (ii) 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 official field notes for some material cases) and that it meets all of the following criteria:

(a) It was either licensee identified as a result of a comprehensive program for problem identification and correction that was developed in response to the shutdown or identified as a result of an employee allegation to the licensee; (if the NRC identifies the violation and all of the other criteria are met, the NRC should determine whether enforcement action is necessary to achieve remedial action, or if discretion may still be appropriate.)

(b) It is based upon activities of the licensee prior to the events leading to the shutdown;

(c) It would not be categorized at a severity level higher than Severity Level II;

(d) It was not willful; and

(e) The licensee's decision to restart the plant requires NRC concurrence.

(4) *Violations Involving Old Design Issues.* The NRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as in engineering, design, or installation, provided that the violation is documented in an inspection report (or official field notes for some material cases) that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee identified as a result of a licensee's voluntary formal initiative, such as a Safety System Functional Inspection, Design Reconstitution Program, or other program that has a defined scope and timetable and is being aggressively implemented;

(b) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

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(c) It was not likely to be identified (after the violation occurred) by routine licensee efforts such as normal surveillance or quality assurance (QA) activities.

In addition, the NRC may refrain from issuing a Notice of Violation for cases that meet the above criteria provided the violation was caused by conduct that is not reasonably linked to present performance (normally, violations that are at least three years old or violations occurring during plant construction) and there had not been prior notice so that the licensee should have reasonably identified the violation earlier. This exercise of discretion is to place a premium on licensees initiating efforts to identify and correct subtle violations that are not likely to be identified by routine efforts before degraded safety systems are called upon to work.

(5) Violations Identified Due to Previous Escalated Enforcement Action. The NRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after the NRC has taken escalated enforcement action for a Severity Level II or III violation, provided that the violation is documented in an inspection report (or official field notes for some material cases) that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee identified as part of the corrective action for the previous escalated enforcement action;

(b) It has the same or similar root cause as the violation for which escalated enforcement action was issued;

(c) It does not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation; and

(d) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification.

(6) Violations Involving Special Circumstances. Notwithstanding the outcome of the normal civil penalty assessment process (i.e., base civil penalty adjusted based on application of the civil penalty adjustment factors addressed in Section VI.B), as provided in Section III, "Responsibilities," the appropriate Deputy Executive Director may reduce or refrain from issuing a civil penalty or a Notice of Violation for a Severity Level II or III 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 safety significance of the violation, the overall

performance of the licensee, and other relevant circumstances, including any that may have changed since the violation, provided prior notice has been given the Commission. This discretion is expected to be exercised only where application of the normal guidance in the policy is unwarranted.

C. Exercise of Discretion for an Operating Facility

On occasion, circumstances may arise where a licensee's compliance with a Technical Specification (TS) Limiting Condition for Operation or with other license conditions would involve an unnecessary plant transient or performance of testing, inspection, or system realignment that is inappropriate with the specific plant conditions, or unnecessary delays in plant startup without a corresponding health and safety benefit. In these circumstances, the NRC staff may choose not to enforce the applicable TS or other license condition. This enforcement discretion will only be exercised if the NRC staff is clearly satisfied that the action is consistent with protecting the public health and safety. A licensee seeking the exercise of enforcement discretion must provide a written justification, or in circumstances where good cause is shown, oral justification followed as soon as possible by written justification, which documents the safety basis for the request and provides whatever other information the NRC staff deems necessary in making a decision on whether or not to exercise enforcement discretion.

The appropriate Regional Administrator, or his designee, may exercise discretion where the noncompliance is temporary and nonrecurring when an amendment is not practical. The Director, Office of Nuclear Reactor Regulation, or his designee, may exercise discretion if the expected noncompliance will occur during the brief period of time it requires the NRC staff to process an emergency or exigent license amendment under the provisions of 10 CFR 50.91(a)(5) or (6). The person exercising enforcement discretion will document the decision.

For an operating plant, this exercise of enforcement discretion is intended to minimize the potential safety consequences of unnecessary plant transients with the accompanying operational risks and impacts or to eliminate testing, inspection, or system realignment which is inappropriate for the particular plant conditions. For plants in a shutdown condition, exercising enforcement discretion is intended to reduce shutdown risk by, again, avoiding testing, inspection or system realignment which is inappropriate for the particular plant conditions, in that, it

does not provide a safety benefit or may, in fact, be detrimental to safety in the particular plant condition. Exercising enforcement discretion for plants attempting to startup is less likely than exercising it for an operating plant, as simply delaying startup does not usually leave the plant in a condition in which it could experience undesirable transients. In such cases, the Commission would expect that discretion would be exercised with respect to equipment or systems only when it has at least concluded that, notwithstanding the conditions of the license: (1) The equipment or system does not perform a safety function in the mode in which operation is to occur; (2) the safety function performed by the equipment or system is of only marginal safety benefit, provided remaining in the current mode increases the likelihood of an unnecessary plant transient; or (3) the TS or other license condition requires a test, inspection or system realignment that is inappropriate for the particular plant conditions, in that it does not provide a safety benefit, or may, in fact, be detrimental to safety in the particular plant condition.

The decision to exercise enforcement discretion does not change the fact that a violation will occur nor does it imply that enforcement discretion is being exercised for any violation that may have led to the violation at issue. In each case where the NRC staff has chosen to exercise enforcement discretion, enforcement action will normally be taken for the root causes, to the extent violations were involved, that led to the noncompliance for which enforcement discretion was used. The enforcement action is intended to emphasize that licensees should not rely on the NRC's authority to exercise enforcement discretion as a routine substitute for compliance or for requesting a license amendment.

Finally, it is expected that the NRC staff will exercise enforcement discretion in this area infrequently. Although a plant must shut down, refueling activities may be suspended, or plant startup may be delayed, absent the exercise of enforcement discretion, the NRC staff is under no obligation to take such a step merely because it has been requested. The decision to forego enforcement is discretionary. Where enforcement discretion is to be exercised, it is to be exercised only if the NRC staff is clearly satisfied that such action is warranted from a health and safety perspective.

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VIII. Enforcement Actions Involving Individuals

Enforcement actions involving individuals, including licensed operators, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action involving an individual will normally be taken only when the NRC is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew, or should have known, the required actions; and knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV, or V violations will be handled by citing only the facility licensee.

More serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as against the facility licensee. Action against the individual, however, will not be taken if the improper action by the individual was caused by management failures. The following examples of situations illustrate this concept:

- Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee.

- Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.

- Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.

- Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

- Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Listed below are examples of situations which could result in enforcement actions involving individuals, licensed or unlicensed. If the actions described in these examples are taken by a licensed operator or taken deliberately by an unlicensed individual, enforcement action may be taken directly against the individual. However, violations involving willful conduct not amounting to deliberate action by an unlicensed individual in these situations may result in enforcement action against a licensee that may impact an individual. The situations include, but are not limited to, violations that involve:

- Willfully causing a licensee to be in violation of NRC requirements.

- Willfully taking action that would have caused a licensee to be in violation of NRC requirements but the action did not do so because it was detected and corrective action was taken.

- Recognizing a violation of procedural requirements and willfully not taking corrective action.

- Willfully defeating alarms which have safety significance.

- Unauthorized abandoning of reactor controls.

- Dereliction of duty.

- Falsifying records required by NRC regulations or by the facility license.

- Willfully providing, or causing a licensee to provide, an NRC inspector or investigator with inaccurate or incomplete information on a matter material to the NRC.

- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization.

- Submitting false information and as a result gaining unescorted access to a nuclear power plant.

- Willfully providing false data to a licensee by a contractor or other person who provides test or other services, when the data affects the licensee's compliance with 10 CFR part 50, appendix B, or other regulatory requirement.

- Willfully providing false certification that components meet the requirements of their intended use, such as ASME Code.

- Willfully supplying, by vendors of equipment for transportation of radioactive material, casks that do not comply with their certificates of compliance.

- Willfully performing unauthorized bypassing of required reactor or other facility safety systems.

- Willfully taking actions that violate Technical Specification Limiting Conditions for Operation or other license conditions (enforcement action for a willful violation will not be taken if that violation is the result of action taken following the NRC's decision to forego enforcement of the Technical Specification or other license condition or if the operator meets the requirements of 10 CFR 50.54 (x), i.e., unless the operator acted unreasonably considering all the relevant circumstances surrounding the emergency)

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In deciding whether to issue an enforcement action to an unlicensed person rather than to the licensee, the NRC recognizes that judgments will have to be made on a case by case basis. In making these decisions, the NRC will consider factors such as the following:

1. The level of the individual within the organization.
2. The individual's training and experience as well as knowledge of the potential consequences of the wrongdoing.
3. The safety consequences of the misconduct.
4. The benefit to the wrongdoer, e.g., personal or corporate gain.

5. The degree of supervision of the individual, i.e., how closely is the individual monitored or audited, and the likelihood of detection (such as a radiographer working independently in the field as contrasted with a team activity at a power plant).

6. The employer's response, e.g., disciplinary action taken.

7. The attitude of the wrongdoer, e.g., admission of wrongdoing, acceptance of responsibility.

8. The degree of management responsibility or culpability.

9. Who identified the misconduct.

Any proposed enforcement action involving individuals must be issued with the concurrence of the appropriate Deputy Executive Director. The Commission will be consulted prior to issuing a civil penalty or order to an unlicensed individual or a civil penalty to a licensed reactor operator. Prior notice will be given to the Commission on Notices of Violation without civil penalties that are issued to unlicensed individuals and enforcement actions taken against other unlicensed persons, such as corporations or partnerships. The particular sanction to be used should be determined on a case-by-case basis.⁴

Examples of sanctions that may be appropriate against individuals are:

- Issuance of a letter of reprimand.
- Issuance of a Notice of Violation, and
- Issuance of Orders.

Orders to NRC-licensed reactor operators may involve suspension for a specified period, modification, or revocation of their individual licenses. Orders to unlicensed individuals might include provisions that would:

- Prohibit involvement in NRC licensed activities for a specified period of time (normally the period of suspension would not exceed five years) or until certain conditions are satisfied, e.g., completing specified training or meeting certain qualifications.
- Require notification to the NRC before resuming work in licensed activities.
- Require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order.

In the case of a licensed operator's failure to meet applicable fitness-for-duty requirements (10 CFR 55.53(j)), the NRC may issue a Notice of Violation or a civil penalty to the Part 55 licensee, or an order to suspend, modify, or revoke the Part 55 license. These actions may be taken the first time a licensed operator fails a drug or alcohol test, that is, receives a confirmed positive test that exceeds the cutoff levels of 10 CFR part 26 or the facility licensee's cutoff levels, if lower. However, normally only a Notice of Violation will be issued for the first confirmed positive test in the absence of aggravating circumstances such as errors in the performance of licensed duties or evidence of prolonged use. In addition, the NRC intends to issue an order to suspend the Part 55 license for up to three years the second time a licensed operator exceeds those cutoff levels. In the event there are less than three years remaining in the term of the individual's license, the NRC may consider not renewing the individual's license or not issuing a new license after the three year period is completed. The NRC intends to issue an order to revoke the Part 55 license the third time a licensed operator exceeds those cutoff levels. A licensed operator or applicant who refuses to participate in the drug and alcohol testing programs established by the facility licensee or

⁴ Except for individuals subject to civil penalties under section 206 of the Energy Reorganization Act of 1974, as amended, NRC will not normally impose a civil penalty against an individual. However, section 234 of the Atomic Energy Act (AEA) gives the Commission authority to impose civil penalties on "any person." "Person" is broadly defined in Section 11a of the AEA to include individuals, a variety of organizations, and any representatives or agents. This gives the Commission authority to impose civil penalties on employees of licensees or on separate entities when a violation of a requirement directly imposed on them is committed.

who is involved in the sale, use, or possession of an illegal drug is also subject to license suspension, revocation, or denial.

In addition, the NRC may take enforcement action against a licensee that may impact an individual, where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted. The NRC may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence, fitness for duty, or other matters that may not necessarily be a violation of specific Commission requirements.

In the case of an unlicensed person, whether a firm or an individual, an order modifying the facility license may be issued to require (1) the removal of the person from all licensed activities for a specified period of time or indefinitely, (2) prior notice to the NRC before utilizing the person in licensed activities, or (3) the licensee to provide notice of the issuance of such an order to other persons involved in licensed activities making reference inquiries. In addition, orders to employers might require retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities.

IX. Inaccurate and Incomplete Information

A violation of the regulations involving submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The 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 normally will be categorized based on the guidance herein, in Section IV "Severity of Violations," and in Supplement VII.

The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given

to such factors as (1) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience, (2) the opportunity and time available prior to the communication to assure 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 which was wrong or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee thereby permitting an opportunity to correct the oral information, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue a Notice of Violation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the NRC or the licensee 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 prior to reliance by the NRC, or before the NRC raised 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 it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new

information became available or the advancement in technology was made, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee 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 later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error, if information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions is not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

X. Enforcement Action Against Non-Licensees

The Commission's enforcement policy is also applicable to non-licensees, including employees of licensees, to contractors and subcontractors, and to employees of contractors and subcontractors, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation. The prohibitions and sanctions for any of these persons who engage in deliberate misconduct or submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct, e.g., 10 CFR 30.10 and 50.5.

Vendors of products or services provided for use in nuclear activities are subject to certain requirements designed to ensure that the products or services supplied that could affect safety are of high quality. Through procurement contracts with reactor licensees, vendors may be required to have quality assurance programs that meet applicable requirements including 10 CFR part 50, appendix B, and 10 CFR part 71, subpart H. Vendors supplying products or services to reactor materials, and 10 CFR part 71 licensees are subject to the requirements of 10 CFR part 21 regarding reporting of defects in basic components.

When inspections determine that violations of NRC requirements have occurred, or that vendors have failed to fulfill contractual commitments (e.g., 10 CFR part 50, appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken. Notices of Violation and civil penalties will be used, as appropriate, for licensee failures to ensure that their vendors have programs that meet applicable requirements. Notices of Violation will be issued for vendors that violate 10 CFR part 21. Civil penalties will be imposed against individual directors or responsible officers of a vendor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(b)(1). Notices of Nonconformance will be used for vendors which fail to meet commitments related to NRC activities.

XI. Referrals to the Department of Justice

Alleged or suspected criminal violations of the Atomic Energy Act (and of other relevant Federal laws) are referred to the Department of Justice (DOJ) for investigation. Referral to the DOJ does not preclude the NRC from taking other enforcement action under this policy. However, enforcement actions will be coordinated with the DOJ in accordance with the Memorandum of Understanding between the NRC and the DOJ, 53 FR 50317 (December 14, 1988).

XII. Public Disclosure of Enforcement Actions

Enforcement actions and licensee responses, in accordance with 10 CFR 2.790, are publicly available for inspection. In addition, press releases are generally issued for orders and civil penalties and are issued at the same time the order or proposed imposition of the civil penalty is issued. In addition, press releases are usually issued when a proposed civil penalty is withdrawn or substantially mitigated by some amount. Press releases are not normally issued for Notices of Violation that are not accompanied by orders or proposed civil penalties.

XIII. Reopening Closed Enforcement Actions

If significant new information is received or obtained by NRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the appropriate Deputy Executive Director.

Supplement I—Reactor Operations

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of reactor operations.

A. Severity Level I—Violations involving for example:

1. A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications being exceeded;

2. A system⁹ designed to prevent or mitigate a serious safety event not being able to perform its intended safety function¹⁰ when actually called upon to work;

3. An accidental criticality; or

4. A licensed operator at the controls of a nuclear reactor, or a senior operator directing licensed activities, involved in procedural errors which result in, or exacerbate the consequences of, an alert or higher level emergency and who, as a result of subsequent testing, receives a confirmed positive test result for drugs or alcohol.

B. Severity Level II—Violations involving for example:

1. A system designed to prevent or mitigate serious safety events not being able to perform its intended safety function;

2. A licensed operator involved in the use, sale, or possession of illegal drugs or the consumption of alcoholic beverages, within the protected area; or

3. A licensed operator at the control of a nuclear reactor, or a senior operator directing licensed activities, involved in procedural errors and who, as a result of subsequent testing, receives a confirmed positive test result for drugs or alcohol.

C. Severity Level III—Violations involving for example:

1. A significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In a pressurized water reactor, in the applicable modes, having one high-

⁹ The term "system" as used in these supplements, includes administrative and managerial control systems, as well as physical systems.

¹⁰ "Intended 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.

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pressure safety injection pump inoperable for a period in excess of that allowed by the action statement; or

(b) In a boiling water reactor, one primary containment isolation valve inoperable for a period in excess of that allowed by the action statement.

2. A system designed to prevent or mitigate a serious safety event:

(a) Not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available; materials or components not environmentally qualified); or

(b) Being degraded to the extent that a detailed evaluation would be required to determine its operability (e.g., component parameters outside approved limits such as pump flow rates, heat exchanger transfer characteristics, safety valve lift setpoints, or valve stroke times);

3. Inattentiveness to duty on the part of licensed personnel;

4. Changes in reactor parameters that cause unanticipated reductions in margins of safety;

5. A significant failure to meet the requirements of 10 CFR 50.59, including a failure such that a required license amendment was not sought;

6. A licensee failure to conduct adequate oversight of vendors resulting in the use of products or services that are of defective or indeterminate quality and that have safety significance;

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities; or

8. A licensed operator's confirmed positive test for drugs or alcohol that does not result in a Severity Level I or II violation.

9. Equipment failures caused by inadequate or improper maintenance that substantially complicates recovery from a plant transient.

D. Severity Level IV—Violations involving for example:

1. A less significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In a pressurized water reactor, a 5% deficiency in the required volume of the condensate storage tank; or

(b) In a boiling water reactor, one subsystem of the two independent MSIV leakage control subsystems inoperable;

2. A failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation;

3. A failure to meet regulatory requirements that have more than minor safety or environmental significance; or

4. A failure to make a required Licensee Event Report.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement II—Part 50 Facility Construction

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of part 50 facility construction.

A. Severity Level I—Violations involving structures or systems that are completed¹¹ in such a manner that they would not have satisfied their intended safety related purpose.

B. Severity Level II—Violations involving for example:

1. A breakdown in the Quality Assurance (QA) program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). These deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

C. Severity Level III—Violations involving for example:

1. A deficiency in a licensee QA program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). This significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. A failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

¹¹ The term "completed" as used in this supplement means completion of construction including review and acceptance by the construction QA organization.

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3. A failure to make a required 10 CFR 50.55(e) report.

D. Severity Level IV—Violations involving failure to meet regulatory requirements including one or more Quality Assurance Criterion not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement III—Safeguards

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of safeguards.

A. Severity Level I—Violations involving for example:

1. An act of radiological sabotage in which the security system did not function as required and, as a result of the failure, there was a significant event, such as:

(a) A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications, was exceeded;

(b) A system designed to prevent or mitigate a serious safety event was not able to perform its intended safety function when actually called upon to work; or

(c) An accidental criticality occurred;

2. The theft, loss, or diversion of a formula quantity¹² of special nuclear material (SNM); or

3. Actual unauthorized production of a formula quantity of SNM.

B. Severity Level II—Violations involving for example:

1. The entry of an unauthorized individual¹³ who represents a threat into a vital area¹⁴ from outside the protected area; or

2. The theft, loss or diversion of SNM of moderate strategic significance¹⁵ in which the security system did not function as required; or

3. Actual unauthorized production of SNM.

¹² See 10 CFR 73.2 for the definition of "formula quantity."

¹³ The term "unauthorized individual" as used in this supplement means someone who was not authorized for entrance into the area in question, or not authorized to enter in the manner entered.

¹⁴ The phrase "vital area" as used in this supplement includes vital areas and material access areas.

¹⁵ See 10 CFR 73.2 for the definition of "special nuclear material of moderate strategic significance."

C. Severity Level III—Violations involving for example:

1. A failure or inability to control access through established systems or procedures, such that an unauthorized individual (i.e., not authorized unescorted access to protected area) could easily gain undetected access¹⁶ into a vital area from outside the protected area;

2. A failure to conduct any search at the access control point or conducting an inadequate search that resulted in the introduction to the protected area of firearms, explosives, or incendiary devices and reasonable facsimiles thereof that could significantly assist radiological sabotage or theft of strategic SNM;

3. A failure, degradation, or other deficiency of the protected area intrusion detection or alarm assessment systems such that an unauthorized individual who represents a threat could predictably circumvent the system or defeat a specific zone with a high degree of confidence without insider knowledge, or other significant degradation of overall system capability;

4. A significant failure of the safeguards systems designed or used to prevent or detect the theft, loss, or diversion of strategic SNM;

5. A failure to protect or control classified or safeguards information considered to be significant while the information is outside the protected area and accessible to those not authorized access to the protected area;

6. A significant failure to respond to an event either in sufficient time to provide protection to vital equipment or strategic SNM, or with an adequate response force;

7. A failure to perform an appropriate evaluation or background investigation so that information relevant to the access determination was not obtained or considered and as a result a person, who would likely not have been granted access by the licensee, if the required investigation or evaluation had been performed, was granted access; or

8. A breakdown in the security program involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

1. A failure or inability to control access such that an unauthorized individual (i.e., authorized to protected area but not to vital area) could easily gain undetected access into a vital area from inside the protected area or into a controlled access area;

2. A failure to respond to a suspected event in either a timely manner or with an adequate response force;

3. A failure to implement 10 CFR parts 25 and 95 with respect to the information addressed under section 142 of the Act, and the NRC approved security plan relevant to those parts;

4. A failure to make, maintain, or provide log entries in accordance with 10 CFR 73.71 (c) and (d), where the omitted information (i) is not otherwise available in easily retrievable records, and (ii) significantly contributes to the ability of either the NRC or the licensee to identify a programmatic breakdown;

5. A failure to conduct a proper search at the access control point;

6. A failure to properly secure or protect classified or safeguards information inside the protected area which could assist an individual in an act of radiological sabotage or theft of strategic SNM where the information was not removed from the protected area;

7. A failure to control access such that an opportunity exists that could allow unauthorized and undetected access into the protected area but which was neither easily or likely to be exploitable;

8. A failure to conduct an adequate search at the exit from a material access area;

9. A theft or loss of SNM of low strategic significance that was not detected within the time period specified in the security plan, other relevant document, or regulation; or

10. Other violations that have more than minor safeguards significance.

E. Severity Level V—Violations that have minor safeguards significance.

¹⁶ In determining whether access can be easily gained, factors such as predictability, identifiability, and ease of passage should be considered.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS •••

Supplement IV—Health Physics (10 CFR Part 20)

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of health physics. 10 CFR part 20¹⁷. Examples A through E are provided to accompany §§ 20.1–20.601. Examples F through J are provided to accompany §§ 20.1001–20.2401.

Sections 20.1–20.601

A. Severity Level I—Violations involving for example:

1. A single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rads to the skin of the whole body, or 375 rads to the feet, ankles, hands, or forearms;
2. An annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
3. A release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106¹⁸;
4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or
5. An exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity Level II—Violations involving for example:

1. A single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;
2. An annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
3. A release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;
4. A failure to make an immediate notification as required by 10 CFR 20.403 (a)(1) and (a)(2);
5. A disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303; or
6. An exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity Level III—Violations involving for example:

1. A single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;
2. A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;
3. A failure to make a 24-hour notification as required by 10 CFR 20.403(b), or an immediate notification required by 10 CFR 20.402(a);
4. A substantial potential for an exposure or release in excess of 10 CFR part 20 whether or not such exposure or release occurs;
5. A release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;
6. An improper disposal of licensed material not covered in Severity Levels I or II;
7. An exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103;
8. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for significant exposure to members of the public, or that reflects a programmatic (rather than isolated) weakness in the radiation control program;
9. A cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
10. Conduct of licensee activities by a technically unqualified person;
11. A significant failure to control licensed material; or
12. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

1. Exposures in excess of the limits of 10 CFR 20.101 not constituting Severity Level I, II, or III violations;
2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;
3. A failure to make a 30-day notification required by 10 CFR 20.405;
4. A failure to make a follow-up written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or
5. Any other matter that has more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Sections 20.1001–20.2401

F. Severity Level I—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
 2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;
 3. A radiation exposure during any year of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems 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 1.0 rem total effective dose equivalent;
 5. A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public as described in 10 CFR 20.1302(b)(2)(i); or
 6. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of 10 CFR 20.2003.
- G. Severity Level II—Violations involving for example:*
1. A radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
 2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 1.0 rem total effective dose equivalent;

¹⁷ Personnel overexposures and associated violations incurred during a life-saving or other emergency response effort will be treated on a case-by-case basis.

¹⁸ The reference to the limits of 10 CFR 20.106 as used in this supplement (Items A, B, C, and E) does not apply to the EPA generally applicable environmental radiation standards mentioned in § 20.106(g).

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS •••

3. A radiation exposure during any year of a minor in excess of 1 rem total effective dose equivalent: 3.0 rems to the lens of the eye, or 10 rems 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 0.5 rem total effective dose equivalent;

5. A release of radioactive material to an unrestricted area at concentrations in excess of 10 times the limits for members of the public as described in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

6. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.2003; or

7. A failure to make an immediate notification as required by 10 CFR 20.2202 (a)(1) or (a)(2).

H. Severity Level III—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 0.5 rem total effective dose equivalent (except when doses are in accordance with the provisions of § 20.1208(d));

3. A radiation exposure during any year of a minor in excess of 0.5 rem total effective dose equivalent: 1.5 rems to the lens of the eye, or 5 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. A worker exposure above regulatory limits when such exposure reflects a programmatic (rather than an isolated) weakness in the radiation control program;

5. An annual exposure of a member of the public in excess of 0.1 rem total effective dose equivalent (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

6. A release of radioactive material to an unrestricted area at concentrations in excess of two times the effluent concentration limits referenced in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

7. 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);

8. A substantial potential for exposures or releases in excess of the applicable limits in 10 CFR part 20 §§ 20.1001–20.2401 whether or not an exposure or release occurs;

9. Disposal of licensed material not covered in Severity Levels I or II;

10. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public, or that reflects a programmatic (rather than an isolated) weakness in the radiation control program;

11. Conduct of licensee activities by a technically unqualified person;

12. A significant failure to control licensed material; or

13. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

I. Severity Level IV—Violations involving for example:

1. Exposures in excess of the limits of 10 CFR 20.1201, 20.1207, or 20.1208 not constituting Severity Level I, II, or III violations;

2. A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public as referenced in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

3. A radiation dose rate in an unrestricted or controlled area in excess of 0.002 rem in any 1 hour (2 millirem/hour) or 50 millirems in a year;

4. Failure to maintain and implement radiation programs to keep radiation exposures as low as is reasonably achievable;

5. Doses to a member of the public in excess of any EPA generally applicable environmental radiation standards, such as 40 CFR part 190;

6. A failure to make the 30-day notification required by 10 CFR 20.2201(a)(1)(ii) or 20.2203(a);

7. A failure to make a timely written report as required by 10 CFR 20.2201(b), 20.2204, or 20.2206; or

8. Any other matter that has more than a minor safety, health, or environmental significance.

J. Severity Level V—Violations that are of a minor safety, health, or environmental significance.

Supplement V—Transportation

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of NRC transportation requirements¹⁹.

A. Severity Level I—Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that the material caused a radiation exposure to a member of the public and there was clear potential for the public to receive more than .1 rem to the whole body;

2. Surface contamination in excess of 50 times the NRC limit; or

3. External radiation levels in excess of 10 times the NRC limit.

B. Severity Level II—Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that there was a clear potential for the member of the public to receive more than .1 rem to the whole body;

2. Surface contamination in excess of 10, but not more than 50 times the NRC limit;

3. External radiation levels in excess of five, but not more than 10 times the NRC limit; or

¹⁹ Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS ...

4. A failure to make required initial notifications associated with Severity Level I or II violations.

C. *Severity Level III*—Violations involving for example:

1. Surface contamination in excess of five but not more than 10 times the NRC limit;

2. External radiation in excess of one but not more than five times the NRC limit;

3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in 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; or

(c) A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material;

4. A failure to make required initial notification associated with Severity Level III violations; or

5. A breakdown in the licensee's program for the transportation of licensed material involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. *Severity Level IV*—Violations involving for example:

1. A breach of package integrity without external radiation levels exceeding the NRC limit or without contamination levels exceeding five times the NRC limits;

2. Surface contamination in excess of but not more than five times the NRC limit;

3. A failure to register as an authorized user of an NRC-Certified Transport package;

4. A noncompliance with shipping papers, marking, labeling, placarding, packaging or loading not amounting to a Severity Level I, II, or III violation;

5. A failure to demonstrate that packages for special form radioactive material meets applicable regulatory requirements;

6. A failure to demonstrate that packages meet DOT Specifications for 7A Type A packages; or

7. Other violations that have more than minor safety or environmental significance.

E. *Severity Level V*—Violations that have minor safety or environmental significance.

Supplement VI—Fuel Cycle and Materials Operations

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations.

A. *Severity Level I*—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;

2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function;

3. A nuclear criticality accident; or

4. A failure to follow the procedures of the quality management program, required by § 35.32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient.

B. *Severity Level II*—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license;

2. A system designed to prevent or mitigate a serious safety event being inoperable; or

3. A substantial programmatic failure in the implementation of the quality management program required by 10 CFR 35.32 that results in a misadministration.

C. *Severity Level III*—Violations involving for example:

1. A failure to control access to licensed materials for radiation purposes as specified by NRC requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified person;

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license;

6. Substantial failure to implement the quality management program as required by § 35.32 that does not result in a misadministration; failure to report a misadministration; or programmatic weakness in the implementation of the quality management program that results in a misadministration.

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities;

8. A failure, during radiographic operations, to have present or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by 10 CFR part 34;

9. A failure to submit an NRC Form 241 in accordance with the requirements in § 150.20 of 10 CFR part 150; or

10. A failure to receive required NRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance.

D. *Severity Level IV*—Violations involving for example:

1. A failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety or environmental significance; or

3. Failure to follow the quality management program, including procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by § 35.32; or

4. A failure to keep the records required by §§ 35.32 or 35.33.

E. *Severity Level V*—Violations that have minor safety or environmental significance.

57 FR 5791

57 FR 5791

58 FR 17321

57 FR 5791

58 PR 17321

57 FR 5791

58 FR 17321

57 FR 5791

Supplement VII—Miscellaneous Matters

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations involving miscellaneous matters.

A. Severity Level I—Violations involving for example:

1. Inaccurate or incomplete information²⁰ that is provided to the NRC (a) deliberately with the knowledge of a licensee official that the information is incomplete or inaccurate, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety.
2. Incomplete or inaccurate information that the NRC requires be kept by a licensee that is (a) incomplete or inaccurate because of falsification by or with the knowledge of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations.
3. Information that the licensee has identified as having significant implications for public health and safety or the common defense and security ("significant information identified by a licensee") and is deliberately withheld from the Commission.
4. Action by senior corporate management in violation of 10 CFR 50.7 or similar regulations against an employee;
5. A knowing and intentional failure to provide the notice required by 10 CFR part 21, or
6. A failure to substantially implement the required fitness-for-duty program.²¹

²⁰ In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference should also be made to the guidance in Section IX, "Inaccurate and Incomplete Information," and to the definition of "licensee official" contained in Section IV.C.

²¹ The example for violations for fitness-for-duty relate to violations of 10 CFR part 26.

B. Severity Level II—Violations involving for example:

1. Inaccurate or incomplete information that is provided to the NRC (a) by a licensee official because of careless disregard for the completeness or accuracy of the information, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
2. Incomplete or inaccurate information that the NRC requires be kept by a licensee which is (a) incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
3. "Significant information identified by a licensee" and not provided to the Commission because of careless disregard on the part of a licensee official;
4. An action by plant management above first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee;
5. A failure to provide the notice required by 10 CFR part 21;
6. A failure to remove an individual from unescorted access who has been involved in the sale, use, or possession of illegal drugs within the protected area or take action for on duty misuse of alcohol, prescription drugs, or over-the-counter drugs;
7. A failure to take reasonable action when observed behavior within the protected area or credible information concerning activities within the protected area indicates possible unfitness for duty based on drug or alcohol use; or
8. A deliberate failure of the licensee's Employee Assistance Program (EAP) to notify licensee's management when EAP's staff is aware that an individual's condition may adversely affect safety related activities.

C. Severity Level III—Violations involving for example:

1. Incomplete or inaccurate information that is provided to the NRC (a) because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
2. Incomplete or inaccurate information that the NRC requires be kept by a licensee that is (a) incomplete or inaccurate because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
3. A failure to provide "significant information identified by a licensee" to the Commission and not amounting to a Severity Level I or II violation;
4. An action by first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee;
5. An inadequate review or failure to review such that, if an appropriate review had been made as required, a 10 CFR part 21 report would have been made;
6. A failure to complete a suitable inquiry on the basis of 10 CFR part 26, keep records concerning the denial of access, or respond to inquiries concerning denials of access so that, as a result of the failure, a person previously denied access for fitness-for-duty reasons was improperly granted access;
7. A failure to take the required action for a person confirmed to have been tested positive for illegal drug use or take action for onsite alcohol use; not amounting to a Severity Level II violation;
8. A failure to assure, as required, that contractors or vendors have an effective fitness-for-duty program; or
9. A breakdown in the fitness-for-duty program involving a number of violations of the basic elements of the fitness-for-duty program that collectively reflect a significant lack of attention or carelessness towards meeting the objectives of 10 CFR 26.10.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS ...

D. Severity Level IV—Violations involving for example:

1. Incomplete or inaccurate information of more than minor significance that is provided to the NRC but not amounting to a Severity Level I, II, or III violation;

2. Information that the NRC requires be kept by a licensee and that is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation;

3. An inadequate review or failure to review under 10 CFR part 21 or other procedural violations associated with 10 CFR part 21 with more than minor safety significance;

4. Isolated failures to meet basic elements of the fitness-for-duty program not involving a Severity Level I, II, or III violation; or

5. A failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.73.

E. Severity Level V—Violations involving for example:

1. Incomplete or inaccurate information that is provided to the Commission and the incompleteness or inaccuracy is of minor significance;

2. Information that the NRC requires be kept by a licensee that is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance;

3. Minor procedural requirements of 10 CFR part 21; or

4. Minor violations of fitness-for-duty requirements.

Supplement VIII—Emergency Preparedness

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of emergency preparedness. It should be noted that citations are not normally made for violations involving emergency preparedness occurring during emergency exercises. However, where exercises reveal (i) training, procedural, or repetitive failures for which corrective actions have not been taken, (ii) an overall concern regarding the licensee's ability to implement its plan in a manner that adequately protects public health and safety, or (iii) poor self critiques of the licensee's exercises, enforcement action may be appropriate.

A. Severity Level I—Violations involving for example:

In a general emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff.)

B. Severity Level II—Violations involving for example:

In a site emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

2. A licensee failure to meet or implement one emergency planning standard involving assessment or notification; or

C. Severity Level III—Violations involving for example:

In an alert, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);

2. A licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

A licensee failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.

E. Severity Level V—Violations that have minor safety or environmental significance.

bcc:
 DMB - Original (IE-07)
 LJCallan
 SJCollins
 RAScarano
 DWeiss, OC/LFDCB (T-9E10)
 WLFisher
 CLCain
 FAWenslawski
 MRShaffer
 NMIB
 MIS System
 RIV Files (2)
 RWis, AC
 GFSanborn, OE
 JLieberman, EO (7 H5)

RIV:NMIB	AC:NMIB <i>JJK</i>	DD:DRSS	D:DRSS	
MRShaffer*	CLCain <i>JJK</i>	RAScarano	SJCollins	
1 / 94	6/3/94	1 / 94	6/3/94	

*previously concurred



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN 6 1994

Docket: 030-32223
License: 11-27398-01MD
EA: 94-096

Nuclear Pharmacy of Idaho, Inc.
ATTN: Mr. Ned Gregorio
6053 Corporal Lane
Boise, Idaho 83702

SUBJECT: NRC INSPECTION REPORT 030-32223/94-02

This refers to the special, unannounced inspection conducted by Mr. Mark R. Shaffer of this office on May 16-17, 1994. The inspection included a review of activities authorized by Byproduct Materials License 11-27398-01MD. At the conclusion of the inspection, the findings were discussed with members of your staff. The enclosed NRC Inspection Report 030-32223/94-02 documents this inspection.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C. This violation related to airborne radioiodine effluent exceeding the maximum permissible concentration (MPC) prescribed in 10 CFR part 20 for the calendar year 1993. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

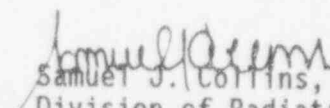
An enforcement conference to discuss this apparent violation has been scheduled for 9:00 a.m. (CDT) on July 1, 1994. The decision to hold an enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violation, its cause and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for you to present your proposed corrective action.

In particular we expect you to address why you took no corrective action to mitigate airborne emissions even though your air sample data indicated that the MPC was regularly exceeded. In addition, this is an opportunity for you to provide any information concerning your perspectives on 1) the severity of the violation, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the apparent violation is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Should you have any questions concerning this letter, please contact the Mr. Charles Cain of my staff at (817) 860-8186.

Sincerely,


Samuel J. Collins, Director
Division of Radiation Safety
and Safeguards

Enclosures:

1. Appendix A - NRC Inspection Report
030-32223/94-02
2. Appendix B - Proposed Enforcement
Conference Agenda
3. Copy of the NRC Enforcement Policy

cc:

Idaho Radiation Control Program Director

Consolidated Property Management
ATTN: Jerry Jansen, Property Manager
P.O. Box 2666
Boise, Idaho 83701

bcc:
DMB - Original (IE-07)
LJCallan
SJCcollins
RAScarano
DWeiss, OC/LFDCB (T-9E10)
WLFisher
CLCain
FAWenslawski
MRShaffer
NMIB
MIS System
RIV Files (2)
Rwise, AC
GFSanborn, OE
JLieberman, EO (7 H5)

RIV:NMIB	AC:NMIB <i>JH</i>	DD:DRSS	D:DRSS	
MRShaffer*	CLCain <i>JH</i>	RAScarano	SJCcollins	
1 / 94	6/3/94	1 / 94	6/3/94	

*previously concurred

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-32223/94-02

License: 11-27398-01MD

Licensee: Nuclear Pharmacy of Idaho, Inc.
6053 Corporal Lane
Boise, Idaho 83702

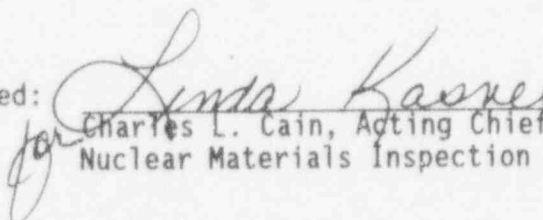
Facility Name: Nuclear Pharmacy of Idaho, Inc.

Inspection At: Boise, Idaho

Inspection Conducted: May 16-17, 1994

Inspector: Mark R. Shaffer, Radiation Specialist
Nuclear Materials Inspection Branch

Approved:


for Charles L. Cain, Acting Chief
Nuclear Materials Inspection Branch

6/3/94
Date

Inspection Summary

Areas Inspected: Special, unannounced inspection of licensed activities involving the use of byproduct material for the production, preparation, and distribution of radiopharmaceuticals.

The inspection was limited to a review of radiation levels present in unrestricted areas surrounding the licensee's facility and an evaluation of iodine-131 air effluent concentrations released by the licensee during calendar year 1993.

Results:

- Within the scope of this inspection, one apparent violation was identified. This violation relates to the failure of the licensee to maintain airborne effluent concentrations in unrestricted areas below the limits established in Table 2 of Appendix B to 10 CFR Part 20 as averaged over a year (Section 2).

Summary of Inspection Findings:

- Failure to comply with 10 CFR 20.106(a) which requires that airborne effluent concentrations of iodine-131 be maintained below the limits established in Table 2 of Appendix B to 10 CFR Part 20 as averaged over a year (Section 2).

Attachment:

- Persons Contacted and Exit Meeting

DETAILS

1 PROGRAM OVERVIEW (87100)

The licensee operates a nuclear pharmacy which prepares and distributes radiopharmaceuticals to medical licensees (hospitals and physicians). The NRC license for these operations was issued in September 1991. Licensed activities have been performed under the supervision of one authorized user who is also the licensee's Radiation Safety Officer (RSO). The majority of activity involved (1) the production of technetium-99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals and (2) the compounding and dispensing of iodine-131 therapy capsules.

Radiopharmaceutical distribution records revealed that the licensee prepared 50-60 unit doses each day. Approximately two iodine-131 therapy capsules were compounded per week, and the licensee received and processed approximately 8,700 millicuries of iodine-131 during calendar year 1993.

2 RADIATION SURVEYS, RECORDS, AND INDEPENDENT MEASUREMENTS (87100, 83822)

The licensee is required to perform surveys for effluent concentrations, removable contamination, and ambient radiation dose rates at intervals prescribed under the license and by NRC regulations.

2.1 Radiation Dose Rates

As a result of an NRC inspection conducted on February 3-4, 1994, a Notice of Violation (Notice) was issued to the licensee on April 4, 1994, regarding the failure to adequately evaluate radiation levels in unrestricted areas. During this inspection, NRC identified that the licensee had not measured the dose rates in areas immediately adjacent to the licensee's facility to demonstrate compliance with dose limits to individuals of the public. These areas consisted of offices where other businesses were located. (It should be noted that these unrestricted area offices were not residential quarters; therefore, due to occupancy times, doses received by members of the public could be reduced by an occupancy factor.)

In response to this Notice, the licensee performed radiation dose rate surveys within the neighboring offices (Building Nos. 6051 and 6055) on May 6, 1994. Records of these surveys indicated a maximum dose rate in adjacent offices to be 0.12 milliroentgens per hour (mR/hr) at the surface of the wall.

Additionally, at the request of the tenants occupying Building No. 6055, a representative from the State of Idaho, Department of Health and Welfare, Idaho National Engineering Laboratory (INEL) Oversight Program, also performed radiation dose rate measurements within the unrestricted areas located in Building 6055. In a letter dated May 9, 1994, INEL describes their independent measurements. This letter indicates that all measurements were at background radiation levels with the exception of one particular office. Within this office, INEL measured a maximum radiation dose rate of 1.3 mR/hr

at the surface of the wall. Background radiation was measured to be 0.015 mR/hr.

An NRC inspection was conducted to perform additional independent measurements to verify the licensee's level of compliance regarding dose limits to individual members of the public. The inspector performed surveys of the ambient dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to verify compliance. 10 CFR 20.1301 limits, in part, the total effective dose equivalent to individual members of the public from licensed operations to 0.1 rem in a year. Additionally, the dose in any unrestricted area from external sources must not exceed 2 millirems in any one hour.

Within Building No. 6051, the highest dose rate measured by the inspector was 0.2 mR/hr at the surface of the wall immediately adjacent to an area where the licensee stored iodine-131 and strontium-89 waste for decay. The dose rate at 30 centimeters from this point was measured to be 0.09 mR/hr. Background radiation was measured to be approximately 0.01 mR/hr. Although this dose rate demonstrates compliance regarding 2 millirems in any one hour, the inspector noted that if an individual were continually present in this area, and if the exposure rates were consistent, the dose limit of 0.1 rem in a year could be exceeded. However, the dose rates in this area vary significantly depending upon the quantity of radioactive waste material present at a given time. In this regard, in an effort to demonstrate compliance with the yearly limit of exposure to individual members of the public, on May 6, 1994, the licensee placed a thermoluminescent dosimeter (TLD) in this area to evaluate accumulated exposure over a specified period of time, and thereby take into account the multiple conditions that exist which vary exposure rates. Additionally, prior to the conclusion of the inspection, the RSO informed the inspector of the licensee's intent to place additional shielding in this area, and to relocate some of the waste which was contributing to the dose rate. The licensee expects to reduce exposure rates to background levels within this area.

Because the exposure levels measured by the inspector were ones which existed only during the first 5 months of the calendar year, and because the licensee's increased shielding is expected to reduce exposure levels to essentially background radiation, it appears unlikely that an individual of the public would receive a total effective dose equivalent in excess of 0.1 rem in a year as a result of the licensee's operations.

Within Building No. 6055, the location of the highest exposure rate measured by the inspector was within an office immediately adjacent to the licensee's technetium-99m preparation area. The inspector measured 1.2 mR/hr at the surface of the wall and at a height of approximately 6 feet from the floor. (Thus, this measurement was similar to the one obtained by the INEL official.) The dose rate at 30 centimeters from this point was measured to be 0.35 mR/hr. Background radiation was measured to be approximately 0.01 mR/hr. However, it was noted that these measurements were taken during afternoon hours when radiopharmaceuticals were not being prepared. The dose rate was attributed to

a storage container ("red needle bucket") containing syringes contaminated with technetium-99m. Due to the rapid decay of technetium-99m, it was noted that dose rates within this area would vary greatly depending upon the time of day and the day of the week. Furthermore, the licensee's workload (amount of doses prepared) during a given day would significantly affect the accumulated dose one might receive in any 1 hour. Therefore, to further assess the average dose rates in this area, the inspector performed additional surveys during the licensee's peak working hours (5:00 a.m. - 7:00 a.m.) and compared dose rate measurements with a set of simulated work conditions.

With a vial containing approximately 400 millicuries of technetium-99m left out of its leaded vial shield, the inspector measured a maximum dose rate in unrestricted areas to be 13 mR/hr. This dose rate was measured at approximately the same location as described above. The dose rate at 30 centimeters from this point was measured to be 9 mR/hr. With a syringe containing approximately 40 millicuries of technetium-99m left out of its leaded syringe shield, the inspector measured a maximum dose rate of 4 mR/hr. The dose rate at 30 centimeters from this point was measured to be 2 mR/hr. Although both conditions yielded dose rates greater than 2 mR/hr, these were conditions that were expected to exist for only seconds of time during any given hour (i.e., a vial and/or syringe is only unshielded during brief periods when the dose is assayed in a dose calibrator).

In this regard, in an effort to demonstrate compliance with the yearly limit of exposure to individuals of the public, on May 6, 1994, the licensee placed a TLD in this area to evaluate accumulated exposure over a specified period of time, and thereby take into account the multiple conditions that exist which vary exposure rates. Additionally, prior to the conclusion of this inspection, the licensee installed additional lead shielding surrounding the radiopharmaceutical preparation area to further reduce dose rates in unrestricted areas. Measurements taken after the installation of the shielding indicate dose rates which were essentially background radiation.

Therefore, because the exposure levels measured by the inspector were ones which existed only during the first 5 months of the calendar year, and because the licensee's increased shielding is expected to reduce exposure levels to essentially background radiation, it appears unlikely that an individual of the public would receive a total effective dose equivalent in excess of 0.1 rem in a year as a result of the licensee's operations.

Again, it should be noted that factors relating to occupancy times and distances from the wall by members of the public would significantly further reduce exposure estimates.

2.2 Effluent Concentrations

Also evaluated during this inspection was the licensee's air effluent concentrations of iodine-131 released to the environment during calendar year 1993. To demonstrate compliance with 10 CFR 20.106, Radioactivity in effluents to unrestricted areas, the licensee acquired air samples weekly to

measure the quantity of iodine-131 being release to the atmosphere. Table II of Appendix B to 10 CFR Part 20 limits the release of iodine-131 in air, in an unrestricted area, to a maximum of 1×10^{-10} microcuries per milliliter of air. Concentrations may be averaged over a period not greater than 1 year.

As noted in Section 1, the licensee handles millicurie quantities of unsealed radioiodine (iodine-131 sodium iodide solution) for compounding therapy capsules. The process is performed in a fume hood located in the licensee's hot lab. The hood is equipped with an activated charcoal filter to reduce air concentrations of iodine-131 prior to release to the atmosphere.

Using the data collected from weekly air samples, the licensee divided the total amount of iodine-131 released year to date, by the total air volume released through the hood's stack year to date, to calculate the total amount of iodine-131 released. The data were logged on the licensee's worksheet titled, "Year-to-Date Iodine-131 Released Air Concentrations." A review of these worksheets indicated that the licensee had exceeded the maximum allowable air concentration limits during 1993. The licensee's calculations, dated December 31, 1993, indicate an average release to unrestricted areas for 1993 to be 2.7×10^{-10} microcuries per milliliter of air. Further review of the licensee's sampling method suggests that the calculations may have underestimated the total quantity actually released during 1993.

The inspector noted that the licensee's weekly calculations did not account for the decay of iodine-131 prior to the sample collection, nor did the calculations consider the collection efficiency of the sample media used (4.7 centimeter impregnated carbon filter). The Notice to the licensee dated April 4, 1994, related to the licensee's failure to evaluate these effluents and compare them with the annual limit. It further suggested the potential to exceed air concentration limits during 1994. Based upon the licensee's records documenting air concentrations of iodine-131 released to an unrestricted area during 1993, this was identified as an apparent violation of 10 CFR 20.106(a) which requires, in part, that the licensee not release to an unrestricted area radioactive material in annual average concentrations which exceed the limits specified in Table II of Appendix B to 10 CFR Part 20 (1×10^{-10} microcuries per milliliter of air for soluble iodine-131). It should be noted that the concentration limit in revised Part 20 has been changed to 2×10^{-10} microcuries per milliliter of air for soluble iodine-131. This expanded limit was effective as of January 1, 1994.

Also responding to NRC's Notice, the licensee employed the services of a consultant physicist to assist in evaluating air effluents. The consultant's report, dated May 16, 1994, discusses similar concerns regarding the licensee's methods of calculating air concentrations (sampling efficiency and corrections for decay). Therefore, the consultant performed calculations using Environmental Protection Agency (EPA) approved methods outlined in 40 CFR 61, Appendix D. When the EPA methods were used to estimate the source term, and with the carbon filters being taken into account, the concentration of iodine-131 in the stack effluent was estimated to be 5×10^{-10} microcuries per milliliter of air for 1993. This method assumes the stack's point of

release (located on the roof of the licensee's facility) to be the unrestricted area. Since the licensee does not control access to the roof, this assumption would be valid.

The inspector did note that following NRC's inspection in February 1994, the licensee has purchased a glove box equipped with a three-layer activated charcoal bed, to be used in conjunction with the licensee's fume hood, to reduce effluent releases. At the time of this inspection, the glove box had not been installed but was expected to be within several days. The installation of these filters is expected to bring the licensee into compliance with 10 CFR 20.

ATTACHMENT

1 PERSONS CONTACTED

1.1 Licensee Personnel

*Kay Gregorio, Pharmacist Assistant
*Ned Gregorio, Radiation Safety Officer
Bob Santos, Courier/Pharmacist Assistant

1.2 NRC Personnel

Charles L. Cain, Acting Chief, Nuclear Materials Inspection Branch
*Mark R. Shaffer, Radiation Specialist

1.3 Other Individuals Contacted

SGT Crista Buchman, National Guard Liaison
+Richard Cade, Director, Idaho Department of Law Enforcement
Glenn Ford, Chief, Bureau of Narcotics, Idaho Department of Law Enforcement
+William Hladik III, Consultant Physicist
John Lewis, Assistant Deputy Director, Idaho Department of Law Enforcement
Monte MacConnell, Deputy Director, Idaho Department of Law Enforcement
Ronda Morton, Office Secretary, Bureau of Narcotics,
Idaho Department of Law Enforcement
Steven Oberg, Ph.D., INEL Oversight Program
Ed Rankin, Special Agent-In-Charge, Bureau of Narcotics,
Idaho Department of Law Enforcement
+David Salmon, Health Physics Northwest
Don VanCleave, Special Agent, Bureau of Narcotics,
Idaho Department of Law Enforcement
Roy Weston, Office Accountant, Bureau of Narcotics,
Idaho Department of Law Enforcement

*Indicates those present during exit meeting on May 17, 1994.

+Indicates those contacted by phone only.

2 EXIT MEETINGS

A preliminary site exit briefing was conducted on May 17, 1994, with those individuals identified in Section 1.

Additionally, a formal exit briefing was conducted telephonically between the licensee's Radiation Safety Officer and Messrs. Charles L. Cain and Mark R. Shaffer on May 26, 1994, to review the specific findings as presented in the report.

APPENDIX B

PROPOSED ENFORCEMENT CONFERENCE AGENDA

NUCLEAR PHARMACY OF IDAHO, INC

July 1, 1994 - 9:00 a.m. (CDT)

- | | |
|---|----------------|
| I. INTRODUCTION AND PURPOSE | L. J. CALLAN |
| II. EXPLANATION OF ENFORCEMENT POLICY | G. F. SANBORN |
| III. NRC DISCUSSION OF APPARENT VIOLATIONS | C. L. CAIN |
| IV. LICENSEE COMMENTS AND RESPONSE/
CORRECTIVE ACTIONS | S. N. GREGORIO |
| V. CLOSING COMMENTS | S. J. COLLINS |

tion for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license, provided that the permit or license so issued contains the condition specified in § 50.55b of this chapter.

(f) Hearings on antitrust aspects will be conducted by a presiding officer, either an Administrative Law Judge or an atomic safety and licensing board comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom will have such technical or other qualifications as the Commission deems appropriate to the issues to be decided.

(g) When the Attorney General has advised that there may be adverse antitrust aspects and recommends that a hearing be held, the Attorney General or his designee may participate as a party in the proceedings.

(h) At the hearing, the presiding officer will give due consideration to the advice received from the Attorney General and to evidence pertaining to antitrust aspects received at the hearing.

(i) The presiding officer will, in the initial decision, make a finding as to whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act. If the presiding officer finds that such a situation would be created or maintained, it will consider, in determining whether the permit or license should be issued or continued, such other factors as it deems necessary to protect the public interest, including the need for power in the affected area. The certainty of contravening the antitrust laws or the policies clearly underlying these laws is not intended to be implicit in this standard, nor is mere possibility of inconsistency. The finding will be based on reasonable probability of contravention of the antitrust laws or the policies clearly underlying these laws. The presiding officer will conclude whether, in its judgment, it is reasonably probable that the activities under the license would, when the license is issued or thereafter, be inconsistent with any of the antitrust laws or the policies clearly underlying these laws.

(j) On the basis of the findings in the proceeding on the antitrust aspect of the application, the presiding officer may (i) authorize the issuance of the permit or license after favorable consideration of matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, at the hearing described in sections I-VIII of this appendix; (ii) authorize the continuation of a permit or license already issued; (iii) direct the denial of the application for the permit or license, or the rescission of a permit or license already issued; or (iv) authorize the issuance of a permit or license subject to appropriate conditions, and subject to favorable consideration of matters of radiological health and safety and common defense matters raised under the National Environmental Policy Act of 1969 at the hearing described in sections I-VIII of this appendix.

➤ Appendix B to Part 2
[Reserved 58 FR 46610.]

Appendix C — General Statement of Policy and Procedure for NRC Enforcement Actions

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 - B. Repetitive Violations
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Supplements

37 FR 15127-46 FR 55083

39 FR 13655

46 FR 55083

30 FR 14308

Preface

The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions, and of the presiding officers and the Commission in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety, the common defense and security, and the environment.¹ This statement of general policy and procedure is published in the Code of Federal Regulations to provide widespread dissemination of the Commission's Enforcement Policy. However, this is a policy statement and not a regulation. The Commission may deviate from this statement of policy and procedure as appropriate under the circumstances of a particular case.

I. Introduction and Purpose

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by:

- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
- Deterring future violations and occurrences of conditions adverse to quality; and
- Encouraging improvement of licensee and vendor² performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees, vendors, contractors, and employees of any of them, who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects.³ Each enforcement action is dependent on the circumstances of the

¹ Antitrust enforcement matters will be dealt with on a case-by-case basis.

² The term "vendor" as used in this policy means a supplier of products or services to be used in an NRC-licensed facility or activity.

³ This policy primarily addresses the activities of NRC licensees. Therefore, the term "licensee" is used throughout the policy. However, in those cases where the NRC determines that it is appropriate to take enforcement action against a non-licensee or individual, the guidance in this policy will be used, as applicable. Specific guidance regarding enforcement action against individuals and non-licensees is addressed in Sections VIII and X, respectively.

case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

II. Statutory Authority and Procedural Framework

A. Statutory Authority

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Section 186 authorizes NRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's failure to build or operate a facility in accordance with the terms of the permit or license, and for violation of an NRC regulation). Section 234 authorizes NRC to impose civil penalties not to exceed \$100,000 per violation per day for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. In addition to the enumerated provisions in section 234, sections 84 and 147 authorize the imposition of civil penalties for violations of regulations implementing those provisions. Section 232 authorizes NRC to seek injunctive or other equitable relief for violation of regulatory requirements.

Section 206 of the Energy Reorganization Act authorizes NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

Chapter 18 of the Atomic Energy Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of the Act and regulations or orders issued under sections 65, 161(b), 161(i), or 161(o) of the Act. Section 223 provides that criminal penalties may be imposed on certain individuals employed by firms constructing or supplying basic components of any utilization facility if the individual knowingly and willfully

violates NRC requirements such that a basic component could be significantly impaired. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the Atomic Energy Act are referred to the Department of Justice for appropriate action.

B. Procedural Framework

Subpart B of 10 CFR part 2 of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the civil penalty process is initiated by issuing a Notice of Violation and Proposed Imposition of a Civil Penalty. The licensee or other person is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the response, the civil penalty may be mitigated, remitted, or imposed. An opportunity is provided for a hearing if a civil penalty is imposed. If a civil penalty is not paid following a hearing or if a hearing is not requested, the matter may be referred to the U.S. Department of Justice to institute a civil action in District Court.

The procedure for issuing an order to institute a proceeding 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 is set forth in 10 CFR 2.202. The licensee or any other person adversely affected by the order may request a hearing. The NRC is authorized to make orders immediately effective if required to protect the public health, safety, or interest, or if the violation is willful. Section 2.204 sets out the procedures for issuing a Demand for Information (Demand) to a licensee or other person subject to the Commissioner's jurisdiction for the purpose of determining whether an order or other enforcement action should be issued. The Demand does not provide hearing rights, as only information is being sought. A licensee must answer a Demand. An unlicensed person may answer a Demand by either providing the requested information or explaining why the Demand should not have been issued.

III. Responsibilities

The Executive Director for Operations (EDO) and the principal enforcement officers of the NRC, the Deputy Executive Director for Nuclear Material Safety Safeguards and Operations Support (DEDS) and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research (DEDR), have been delegated the authority to approve or issue all escalated enforcement actions.* The DEDS is responsible to the EDO for the NRC enforcement programs. The Office of Enforcement (OE) exercises oversight of and implements the NRC enforcement programs. The Director, OE, acts for the Deputy Executive Directors in enforcement matters in their absence or as delegated. Subject to the oversight and direction of OE, and with the approval of the appropriate Deputy Executive Director, where necessary, the regional offices normally issue Notices of Violation and proposed civil penalties. However, subject to the same oversight as the regional offices, the Office of Nuclear Reactor Regulation (NRR) issues Notices of Violation and proposed civil penalties to vendors and suppliers and the Office of Nuclear Material Safety and Safeguards (NMSS) issues Notices of Violation and proposed civil penalties to certificate holders and to fuel cycle facilities for violations involving material control and accounting. Escalated enforcement actions are normally coordinated with the appropriate offices by the OE. Enforcement orders are normally issued by a Deputy Executive Director or the Director, OE. However, orders may also be issued by the EDO, especially those involving the more significant matters. The Directors of NRR and NMSS have also been delegated authority to issue orders, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions not associated with compliance issues. The Director, Office of the Controller, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license and inspection fees.

* The term "escalated enforcement action" as used in this policy means a Notice of Violation for any Severity Level I, II, or III violation; a civil penalty for any Severity Level I, II, III, or IV violation; and any order based upon a violation.

In recognition 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, including the decision to issue a Notice of Violation, 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 technical significance of the violations and the surrounding circumstances.

Unless Commission consultation or notification is required by this policy, the staff may depart, where warranted in the public's interest, from this policy with the approval of the appropriate Deputy Executive Director and consultation with the EDO as warranted. (See also Section VII "Exercise of Discretion.")

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will also be provided notice in those cases where discretion is exercised and discussed in Section VII.B.6. In addition, the Commission will be consulted prior to taking action in the following situations (unless the urgency of the situation dictates immediate action):

- (1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation;
- (2) Proposals to impose civil penalties in amounts greater than 3 times the Severity Level I values shown in Table 1A;
- (3) Any proposed enforcement action that involves a Severity Level I violation;
- (4) Any enforcement action that involves a finding of a material false statement;
- (5) Exercising discretion for matters meeting the criteria of Section VII.A.1 for Commission consultation;
- (6) Refraining from taking enforcement action for matters meeting the criteria of Section VII.B.3;
- (7) Any proposed enforcement action that involves the issuance of a civil penalty or order to an unlicensed individual or a civil penalty to a licensed reactor operator;

8) Any action the EDO believes warrants Commission involvement.

9) Any enforcement case involving an Office of Investigation (OI) report where NRC staff (other than OI staff) does not arrive at the same conclusions as those in the OI report concerning issues of intent.

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

IV. Severity of Violations

Regulatory requirements³ have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation, including both the technical significance and the regulatory significance is evaluated as the first step in the enforcement process.

Consequently, violations are normally categorized in terms of five levels of severity to show their relative importance within each of the following eight activity areas:

- I. Reactor Operations;
- II. Facility Construction;
- III. Safeguards;
- IV. Health Physics;
- V. Transportation;
- VI. Fuel Cycle and Materials Operations;
- VII. Miscellaneous Matters; and
- VIII. Emergency Preparedness.

Licensed activities will be placed in the activity area most suitable in light of the particular violation involved including activities not directly covered by one of the above listed areas, e.g., export license activities. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant regulatory concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

³ The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Reactor Operations is not directly comparable to that associated with Severity Level I violations in Facility Construction.

Supplements I through VIII provide examples and serve as guidance in determining the appropriate severity level for violations in each of the eight activity areas. However, the examples are neither exhaustive nor controlling. In addition, these examples do not create new requirements. Each is designed to illustrate the significance that the NRC places on a particular type of violation of NRC requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

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 best suited to the significance of the particular violation. In some cases, special circumstances may warrant an adjustment to the severity level categorization.

A. Aggregation of Violations

A group of violations may be evaluated in the aggregate and assigned a single, increased severity level, thereby resulting in a Severity Level III problem, if the violations have the same underlying cause or programmatic deficiencies, or the violations contributed to or were unavoidable consequences of the underlying problem. Normally, Severity Level I and II violations are not aggregated into a higher severity level.

The purpose of aggregating violations is to focus the licensee's attention on the fundamental underlying causes for which enforcement action appears warranted and to reflect the fact that several violations with a common cause may be more significant collectively than individually and may therefore, warrant a more substantial enforcement action. In addition, a civil penalty for multiple occurrences of a violation with the same root cause may be subject to escalation of the base civil penalty. (See Section VI.B.2.(e))

B. Repetitive Violations

The severity level of a Severity Level V or IV violation may be increased to Severity Level IV or III respectively, if the violation can be considered a repetitive violation.⁴ The purpose of escalating the severity level of a repetitive violation is to acknowledge the added significance of the situation based on the licensee's failure to implement effective corrective action for the previous violation. The decision to escalate the severity level of a repetitive violation will depend on the circumstances, such as, but not limited to, the number of times the violation has occurred, the similarity of the violations and their root causes, the adequacy of previous corrective actions, the period of time between the violations, and the significance of the violations. (Civil penalties may also be proposed for repetitive Severity Level IV violations as discussed in Section VI.B.)

C. Willful Violations

Willful violations are by definition of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. Willful violations cannot be tolerated by either the Commission or a licensee. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances such that it demonstrates the seriousness of the violation thereby creating a deterrent effect within the licensee's organization. While removal of the person is not necessarily required, substantial disciplinary action is expected.

⁴ The term "repetitive violation" or "similar violation" as used in this policy statement means a violation that reasonably could have been prevented by a licensee's corrective action for a previous violation normally occurring (1) within the past two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer.

Therefore, the severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used in this policy embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the NRC. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position and responsibilities of the person involved in the violation (e.g., licensee official⁷ or non-supervisory employee), the significance of any underlying violation, the intent of the violator (i.e., careless disregard or deliberateness), and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation. However, the severity level of a willful severity level V violation will be increased to at least a severity level IV.

D. Violations of Reporting Requirements

The NRC expects licensees to provide complete, accurate, and timely information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the

circumstances surrounding the matter. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report. A licensee will, on the other hand, normally be cited for a failure to report a condition or event if the licensee knew of the information to be reported, but did not recognize that it was required to make a report.

V. Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the NRC will normally provide an opportunity for an enforcement conference with the licensee, vendor, or other person prior to taking enforcement action. Although enforcement conferences are not normally held for Severity Level IV violations, they may be scheduled if increased management attention is warranted e.g., if the violations are repetitive. The purpose of the enforcement conference is to (1) discuss the violations or nonconformances, their significance, the reason for their occurrence, including the apparent root causes, and the licensee's or vendor's corrective actions, (2) determine whether there were any aggravating or mitigating circumstances, and (3) obtain other information that will help the NRC determine the appropriate enforcement action.

During the enforcement conference, the licensee, vendor, or other person will be given an opportunity to provide information consistent with the purpose of the conference, including an explanation to the NRC of the immediate corrective actions (if any) that were taken following identification of the potential violation or nonconformance and the long term comprehensive actions that were taken or will be taken to prevent recurrence. Licensees, vendors, or other persons will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be open to the public.

When needed to protect the public health and safety or common defense and security, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In these cases, an enforcement conference may be held after the escalated enforcement action is taken.

VI. Enforcement Actions

This section describes the enforcement sanctions available to the NRC and specifies the conditions under which each may be used. The basic sanctions are Notices of Violation, civil penalties, and orders of various types. As discussed further in Section VI.D, related administrative mechanisms such as Notices of Nonconformance, Notices of Deviation, Confirmatory Action Letters, letters of reprimand, and Demands for Information are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. Usually, whenever a violation of NRC requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, a Notice of Violation or a Notice of Nonconformance is the normal enforcement action.

⁷ The term "licensee official" as used in this policy statement means a first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material, whether or not listed on a license. Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered licensee officials will consider several factors, including the position of the individual relative to the licensee's organizational structure and the individual's responsibilities relative to the oversight of licensed activities and to the use of licensed material.

A. Notice of Violation

A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The Notice of Violation normally requires the recipient to provide a written statement describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) corrective steps that have been taken and the results achieved; (3) corrective steps that will be taken to prevent recurrence; and (4) the date when full compliance will be achieved. The NRC may require responses to Notices of Violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

The NRC uses the Notice of Violation as the usual method for formalizing the existence of a violation. Issuance of a Notice of Violation is normally the only enforcement action taken, except in cases where the criteria for issuance of civil penalties and orders, as set forth in Sections VI.B and VI.C, respectively, are met. However, special circumstances regarding the violation findings may warrant discretion being exercised such that the NRC refrains from issuing a Notice of Violation. (See Section VII.B, "Mitigation of Enforcement Sanctions.") In addition, licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of (1) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders; (2) any requirement for which a license may be revoked; or (3) reporting requirements under section 206 of the Energy Reorganization Act. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations both by the involved licensee as well as by other licensees conducting similar activities.

Civil penalties are proposed (absent mitigating circumstances) for Severity Level I, II, and III violations, and may be proposed for repetitive Severity Level IV violations or for any willful violation. In addition, civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act.

1. Base Civil Penalty

The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, materials, and vendor programs. (Civil penalties issued to individuals are determined on a case-by-case basis.) The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of 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 puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of the penalties take into account a licensee's "ability to pay." In determining the amount of civil penalties for licensees for whom the tables do not reflect the ability to pay, the NRC will consider as necessary an increase or decrease on a case-by-case basis. Normally, if a licensee can demonstrate financial hardship, the NRC will consider payments over time, including interest, rather than reducing the amount of the civil penalty. However, where a licensee claims financial hardship, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees.

2. Civil Penalty Adjustment Factors

In an effort to recognize and encourage good performance, deter poor performance, and emphasize violations of particular regulatory concern, the NRC reviews each proposed civil penalty on its own merits and, after considering all relevant circumstances, may adjust the base civil penalties shown in Table 1A and 1B for Severity Level I, II, and III violations based on an assessment of the following civil penalty adjustment factors. Civil penalties for Severity Level IV violations are normally proposed at the base values identified in the tables without assessing the civil penalty adjustment factors.

While management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of management involvement may not be used to mitigate a civil penalty. Allowing mitigation in the latter case could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

(a) *Identification.* The purposes of this factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance. Therefore, the base civil penalty shown in Tables 1A and 1B may be mitigated up to 50% when a licensee identifies a violation and escalated up to 50% if the NRC identifies a violation. The base civil penalty may also be mitigated up to 25% when a licensee identifies a violation resulting from a self-disclosing event* where the licensee demonstrates initiative in identifying the root cause of the violation. In addition, the base civil penalty may also be mitigated where warranted if a licensee identifies a violation as a result of its review of a generic notification. While mitigation under this factor is appropriate for a licensee identified violation that was not reported to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make the required report.

* The term "self-disclosing event" as used in this policy statement means an event that is readily obvious by human observation or mechanical instrumentation such as a spill of liquid, an open door (required to be closed), an overexposure documented in a dosimetry report, an annunciator alarm, or a reactor trip.

(b) *Corrective action.* The purposes of this factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of similar violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be either mitigated or escalated by as much as 50% depending on the promptness and extensiveness of the licensee's corrective action. In assessing this factor, consideration will be given to, among other things, the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action), the degree of licensee initiative (i.e., whether NRC involvement was required before acceptable action was taken), the adequacy of the licensee's root cause analysis for the violation, and, given the significance and complexity of the issue, the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). Notwithstanding good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, mitigation of the civil penalty based on this factor will not normally be considered and escalation may be considered to address the licensee's failure.

(c) *Licensee performance.* The purpose of this factor is to recognize and encourage good or improving licensee performance and to recognize and deter poor or declining performance. Therefore, the base civil penalty shown in Tables 1A and 1B may be mitigated by as much as 100% if the current violation is an isolated failure that is inconsistent with a licensee's outstandingly good prior performance. The base civil penalty may also be escalated by as much as 100% if the current violation is reflective of the licensee's poor or declining prior performance. Neither mitigation nor escalation may be appropriate based on

this factor where a licensee's poor prior performance appears to clearly be improving. Prior performance, as used in this policy statement, refers to the licensee's performance normally (1) within the last two years of the inspection at issue, or (2) the period within the last two inspections, whichever is longer. In assessing the licensee's prior performance, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as Systematic Assessment of Licensee Performance (SALP) evaluations for power reactors, and the licensee's prior enforcement history overall and in the area of concern, including escalated and non-escalated enforcement actions and any enforcement actions that the NRC exercised discretion and refrained from issuing in accordance with Section VII.B. Notwithstanding good prior performance, mitigation of the civil penalty based on this factor is not normally warranted where the current violation reflects a substantial decline in performance that has occurred over the time since the last NRC inspection. In addition, this factor should not be applied for those cases where the licensee has not been in existence long enough to establish a prior performance or inspection history. Similarly, mitigation based on this factor is not normally appropriate where the area of concern has not been previously inspected, unless overall performance is good.

(d) *Prior opportunity to identify.* The purpose of this factor is to encourage licensees to take effective action in response to opportunities to identify or prevent problems or violations. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% for cases where the licensee should have identified the violation sooner as a result of prior opportunities, such as (1) through normal surveillances, audits, or quality assurance (QA) activities; (2) through prior notice (i.e., specific NRC or industry

notification; or (3) through other reasonable indication of a potential problem or violation, such as observations of employees and contractors, and had failed to take effective corrective steps. Prior notification may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue. In assessing this factor, consideration will be given to, among other things, the opportunities available to discover the violation, the ease of discovery, the similarity between the violation and the notification, the period of time between when the violation occurred and when the notification was issued, the action taken (or planned) by the licensee in response to the notification, and the level of management review that the notification received (or should have received). Escalation of the civil penalty based solely on prior notification is normally not warranted where the licensee appropriately reviewed the notification for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.

(e) *Multiple occurrences.* The purpose of this factor is to reflect the added significance resulting from multiple occurrences of the violation. Therefore, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% where multiple examples of a particular violation are identified during the inspection period. Escalation of the civil penalty based on this factor will normally be considered only when there are multiple examples of Severity Level I, II, or III violations with the same root causes. Alternatively, separate civil penalties may be imposed for each violation.

(f) *Duration.* The purpose of this factor is to recognize the added significance associated with those violations (or the impact of those violations) that continue

or remain uncorrected for more than one day. Therefore, whether or not a licensee is aware or clearly should have been aware of a violation, the base civil penalty shown in Tables 1A and 1B may be escalated by as much as 100% to reflect the added technical and/or regulatory significance resulting from the violation or the impact of it remaining uncorrected for more than one day. This factor should normally be applied in cases involving particularly safety significant violations or where a significant regulatory message is warranted. In lieu of escalating the civil penalty based on this factor, the NRC may impose daily civil penalties for violations that continue for more than one day. (See Section VII.A.3. "Daily Civil Penalties.")

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The civil penalty adjustment factors presented in paragraphs (a) through (f) are additive. However, in no instance will a civil penalty for any one violation exceed \$100,000 per day.

Notwithstanding the application of the civil penalty adjustment factors, a civil penalty will normally be proposed in an amount of at least 50% of the base value in Tables 1A and 1B for Severity Level I and II violations involving overexposures, release of radioactive material, or loss of radioactive material to emphasize to the licensee the seriousness with which the NRC views these events and the importance of conducting licensed activities in a manner to avoid these violations. In considering mitigation for these cases,

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normally the only adjustment factors that will be considered to lower a base civil penalty will be identification and corrective action factors. In addition, as provided in Section VII, "Exercise of Discretion," discretion may be exercised by either escalating or mitigating the amount of the civil penalty arrived at after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects the NRC's concern regarding the violation at issue and that it conveys the appropriate message to the licensee.

TABLE 1A—BASE CIVIL PENALTIES

	Plant operations, construction, health physics and EP	Safeguards	Transportation	
			Greater than Type A quantity ¹	Type A quantity or less ²
a. Power reactors	\$100,000	\$100,000	\$100,000	\$5,000
b. Test reactors	10,000	10,000	10,000	2,000
c. Research reactors and critical facilities	5,000	5,000	5,000	1,000
d. Fuel fabricators and industrial processors ³	25,000	100,000	25,000	5,000
e. Mills and Uranium conversion facilities	10,000	—	5,000	2,000
f. Industrial users of materials ⁴ and contractors and vendors	10,000	—	5,000	2,000
g. Waste disposal licensees	10,000	—	5,000	2,000
h. Academic or medical institutions ⁵	5,000	—	2,500	1,000
Independent spent fuel and monitored retrievable storage installations	25,000	100,000	25,000	5,000
Other material licensees	1,000	—	2,500	1,000

¹ Includes irradiated fuel, high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.

² Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.

³ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.

⁴ This amount refers to Category 1 licensees (as defined in 10 CFR 73.2). Licensed fuel fabricators not authorized to possess Category 1 material have a base penalty amount of \$50,000.

⁵ Includes industrial radiographers, nuclear pharmacies, and other industrial users.

⁶ This applies to nonprofit institutions not otherwise categorized under sections (a) through (g) in this table and mobile nuclear services.

TABLE 1 B—BASE CIVIL PENALTIES

Severity Level	Base Civil Penalty Amount	
	(Percent of amount listed in Table 1A)	
I	100	
II	80	
III	50	
IV	15	

C. 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 may also be issued in lieu of, or in addition to, civil penalties, as appropriate for Severity Level I, II, or III violations. Orders may be issued as follows:

(1) License Modification orders are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.

(2) Suspension Orders may be used:

(a) To remove a threat to the public health and safety, common defense and security, or the environment;

(b) To stop facility construction when:

(i) Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component; or

(ii) The licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to

comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation Orders may be used:

(a) When a licensee is unable or unwilling to comply with NRC requirements;

(b) When a licensee refuses to correct a violation;

(c) When licensee does not respond to a Notice of Violation where a response was required;

(d) When a licensee refuses to pay an applicable fee under the Commission's regulations; or

(e) For any other reason for which revocation is authorized under section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.

(5) Orders to unlicensed persons, including vendors and contractors, and employees of any of them, are used when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities.

Unless a separate response is warranted pursuant to 10 CFR 2.201, a Notice of Violation need not be issued where an order is based on violations described in the order. The violations described in an order need not be categorized by severity level.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the NRC believes a basis could reasonably exist

for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show why the order should not be issued in the proposed manner by way of a Demand for Information. (See 10 CFR 2.204)

D. Related Administrative Actions

In addition to the formal enforcement mechanisms of Notices of Violation, civil penalties, and orders, the NRC also uses administrative mechanisms, such as Notices of Deviation, Notices of Nonconformance, Confirmatory Action Letters, letters of reprimand, and Demands for Information to supplement its enforcement program. The NRC expects licensees and vendors to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met.

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

(2) Notices of Nonconformance are written notices describing vendor's failures to meet commitments which have not been made legally binding requirements by NRC. An example is a commitment made in a procurement contract with a licensee as required by 10 CFR part 50, appendix B. Notices of Nonconformance request non-licensees to 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.

(3) Confirmatory Action Letters (CALs) are letters confirming a licensee's or vendor's agreement to take

certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(4) Letters of reprimand are letters addressed to individuals subject to Commission jurisdiction identifying a significant deficiency in their performance of licensed activities.

(5) Demands for Information are demands for information from licensees or other persons for the purpose of enabling NRC to determine whether an order or other enforcement action should be issued.

VII. Exercise of Discretion

Notwithstanding the normal guidance contained in this policy, the NRC may choose to exercise discretion and either escalate or mitigate enforcement sanctions within the Commission's statutory authority to ensure that the resulting enforcement action appropriately reflects the level of NRC concern regarding the violation at issue and conveys the appropriate message to the licensee.

A. Escalation of Enforcement Sanctions

The NRC considers violations categorized at Severity Level I, II, or III

to be of significant regulatory concern. If the application of the normal guidance in this policy does not provide an appropriate sanction, or if particularly serious violations occur, such as in cases involving willfulness, repeated poor performance in an area of concern, or serious breakdowns in management controls, the NRC may apply its full enforcement authority where the action is warranted. NRC action may include (1) escalating civil penalties, (2) issuing appropriate orders, and (3) assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$100,000 per violation, per day.

(1) *Civil penalties.* Notwithstanding the outcome of the normal civil penalty assessment process (i.e., base civil penalty adjusted based on application of the civil penalty adjustment factors addressed in Section VI.B), with the approval of the appropriate Deputy Executive Director and consultation with the EDO as warranted, the NRC may exercise discretion by either proposing a civil penalty where application of the factors would otherwise result in zero penalty or by further escalating the amount of the

adjusted civil penalty to ensure that the proposed civil penalty reflects the NRC's concern regarding the violation at issue and that it conveys the appropriate message to the licensee. In addition to the approval of the appropriate Deputy Executive Director, consultation with the Commission is required if the deviation in the amount of the civil penalty proposed under this discretion from the amount of the civil penalty assessed under the normal process is more than two times the base civil penalty shown in Tables 1A and 1B.

(2) *Orders.* The NRC will, where necessary, issue orders in conjunction with civil penalties to achieve or formalize corrective actions and to deter further recurrence of serious violations. Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. Enforcement sanctions will normally escalate for recurring similar violations.

TABLE 2.—EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous two years, whichever period is greater		
	1st	2nd	3rd
I	a - c	a - b - c	d
II	b	b - b - c	b - b - c
III	b	b - c	b - b

Notes:
 a. Civil penalty
 b. Suspension of affected operations until the Office Director is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements, or modification of the license, as appropriate
 c. Consider issuing an order for modification, suspension, or revocation of the license, as appropriate, through use of a Demand for Information
 d. Further action, as appropriate

(3) *Daily civil penalties.* In order to recognize the added technical safety significance or regulatory significance for those cases where a very strong message is warranted for a significant violation that continues for more than one day, the NRC may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit of \$100,000 for each day the violation continues. The NRC may exercise this discretion if a licensee was aware or clearly should have been aware of a violation, or if the licensee had an opportunity to identify and correct the violation but failed to do so.

B. Mitigation of Enforcement Sanctions

Because the NRC wants to encourage and support licensee initiative for self identification and correction of problems, the NRC may exercise discretion and refrain from issuing a civil penalty and/or issuing a Notice of Violation under certain circumstances. In addition, while the NRC may exercise this discretion for violations meeting the required criteria where the licensee failed to make a required report to the NRC, a separate enforcement action will normally be issued for the licensee's failure to make a required report. The circumstances under which this discretion may be exercised are as follows:

(1) *Severity Level V Violations.* The NRC may refrain from issuing a Notice of Violation for a Severity Level V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(b) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(c) It was not a willful violation.

(2) *Licensee Identified Severity Level IV and V Violations.* The NRC may refrain from issuing a Notice of Violation for a Severity Level IV or V violation that is documented in an inspection report (or official field notes for some material cases) provided that the inspection report includes a brief description of the corrective action and that the violation meets all of the following criteria:

(a) It was identified by the licensee, including as a result of a self-disclosing event;

(b) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation or a previous licensee finding that occurred within the past two years of the inspection at issue, or the period within the last two inspections, whichever is longer;

(c) It was or will be corrected within a reasonable time, by specific corrective action committed to by the licensee by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;

(d) It was not a willful violation or if it was a willful violation:

(i) The information concerning the violation, if not required to be reported, was promptly provided to appropriate NRC personnel, such as a resident inspector or regional section or branch chief;

(ii) The violation involved the acts of a low level individual (and not a licensee official as defined in section IV.C);

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

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

(3) *Violations Identified During Extended Shutdowns or Work Stoppages.* The NRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after (i) the NRC has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of an operating reactor or a material licensee (or a work stoppage at a construction site), or (ii) 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 official field notes for some material cases) and that it meets all of the following criteria:

(a) It was either licensee identified as a result of a comprehensive program for problem identification and correction that was developed in response to the shutdown or identified as a result of an employee allegation to the licensee; if the NRC identifies the violation and all of the other criteria are met, the NRC should determine whether enforcement action is necessary to achieve remedial action, or if discretion may still be appropriate;

(b) It is based upon activities of the licensee prior to the events leading to the shutdown;

(c) It would not be categorized at a severity level higher than Severity Level II;

(d) It was not willful; and

(e) The licensee's decision to restart the plant requires NRC concurrence.

(4) *Violations Involving Old Design Issues.* The NRC may refrain from proposing a civil penalty for a Severity Level II or III violation involving a past problem, such as in engineering, design, or installation, provided that the violation is documented in an inspection report (or official field notes for some material cases) that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee identified as a result of a licensee's voluntary formal initiative, such as a Safety System Functional Inspection, Design Reconstitution Program, or other program that has a defined scope and timetable and is being aggressively implemented;

(b) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification (this action should involve expanding the initiative, as necessary, to identify other failures caused by similar root causes); and

(c) It was not likely to be identified (after the violation occurred) by routine licensee efforts such as normal surveillance or quality assurance (QA) activities.

In addition, the NRC may refrain from issuing a Notice of Violation for cases that meet the above criteria provided the violation was caused by conduct that is not reasonably linked to present performance (normally, violations that are at least three years old or violations occurring during plant construction) and there had not been prior notice so that the licensee should have reasonably identified the violation earlier. This exercise of discretion is to place a premium on licensees initiating efforts to identify and correct subtle violations that are not likely to be identified by routine efforts before degraded safety systems are called upon to work.

(5) Violations Identified Due to Previous Escalated Enforcement Action. The NRC may refrain from issuing a Notice of Violation or a proposed civil penalty for a violation that is identified after the NRC has taken escalated enforcement action for a Severity Level II or III violation, provided that the violation is documented in an inspection report (or official field notes for some material cases) that includes a description of the corrective action and that it meets all of the following criteria:

(a) It was a licensee identified as part of the corrective action for the previous escalated enforcement action;

(b) It has the same or similar root cause as the violation for which escalated enforcement action was issued;

(c) It does not substantially change the safety significance or the character of the regulatory concern arising out of the initial violation; and

(d) It was or will be corrected, including immediate corrective action and long term comprehensive corrective action to prevent recurrence, within a reasonable time following identification.

(6) Violations Involving Special Circumstances. Notwithstanding the outcome of the normal civil penalty assessment process (i.e., base civil penalty adjusted based on application of the civil penalty adjustment factors addressed in Section VI.B), as provided in Section III, "Responsibilities," the appropriate Deputy Executive Director may reduce or refrain from issuing a civil penalty or a Notice of Violation for a Severity Level II or III 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 safety significance of the violation, the overall

performance of the licensee, and other relevant circumstances, including any that may have changed since the violation, provided prior notice has been given the Commission. This discretion is expected to be exercised only where application of the normal guidance in the policy is unwarranted.

C. Exercise of Discretion for an Operating Facility

On occasion, circumstances may arise where a licensee's compliance with a Technical Specification (TS) Limiting Condition for Operation or with other license conditions would involve an unnecessary plant transient or performance of testing, inspection, or system realignment that is inappropriate with the specific plant conditions, or unnecessary delays in plant startup without a corresponding health and safety benefit. In these circumstances, the NRC staff may choose not to enforce the applicable TS or other license condition. This enforcement discretion will only be exercised if the NRC staff is clearly satisfied that the action is consistent with protecting the public health and safety. A licensee seeking the exercise of enforcement discretion must provide a written justification, or in circumstances where good cause is shown, oral justification followed as soon as possible by written justification, which documents the safety basis for the request and provides whatever other information the NRC staff deems necessary in making a decision on whether or not to exercise enforcement discretion.

The appropriate Regional Administrator, or his designee, may exercise discretion where the noncompliance is temporary and nonrecurring when an amendment is not practical. The Director, Office of Nuclear Reactor Regulation, or his designee, may exercise discretion if the expected noncompliance will occur during the brief period of time it requires the NRC staff to process an emergency or exigent license amendment under the provisions of 10 CFR 50.91(a)(5) or (6). The person exercising enforcement discretion will document the decision.

For an operating plant, this exercise of enforcement discretion is intended to minimize the potential safety consequences of unnecessary plant transients with the accompanying operational risks and impacts or to eliminate testing, inspection, or system realignment which is inappropriate for the particular plant conditions. For plants in a shutdown condition, exercising enforcement discretion is intended to reduce shutdown risk by, again, avoiding testing, inspection or system realignment which is inappropriate for the particular plant conditions, in that, it

does not provide a safety benefit or may, in fact, be detrimental to safety in the particular plant condition. Exercising enforcement discretion for plants attempting to startup is less likely than exercising it for an operating plant, as simply delaying startup does not usually leave the plant in a condition in which it could experience undesirable transients. In such cases, the Commission would expect that discretion would be exercised with respect to equipment or systems only when it has at least concluded that, notwithstanding the conditions of the license: (1) The equipment or system does not perform a safety function in the mode in which operation is to occur; (2) the safety function performed by the equipment or system is of only marginal safety benefit, provided remaining in the current mode increases the likelihood of an unnecessary plant transient; or (3) the TS or other license condition requires a test, inspection or system realignment that is inappropriate for the particular plant conditions, in that it does not provide a safety benefit, or may, in fact, be detrimental to safety in the particular plant condition.

The decision to exercise enforcement discretion does not change the fact that a violation will occur nor does it imply that enforcement discretion is being exercised for any violation that may have led to the violation at issue. In each case where the NRC staff has chosen to exercise enforcement discretion, enforcement action will normally be taken for the root causes, to the extent violations were involved, that led to the noncompliance for which enforcement discretion was used. The enforcement action is intended to emphasize that licensees should not rely on the NRC's authority to exercise enforcement discretion as a routine substitute for compliance or for requesting a license amendment.

Finally, it is expected that the NRC staff will exercise enforcement discretion in this area infrequently. Although a plant must shut down, refueling activities may be suspended, or plant startup may be delayed, absent the exercise of enforcement discretion, the NRC staff is under no obligation to take such a step merely because it has been requested. The decision to forego enforcement is discretionary. Where enforcement discretion is to be exercised, it is to be exercised only if the NRC staff is clearly satisfied that such action is warranted from a health and safety perspective.

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VIII. Enforcement Actions Involving Individuals

Enforcement actions involving individuals, including licensed operators, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action involving an individual will normally be taken only when the NRC is satisfied that the individual fully understood, or should have understood, his or her responsibility; knew, or should have known, the required actions; and knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV, or V violations will be handled by citing only the facility licensee.

More serious violations, including those involving the integrity of an individual (e.g., lying to the NRC) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual as well as against the facility licensee. Action against the individual, however, will not be taken if the improper action by the individual was caused by management failures. The following examples of situations illustrate this concept:

- Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee.

- Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.

- Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.

- Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

- Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Listed below are examples of situations which could result in enforcement actions involving individuals, licensed or unlicensed. If the actions described in these examples are taken by a licensed operator or taken deliberately by an unlicensed individual, enforcement action may be taken directly against the individual. However, violations involving willful conduct not amounting to deliberate action by an unlicensed individual in these situations may result in enforcement action against a licensee that may impact an individual. The situations include, but are not limited to, violations that involve:

- Willfully causing a licensee to be in violation of NRC requirements.

- Willfully taking action that would have caused a licensee to be in violation of NRC requirements but the action did not do so because it was detected and corrective action was taken.

- Recognizing a violation of procedural requirements and willfully not taking corrective action.

- Willfully defeating alarms which have safety significance.

- Unauthorized abandoning of reactor controls.

- Dereliction of duty.

- Falsifying records required by NRC regulations or by the facility licensee.

- Willfully providing, or causing a licensee to provide, an NRC inspector or investigator with inaccurate or incomplete information on a matter material to the NRC.

- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization.

- Submitting false information and as a result gaining unescorted access to a nuclear power plant.

- Willfully providing false data to a licensee by a contractor or other person who provides test or other services, when the data affects the licensee's compliance with 10 CFR part 50, appendix B, or other regulatory requirement.

- Willfully providing false certification that components meet the requirements of their intended use, such as ASME Code.

- Willfully supplying, by vendors of equipment for transportation of radioactive material, casks that do not comply with their certificates of compliance.

- Willfully performing unauthorized bypassing of required reactor or other facility safety systems.

- Willfully taking actions that violate Technical Specification Limiting Conditions for Operation or other license conditions (enforcement action for a willful violation will not be taken if that violation is the result of action taken following the NRC's decision to forego enforcement of the Technical Specification or other license condition or if the operator meets the requirements of 10 CFR 50.54 (x), i.e., unless the operator acted unreasonably considering all the relevant circumstances surrounding the emergency.)

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In deciding whether to issue an enforcement action to an unlicensed person rather than to the licensee, the NRC recognizes that judgments will have to be made on a case by case basis. In making these decisions, the NRC will consider factors such as the following:

1. The level of the individual within the organization.
2. The individual's training and experience as well as knowledge of the potential consequences of the wrongdoing.
3. The safety consequences of the misconduct.
4. The benefit to the wrongdoer, e.g., personal or corporate gain.

5. The degree of supervision of the individual, i.e., how closely is the individual monitored or audited, and the likelihood of detection (such as a radiographer working independently in the field as contrasted with a team activity at a power plant).

6. The employer's response, e.g., disciplinary action taken.

7. The attitude of the wrongdoer, e.g., admission of wrongdoing, acceptance of responsibility.

8. The degree of management responsibility or culpability.

9. Who identified the misconduct.

Any proposed enforcement action involving individuals must be issued with the concurrence of the appropriate Deputy Executive Director. The Commission will be consulted prior to issuing a civil penalty or order to an unlicensed individual or a civil penalty to a licensed reactor operator. Prior notice will be given to the Commission on Notices of Violation without civil penalties that are issued to unlicensed individuals and enforcement actions taken against other unlicensed persons, such as corporations or partnerships. The particular sanction to be used should be determined on a case-by-case basis.*

Examples of sanctions that may be appropriate against individuals are:

- Issuance of a letter of reprimand.
- Issuance of a Notice of Violation, and
- Issuance of Orders.

Orders to NRC-licensed reactor operators may involve suspension for a specified period, modification, or revocation of their individual licenses. Orders to unlicensed individuals might include provisions that would:

- Prohibit involvement in NRC licensed activities for a specified period of time (normally the period of suspension would not exceed five years) or until certain conditions are satisfied, e.g., completing specified training or meeting certain qualifications.
- Require notification to the NRC before resuming work in licensed activities.
- Require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order.

In the case of a licensed operator's failure to meet applicable fitness-for-duty requirements (10 CFR 55.53(j)), the NRC may issue a Notice of Violation or a civil penalty to the Part 55 licensee, or an order to suspend, modify, or revoke the Part 55 license. These actions may be taken the first time a licensed operator fails a drug or alcohol test, that is, receives a confirmed positive test that exceeds the cutoff levels of 10 CFR part 26 or the facility licensee's cutoff levels, if lower. However, normally only a Notice of Violation will be issued for the first confirmed positive test in the absence of aggravating circumstances such as errors in the performance of licensed duties or evidence of prolonged use. In addition, the NRC intends to issue an order to suspend the Part 55 license for up to three years the second time a licensed operator exceeds those cutoff levels. In the event there are less than three years remaining in the term of the individual's license, the NRC may consider not renewing the individual's license or not issuing a new license after the three year period is completed. The NRC intends to issue an order to revoke the Part 55 license the third time a licensed operator exceeds those cutoff levels. A licensed operator or applicant who refuses to participate in the drug and alcohol testing programs established by the facility licensee or

* Except for individuals subject to civil penalties under section 206 of the Energy Reorganization Act of 1974, as amended, NRC will not normally impose a civil penalty against an individual. However, section 234 of the Atomic Energy Act (AEA) gives the Commission authority to impose civil penalties on "any person." "Person" is broadly defined in Section 11a of the AEA to include individuals, a variety of organizations, and any representatives or agents. This gives the Commission authority to impose civil penalties on employees of licensees or on separate entities when a violation of a requirement directly imposed on them is committed.

who is involved in the sale, use, or possession of an illegal drug is also subject to license suspension, revocation, or denial.

In addition, the NRC may take enforcement action against a licensee that may impact an individual, where the conduct of the individual places in question the NRC's reasonable assurance that licensed activities will be properly conducted. The NRC may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, appropriate enforcement actions may be taken regarding matters that raise issues of integrity, competence, fitness for duty, or other matters that may not necessarily be a violation of specific Commission requirements.

In the case of an unlicensed person, whether a firm or an individual, an order modifying the facility license may be issued to require (1) the removal of the person from all licensed activities for a specified period of time or indefinitely, (2) prior notice to the NRC before utilizing the person in licensed activities, or (3) the licensee to provide notice of the issuance of such an order to other persons involved in licensed activities making reference industries. In addition, orders to employers might require retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities.

IX. Inaccurate and Incomplete Information

A violation of the regulations involving submittal of incomplete and/or inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The 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 normally will be categorized based on the guidance herein, in Section IV "Severity of Violations," and in Supplement VII.

The Commission recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Commission must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given

to such factors as (1) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience, (2) the opportunity and time available prior to the communication to assure 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 which was wrong or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the NRC by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee thereby permitting an opportunity to correct the oral information, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue a Notice of Violation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the NRC or the licensee 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 prior to reliance by the NRC, or before the NRC raised 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 it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new

information became available or the advancement in technology was made, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee 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 later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions is not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

X. Enforcement Action Against Non-Licensees

The Commission's enforcement policy is also applicable to non-licensees, including employees of licensees, to contractors and subcontractors, and to employees of contractors and subcontractors, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation. The prohibitions and sanctions for any of these persons who engage in deliberate misconduct or submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct, e.g., 10 CFR 30.10 and 50.5.

Vendors of products or services provided for use in nuclear activities are subject to certain requirements designed to ensure that the products or services supplied that could affect safety are of high quality. Through procurement contracts with reactor licensees, vendors may be required to have quality assurance programs that meet applicable requirements including 10 CFR part 50, appendix B, and 10 CFR part 71, subpart H. Vendors supplying products or services to reactor materials, and 10 CFR part 71 licensees are subject to the requirements of 10 CFR part 21 regarding reporting of defects in basic components.

When inspections determine that violations of NRC requirements have occurred, or that vendors have failed to fulfill contractual commitments (e.g., 10 CFR part 50, appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken. Notices of Violation and civil penalties will be used, as appropriate, for licensee failures to ensure that their vendors have programs that meet applicable requirements. Notices of Violation will be issued for vendors that violate 10 CFR part 21. Civil penalties will be imposed against individual directors or responsible officers of a vendor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(b)(1). Notices of Nonconformance will be used for vendors which fail to meet commitments related to NRC activities.

XI. Referrals to the Department of Justice

Alleged or suspected criminal violations of the Atomic Energy Act (and of other relevant Federal laws) are referred to the Department of Justice (DOJ) for investigation. Referral to the DOJ does not preclude the NRC from taking other enforcement action under this policy. However, enforcement actions will be coordinated with the DOJ in accordance with the Memorandum of Understanding between the NRC and the DOJ, 53 FR 50317 (December 14, 1988).

XII. Public Disclosure of Enforcement Actions

Enforcement actions and licensee responses, in accordance with 10 CFR 2.790, are publicly available for inspection. In addition, press releases are generally issued for orders and civil penalties and are issued at the same time the order or proposed imposition of the civil penalty is issued. In addition, press releases are usually issued when a proposed civil penalty is withdrawn or substantially mitigated by some amount. Press releases are not normally issued for Notices of Violation that are not accompanied by orders or proposed civil penalties.

XIII. Reopening Closed Enforcement Actions

If significant new information is received or obtained by NRC which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the appropriate Deputy Executive Director.

Supplement I—Reactor Operations

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of reactor operations.

A. *Severity Level I*—Violations involving for example:

1. A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications being exceeded;

2. A system⁹ designed to prevent or mitigate a serious safety event not being able to perform its intended safety function¹⁰ when actually called upon to work;

3. An accidental criticality; or

4. A licensed operator at the controls of a nuclear reactor, or a senior operator directing licensed activities, involved in procedural errors which result in, or exacerbate the consequences of, an alert or higher level emergency and who, as a result of subsequent testing, receives a confirmed positive test result for drugs or alcohol.

B. *Severity Level II*—Violations involving for example:

1. A system designed to prevent or mitigate serious safety events not being able to perform its intended safety function;

2. A licensed operator involved in the use, sale, or possession of illegal drugs or the consumption of alcoholic beverages, within the protected area; or

3. A licensed operator at the control of a nuclear reactor, or a senior operator directing licensed activities, involved in procedural errors and who, as a result of subsequent testing, receives a confirmed positive test result for drugs or alcohol.

C. *Severity Level III*—Violations involving for example:

1. A significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In a pressurized water reactor, in the applicable modes, having one high-

⁹ The term "system" as used in these supplements, includes administrative and managerial control systems, as well as physical systems.

¹⁰ "Intended 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.

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pressure safety injection pump inoperable for a period in excess of that allowed by the action statement; or

(b) In a boiling water reactor, one primary containment isolation valve inoperable for a period in excess of that allowed by the action statement.

2. A system designed to prevent or mitigate a serious safety event:

(a) Not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available; materials or components not environmentally qualified); or

(b) Being degraded to the extent that a detailed evaluation would be required to determine its operability (e.g., component parameters outside approved limits such as pump flow rates, heat exchanger transfer characteristics, safety valve lift setpoints, or valve stroke times);

3. Inattentiveness to duty on the part of licensed personnel;

4. Changes in reactor parameters that cause unanticipated reductions in margins of safety;

5. A significant failure to meet the requirements of 10 CFR 50.59, including a failure such that a required license amendment was not sought;

6. A licensee failure to conduct adequate oversight of vendors resulting in the use of products or services that are of defective or indeterminate quality and that have safety significance;

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities; or

8. A licensed operator's confirmed positive test for drugs or alcohol that does not result in a Severity Level I or II violation.

9. Equipment failures caused by inadequate or improper maintenance that substantially complicates recovery from a plant transient.

D. Severity Level IV—Violations involving for example:

1. A less significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In a pressurized water reactor, a 5% deficiency in the required volume of the condensate storage tank; or

(b) In a boiling water reactor, one subsystem of the two independent MSIV leakage control subsystems inoperable;

2. A failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation;

3. A failure to meet regulatory requirements that have more than minor safety or environmental significance; or

4. A failure to make a required Licensee Event Report.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement II—Part 50 Facility Construction

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of part 50 facility construction.

A. Severity Level I—Violations involving structures or systems that are completed¹¹ in such a manner that they would not have satisfied their intended safety related purpose.

B. Severity Level II—Violations involving for example:

1. A breakdown in the Quality Assurance (QA) program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). These deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

C. Severity Level III—Violations involving for example:

1. A deficiency in a licensee QA program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). This significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. A failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

¹¹ The term "completed" as used in this supplement means completion of construction including review and acceptance by the construction QA organization.

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A failure to make a required 10 CFR 50.55(e) report.

D. Severity Level IV—Violations involving failure to meet regulatory requirements including one or more Quality Assurance Criterion not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement III—Safeguards

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of safeguards.

A. Severity Level I—Violations involving for example:

1. An act of radiological sabotage in which the security system did not function as required and, as a result of the failure, there was a significant event, such as:

(a) A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications, was exceeded;

(b) A system designed to prevent or mitigate a serious safety event was not able to perform its intended safety function when actually called upon to work; or

(c) An accidental criticality occurred;

2. The theft, loss, or diversion of a formula quantity¹³ of special nuclear material (SNM); or

3. Actual unauthorized production of a formula quantity of SNM.

B. Severity Level II—Violations involving for example:

1. The entry of an unauthorized individual¹⁴ who represents a threat into a vital area¹⁵ from outside the protected area; or

2. The theft, loss or diversion of SNM of moderate strategic significance¹⁶ in which the security system did not function as required; or

3. Actual unauthorized production of SNM.

¹³ See 10 CFR 73.2 for the definition of "formula quantity."

¹⁴ The term "unauthorized individual" as used in this supplement means someone who was not authorized for entrance into the area in question, or not authorized to enter in the manner entered.

¹⁵ The phrase "vital area" as used in this supplement includes vital areas and material access areas.

¹⁶ See 10 CFR 73.2 for the definition of "special nuclear material of moderate strategic significance."

C. Severity Level III—Violations involving for example:

1. A failure or inability to control access through established systems or procedures such that an unauthorized individual (i.e., not authorized unescorted access to protected area) could easily gain undetected access¹⁶ into a vital area from outside the protected area;

2. A failure to conduct any search at the access control point or conducting an inadequate search that resulted in the introduction to the protected area of firearms, explosives, or incendiary devices and reasonable facsimiles thereof that could significantly assist radiological sabotage or theft of strategic SNM;

3. A failure, degradation, or other deficiency of the protected area intrusion detection or alarm assessment systems such that an unauthorized individual who represents a threat could predictably circumvent the system or defeat a specific zone with a high degree of confidence without insider knowledge, or other significant degradation of overall system capability;

4. A significant failure of the safeguards systems designed or used to prevent or detect the theft, loss, or diversion of strategic SNM;

5. A failure to protect or control classified or safeguards information considered to be significant while the information is outside the protected area and accessible to those not authorized access to the protected area;

6. A significant failure to respond to an event either in sufficient time to provide protection to vital equipment or strategic SNM, or with an adequate response force;

7. A failure to perform an appropriate evaluation or background investigation so that information relevant to the access determination was not obtained or considered and as a result a person, who would likely not have been granted access by the licensee, if the required investigation or evaluation had been performed, was granted access; or

8. A breakdown in the security program involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

1. A failure or inability to control access such that an unauthorized individual (i.e., authorized to protected area but not to vital area) could easily gain undetected access into a vital area from inside the protected area or into a controlled access area;

2. A failure to respond to a suspected event in either a timely manner or with an adequate response force;

3. A failure to implement 10 CFR parts 25 and 95 with respect to the information addressed under section 142 of the Act, and the NRC approved security plan relevant to those parts;

4. A failure to make, maintain, or provide log entries in accordance with 10 CFR 73.71 (c) and (d), where the omitted information (i) is not otherwise available in easily retrievable records, and (ii) significantly contributes to the ability of either the NRC or the licensee to identify a programmatic breakdown;

5. A failure to conduct a proper search at the access control point;

6. A failure to properly secure or protect classified or safeguards information inside the protected area which could assist an individual in an act of radiological sabotage or theft of strategic SNM where the information was not removed from the protected area;

7. A failure to control access such that an opportunity exists that could allow unauthorized and undetected access into the protected area but which was neither easily or likely to be exploitable;

8. A failure to conduct an adequate search at the exit from a material access area;

9. A theft or loss of SNM of low strategic significance that was not detected within the time period specified in the security plan, other relevant document, or regulation; or

10. Other violations that have more than minor safeguards significance.

E. Severity Level V—Violations that have minor safeguards significance.

¹⁶ In determining whether access can be easily gained, factors such as predictability, identifiability, and ease of passage should be considered.

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Supplement IV—Health Physics (10 CFR Part 20)

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of health physics, 10 CFR part 20.¹⁷ Examples A through E are provided to accompany §§ 20.1–20.601. Examples F through J are provided to accompany §§ 20.1001–20.2401.

Sections 20.1–20.601

A. Severity Level I—Violations involving for example:

1. A single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rads to the skin of the whole body, or 375 rads to the feet, ankles, hands, or forearms;
2. An annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
3. A release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106¹⁸;
4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or
5. An exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity Level II—Violations involving for example:

1. A single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;
2. An annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
3. A release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;
4. A failure to make an immediate notification as required by 10 CFR 20.403 (a)(1) and (a)(2);
5. A disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303; or
6. An exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity Level III—Violations involving for example:

1. A single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;
2. A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;
3. A failure to make a 24-hour notification as required by 10 CFR 20.403(b), or an immediate notification required by 10 CFR 20.402(a);
4. A substantial potential for an exposure or release in excess of 10 CFR part 20 whether or not such exposure or release occurs;
5. A release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;
6. An improper disposal of licensed material not covered in Severity Levels I or II;
7. An exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103;
8. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for significant exposure to members of the public, or that reflects a programmatic (rather than isolated) weakness in the radiation control program;
9. A cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
10. Conduct of licensee activities by a technically unqualified person;
11. A significant failure to control licensed material; or
12. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

1. Exposures in excess of the limits of 10 CFR 20.101 not constituting Severity Level I, II, or III violations;
2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;
3. A failure to make a 30-day notification required by 10 CFR 20.405;
4. A failure to make a follow-up written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or
5. Any other matter that has more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Sections 20.1001–20.2401

F. Severity Level I—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
 2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;
 3. A radiation exposure during any year of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems 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 1.0 rem total effective dose equivalent;
 5. A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public as described in 10 CFR 20.1302(b)(2)(i); or
 6. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of 10 CFR 20.2003.
- G. Severity Level II—Violations involving for example:
1. A radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
 2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 1.0 rem total effective dose equivalent;

¹⁷ Personnel overexposures and associated violations incurred during a life-saving or other emergency response effort will be treated on a case-by-case basis.

¹⁸ The reference to the limits of 10 CFR 20.106 as used in this supplement (Items A, B, C, and C-5) does not apply to the EPA generally applicable environmental radiation standards mentioned in § 20.106(g).

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3. A radiation exposure during any year of a minor in excess of 1 rem total effective dose equivalent: 3.0 rems to the lens of the eye, or 10 rems 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 0.5 rem total effective dose equivalent;

5. A release of radioactive material to an unrestricted area at concentrations in excess of 10 times the limits for members of the public as described in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c)).

6. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.2003, or

7. A failure to make an immediate notification as required by 10 CFR 20.2202 (a)(1) or (a)(2).

H. Severity Level III—Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 0.5 rem total effective dose equivalent (except when doses are in accordance with the provisions of § 20.1208(d));

3. A radiation exposure during any year of a minor in excess of 0.5 rem total effective dose equivalent: 1.5 rems to the lens of the eye, or 5 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. A worker exposure above regulatory limits when such exposure reflects a programmatic (rather than an isolated) weakness in the radiation control program;

5. An annual exposure of a member of the public in excess of 0.1 rem total effective dose equivalent (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

6. A release of radioactive material to an unrestricted area at concentrations in excess of two times the effluent concentration limits referenced in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

7. 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);

8. A substantial potential for exposures or releases in excess of the applicable limits in 10 CFR part 20 §§ 20.1001–20.2401 whether or not an exposure or release occurs;

9. Disposal of licensed material not covered in Severity Levels I or II;

10. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public, or that reflects a programmatic (rather than an isolated) weakness in the radiation control program;

11. Conduct of licensee activities by a technically unqualified person;

12. A significant failure to control licensed material; or

13. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

I. Severity Level IV—Violations involving for example:

1. Exposures in excess of the limits of 10 CFR 20.1201, 20.1207, or 20.1208 not constituting Severity Level I, II, or III violations;

2. A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public as referenced in 10 CFR 20.1302(b)(2)(i) (except when operation up to 0.5 rem a year has been approved by the Commission under § 20.1301(c));

3. A radiation dose rate in an unrestricted or controlled area in excess of 0.002 rem in any 1 hour (2 millirem/hour) or 50 millirems in a year;

4. Failure to maintain and implement radiation programs to keep radiation exposures as low as is reasonably achievable;

5. Doses to a member of the public in excess of any EPA generally applicable environmental radiation standards, such as 40 CFR part 190;

6. A failure to make the 30-day notification required by 10 CFR 20.2201(a)(1)(ii) or 20.2203(a);

7. A failure to make a timely written report as required by 10 CFR 20.2201(b), 20.2204, or 20.2206; or

8. Any other matter that has more than a minor safety, health, or environmental significance.

J. Severity Level V—Violations that are of a minor safety, health, or environmental significance.

Supplement V—Transportation

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of NRC transportation requirements.¹⁹

A. Severity Level I—Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that the material caused a radiation exposure to a member of the public and there was clear potential for the public to receive more than .1 rem to the whole body;

2. Surface contamination in excess of 50 times the NRC limit; or

3. External radiation levels in excess of 10 times the NRC limit.

B. Severity Level II—Violations involving for example:

1. Failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that there was a clear potential for the member of the public to receive more than .1 rem to the whole body;

2. Surface contamination in excess of 10, but not more than 50 times the NRC limit;

3. External radiation levels in excess of five, but not more than 10 times the NRC limit; or

¹⁹ Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

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4. A failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity Level III—Violations involving for example:

1. Surface contamination in excess of five but not more than 10 times the NRC limit;

2. External radiation in excess of one but not more than five times the NRC limit;

3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in 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; or

(c) A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material;

4. A failure to make required initial notification associated with Severity Level III violations; or

5. A breakdown in the licensee's program for the transportation of licensed material involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

1. A breach of package integrity without external radiation levels exceeding the NRC limit or without contamination levels exceeding five times the NRC limits;

2. Surface contamination in excess of but not more than five times the NRC limit;

3. A failure to register as an authorized user of an NRC-Certified Transport package;

4. A noncompliance with shipping papers, marking, labeling, placarding, packaging or loading not amounting to a Severity Level I, II, or III violation;

5. A failure to demonstrate that packages for special form radioactive material meets applicable regulatory requirements;

6. A failure to demonstrate that packages meet DOT Specifications for 7A Type A packages; or

7. Other violations that have more than minor safety or environmental significance.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement VI—Fuel Cycle and Materials Operations

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations.

A. Severity Level I—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;

2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function;

3. A nuclear criticality accident; or

4. A failure to follow the procedures of the quality management program, required by § 35.32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient.

B. Severity Level II—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license;

2. A system designed to prevent or mitigate a serious safety event being inoperable; or

3. A substantial programmatic failure in the implementation of the quality management program required by 10 CFR 35.32 that results in a misadministration.

C. Severity Level III—Violations involving for example:

1. A failure to control access to licensed materials for radiation purposes as specified by NRC requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified person;

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license;

6. Substantial failure to implement the quality management program as required by § 35.32 that does not result in a misadministration; failure to report a misadministration; or programmatic weakness in the implementation of the quality management program that results in a misadministration.

7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities;

8. A failure, during radiographic operations, to have present or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by 10 CFR part 34;

9. A failure to submit an NRC Form 241 in accordance with the requirements in § 150.20 of 10 CFR part 150; or

10. A failure to receive required NRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance.

D. Severity Level IV—Violations involving for example:

1. A failure to maintain patients hospitalized who have cobalt-60, cesium-137, or indium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety or environmental significance; or

3. Failure to follow the quality management program, including procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by § 35.32; or

4. A failure to keep the records required by §§ 35.32 or 35.33.

E. Severity Level V—Violations that have minor safety or environmental significance.

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Supplement VII—Miscellaneous Matters

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations involving miscellaneous matters.

A. Severity Level I—Violations involving for example:

1. Inaccurate or incomplete information²⁰ that is provided to the NRC (a) deliberately with the knowledge of a licensee official that the information is incomplete or inaccurate, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety.

2. Incomplete or inaccurate information that the NRC requires be kept by a licensee that is (a) incomplete or inaccurate because of falsification by or with the knowledge of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations.

3. Information that the licensee has identified as having significant implications for public health and safety or the common defense and security ("significant information identified by a licensee") and is deliberately withheld from the Commission.

4. Action by senior corporate management in violation of 10 CFR 50.7 or similar regulations against an employee.

5. A knowing and intentional failure to provide the notice required by 10 CFR part 21, or

6. A failure to substantially implement the required fitness-for-duty program.²¹

B. Severity Level II—Violations involving for example:

1. Inaccurate or incomplete information that is provided to the NRC (a) by a licensee official because of careless disregard for the completeness or accuracy of the information, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;

2. Incomplete or inaccurate information that the NRC requires be kept by a licensee which is (a) incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;

3. Significant information identified by a licensee and not provided to the Commission because of careless disregard on the part of a licensee official;

4. An action by plant management above first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee;

5. A failure to provide the notice required by 10 CFR part 21;

6. A failure to remove an individual from unescorted access who has been involved in the sale, use, or possession of illegal drugs within the protected area or take action for on duty misuse of alcohol, prescription drugs, or over-the-counter drugs;

7. A failure to take reasonable action when observed behavior within the protected area or credible information concerning activities within the protected area indicates possible unfitness for duty based on drug or alcohol use; or

8. A deliberate failure of the licensee's Employee Assistance Program (EAP) to notify licensee's management when EAP's staff is aware that an individual's condition may adversely affect safety related activities.

C. Severity Level III—Violations involving for example:

1. Incomplete or inaccurate information that is provided to the NRC (a) because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;

2. Incomplete or inaccurate information that the NRC requires be kept by a licensee that is (a) incomplete or inaccurate because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate when reviewed by the NRC, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;

3. A failure to provide "significant information identified by a licensee" to the Commission and not amounting to a Severity Level I or II violation;

4. An action by first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee;

5. An inadequate review or failure to review such that, if an appropriate review had been made as required, a 10 CFR part 21 report would have been made;

6. A failure to complete a suitable inquiry on the basis of 10 CFR part 26, keep records concerning the denial of access, or respond to inquiries concerning denials of access so that, as a result of the failure, a person previously denied access for fitness-for-duty reasons was improperly granted access;

7. A failure to take the required action for a person confirmed to have been tested positive for illegal drug use or take action for onsite alcohol use; not amounting to a Severity Level II violation;

8. A failure to assure, as required, that contractors or vendors have an effective fitness-for-duty program; or

9. A breakdown in the fitness-for-duty program involving a number of violations of the basic elements of the fitness-for-duty program that collectively reflect a significant lack of attention or carelessness towards meeting the objectives of 10 CFR 26.10.

²⁰ In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference should also be made to the guidance in Section IX, "Inaccurate and Incomplete Information," and to the definition of "licensee official" contained in Section IV.C.

²¹ The example for violations for fitness-for-duty relate to violations of 10 CFR part 26.

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D. Severity Level IV—Violations involving for example:

1. Incomplete or inaccurate information of more than minor significance that is provided to the NRC but not amounting to a Severity Level I, II, or III violation;
2. Information that the NRC requires be kept by a licensee and that is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation;
3. An inadequate review or failure to review under 10 CFR part 21 or other procedural violations associated with 10 CFR part 21 with more than minor safety significance;
4. Isolated failures to meet basic elements of the fitness-for-duty program not involving a Severity Level I, II, or III violation; or
5. A failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.73.

E. Severity Level V—Violations involving for example:

1. Incomplete or inaccurate information that is provided to the Commission and the incompleteness or inaccuracy is of minor significance;
2. Information that the NRC requires be kept by a licensee that is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance;
3. Minor procedural requirements of 10 CFR part 21; or
4. Minor violations of fitness-for-duty requirements.

Supplement VIII—Emergency Preparedness

This supplement provides examples of violations in each of the five severity levels as guidance in determining the appropriate severity level for violations in the area of emergency preparedness. It should be noted that citations are not normally made for violations involving emergency preparedness occurring during emergency exercises. However, where exercises reveal (i) training, procedural, or repetitive failures for which corrective actions have not been taken, (ii) an overall concern regarding the licensee's ability to implement its plan in a manner that adequately protects public health and safety, or (iii) poor self critiques of the licensee's exercises, enforcement action may be appropriate.

A. Severity Level I—Violations involving for example:

In a general emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff.)

B. Severity Level II—Violations involving for example:

In a site emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

2. A licensee failure to meet or implement one emergency planning standard involving assessment or notification; or

C. Severity Level III—Violations involving for example:

In an alert, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);

2. A licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

3. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations involving for example:

A licensee failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.

E. Severity Level V—Violations that have minor safety or environmental significance.