

102



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 7, 1991

The Honorable Lane Evans, Chairman
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
United States House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

I am responding to your letter dated November 19, 1990, concerning the November 1, 1990 radioactive contamination incident at the San Diego, California Veterans Affairs Medical Center (licensee or VAMC/SD). While it is indeed fortunate that the amount of material released was small and subsequent analysis has shown that no significant public health and safety hazard resulted, any unplanned release of radioactive materials poses a potential threat to public health and safety. The Commission believes that it is prudent in such cases to cease the activities that led to the release until the contributing causal factors are understood and appropriate corrective measures are in place to prevent recurrence.

Shortly after the incident was reported, the Nuclear Regulatory Commission (NRC) and VAMC/SD initiated a review of the incident and took precautionary actions appropriate under the circumstances as they were understood at that time. On November 2, 1990, the licensee management, on its own initiative, closed the laboratories associated with the incident to permit a safe and orderly cleanup of the contamination and to allow investigation of the incident to determine the cause and to identify appropriate corrective actions. On November 5, 1990, the Director of VAMC/SD and our Region V office mutually agreed that the laboratory closure should be limited only to those laboratories utilized by the two principal parties involved in the incident. It was further agreed that VAMC/SD should review the results of its investigation with Region V no later than November 30, 1990. This decision did not affect any of the other 53 principal VAMC/SD investigators (researchers), whose activities were not suspended.

At the request of the licensee, the review was postponed until December 3, 1990, when a telephone conference was conducted. During the teleconference, licensee representatives described their findings of probable cause and their corrective actions. They also announced their intention to resume the use of licensed radioactive material in the laboratories closed on November 2, 1990. Based on the licensee's short-term corrective actions, the NRC representatives concurred in this decision. It is our understanding that the laboratories have resumed full operation.

Subsequent to your letter, a nuclear medicine misadministration occurred at VAMC/SD on November 26, 1990, under circumstances that again raise concerns about the licensee's control of radioactive materials. The misadministration

9101110279 XA

220616

910123

DFR
11

involved a diagnostic use of radioactive materials resulting in unnecessary radiation exposure to the patient and an overexposure to the physician who administered the radiopharmaceutical. This misadministration and the November 1, 1990 contamination incident suggest failure of VAMC/SD personnel to follow established health and safety procedures. We are actively reviewing both incidents to determine whether a programmatic problem in radiation safety exists at VAMC/SD.

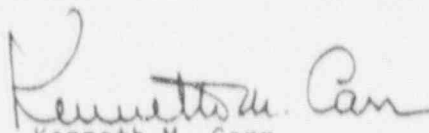
We have records of three similar contamination incidents involving medical or hospital licensees in which the initial response from the NRC was a Confirmatory Action Letter, as with VAMC/SD. One case involved the contamination of two research laboratories resulting in a Severity Level II violation. Two other licensees also have received Confirmatory Action Letters prior to being given notices of violation at Severity Level II with civil penalties of \$24,000. For your information, we have enclosed a copy of NRC's enforcement policy in Appendix C to 10 CFR Part 2.

I want to emphasize that the regulatory importance of these recent incidents at VAMC/SD and elsewhere lies in the unplanned release of radioactive material. Any such release which has the potential to jeopardize public health and safety requires prompt regulatory attention. NRC's inspection and enforcement activities are designed to ensure that the causes of violations which have the potential for significant releases or overexposures are understood and fully corrected.

You asked for a comparison of the risks posed by the November 1, 1990 unplanned release of radioactive material at VAMC/SD to commonplace risks. Based on assessments prepared by the licensee and the NRC staff, the doses to patients and employees from this release were all negligible (e.g., less than one millirem effective dose equivalent). The Commission has recognized the benefits of reducing regulatory oversight where activities result in the planned and verifiable release of such very low levels of radiation and recently issued a Below Regulatory Concern (BRC) Policy Statement for exemptions from regulatory control involving such releases. A copy of this statement (Enclosure 2) and a companion booklet (Enclosure 3) are enclosed for your information. Your support for this approach is appreciated.

The Commission remains committed to the proper regulation of radioactive materials under its jurisdiction based on the risks that those materials pose to public health and safety. I hope our comments will help resolve your concerns about the consistency of NRC's policies, procedures, and actions related to the issuance of the Confirmatory Action letter to the VAMC/SD.

Sincerely,


Kenneth M. Carr

Enclosures:

1. 10 CFR Part 2, Appendix C
2. BRC Policy Statement
3. BRC Explanatory Booklet

cc: Representative Bob Stump

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

expeditious action on the petitions. In addition, the Handbook notes general scheduling advice that proposed rules to grant petitions should be published in 5-12 months after acceptance and publication for comment. Proposed rules will be forwarded to the Commission on a 6-month schedule to the extent permitted by resource limits, the nature and extent of public comments, and internal Control of Rulemakings procedures. Rulemakings involving power reactors must be reviewed by the Committee on Review of Generic Requirements prior to publication. Proposed rules involving reactors will therefore be forwarded to the Commission on a 7-month schedule to the extent permitted by resources, comments, and approval procedures. In both cases, every effort will be made to publish proposed rules no later than 12 months after noticing for public comment.

Although the procedures in Part 31 of NUREG/BR-0053 include fast track processing, the nature of the anticipated petitions do not fully comply with the decision criteria to follow this alternative.

Some of the key features of the handling procedures include the following steps for complete and fully supported petitions.

1. Petitioners may confer on procedural matters with the staff before filing a petition for rulemaking. Requests to confer on procedural matters should be addressed to: The Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Chief, Rules and Procedures Branch.

2. Petitions should be addressed to: The Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Docketing and Service Branch. In keeping with 10 CFR 2.802(f), petitioners will be promptly informed if the petition meets the threshold requirements for a petition for rulemaking in 10 CFR 2.802(c) and can be processed in accordance with this implementation plan. Ordinarily this determination will be made within 30 days after receipt of the petition.

3. Following this determination, the petition will be noticed in the **Federal Register** for a public comment period of at least 60 days.

4. The petitioner will be provided copies of all comments received, scheduling information, and periodic status reports.

The procedures in NUREG/BR-0053 also include the process for denial and withdrawal of petitions.

Footnotes

¹ Copies of NUREG/BR-0053, NUREG/BR-0056 and NUREG/CR-3565 may be purchased through the U.S. Government Printing Office by calling (202) 275-2060 or by writing to the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5165 Port Royal Road, Springfield, VA 22181. Copies are available for inspection and/or copying for a fee in the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

² ICRP Publication 46, "Radiation Protection Principles for the Disposal of Solid Radioactive Waste," adopted July 1985.

³ ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," adopted January 17, 1977. ICRP Publication 30, "Limits for Intake of Radionuclides by Workers," adopted July 1978.

⁴ Copies of the United Kingdom's document are available for inspection as enclosures to SECY-85-147A (relating to 10 CFR Part 20) dated July 25, 1985 in the Commission's Public Document Room, 1717 H Street NW, Washington, DC 20555. The United Kingdom documents are available for sale from: Her Majesty's Stationery Office, P.O. Box 569, London SE1 9NH, United Kingdom, as Advice document ASP-7 and a related technical report, "The Significance of Small Doses of Radiation to Members of the Public," NRPB-R175.

⁵ Copies of the Canadian document are available for inspection as an enclosure to SECY-85-147A (relating to 10 CFR Part 20) dated July 25, 1985 in the Commission's Public Document Room, 1717 H Street NW, Washington, DC 20555. The Canadian document was issued as Consultative Document C-85, "The Basis for Exempting the Disposal of Certain Radioactive Materials from Licensing" by the Atomic Energy Control Board, P.O. Box 1046, Ottawa, Ontario, Canada, K1P 5S9.

⁶ ICRP/85/G-03, "Statement from the 1985 Paris Meeting of the International Commission on Radiological Protection," 1985-04-26.

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

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 presiding officers, the Atomic Safety and Licensing Appeal Boards, 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 is appropriate under the circumstances of a particular case.

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

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 vendor¹ 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 or vendors who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects. Each enforcement action is dependent on the circumstances of the 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 which 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 204 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

¹ The term "vendor" means a supplier of products or services to be used in an NRC-licensed facility or activity.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

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 appropriate NRC Office Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed.

The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken is set forth in 10 CFR 2.202. The mechanism for modifying a license by order is set forth in 10 CFR 2.204. These sections of Part 2 provide an opportunity

for a hearing to the affected licensee. However, the NRC is authorized to make orders immediately effective if the public health, safety or interest so requires or, in the case of an order to show cause, if the alleged violation is willful.

III. Severity of Violations

Regulatory requirements² have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

Consequently, violations are 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 not directly covered by one of the above listed areas, e.g., export license activities, will be placed in the activity area most suitable in light of the particular violation involved. 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 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.

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 Reactor Construction. While examples are provided in Supplements I through VIII for determining the appropriate severity level for violations in each of the eight activity areas, the examples are neither exhaustive nor controlling.

² The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

These examples do not create new requirements. Each is designed to illustrate the significance which 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.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsely 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 of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic 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.

The NRC expects licensees to provide full, complete, timely, and accurate 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. 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 which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

IV. Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring nonconformance on the part of a vendor, the NRC will normally hold

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

an enforcement conference with the licensee or vendor prior to taking enforcement action. The NRC may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to (1) discuss the violations or nonconformance, their significance and causes, and the licensee's or vendor's corrective actions; (2) determine whether there are any aggravating or mitigating circumstances; and (3) obtain other information which will help determine the appropriate enforcement action.

In addition, during the enforcement conference, the licensee or vendor will be given an opportunity to explain to the NRC what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or vendors 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 such cases, an enforcement conference may be held after the escalated enforcement action is taken.

V. Enforcement Actions

This section describes the enforcement sanctions available to 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. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, 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, action by an NRC regional office is appropriate in the form of a Notice of Violation requiring a formal response from the recipient describing its corrective actions. In situations involving nonconformance on the part of vendor, a Notice of Nonconformance will be issued. The relatively small number of cases involving elevated

enforcement action receives substantial attention by the public, and may have significant impact on the licensee's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

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 normally requires the recipient to provide a written statement describing (1) corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to prevent recurrence; and (3) the date when full compliance will be achieved. 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.

NRC uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections V.B and V.C, respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

However, violation findings warranting the exercise of discretion under Section V.G.1 will generally not result in a Notice of Violation. In addition, for isolated Severity Level V violations, a notice of violation normally will not be issued regardless of who identifies the violation provided that the licensee has initiated appropriate corrective action before the inspection ends. In these situations, a formal response from the licensee is not required and the inspection report or official field notes serves to document the violations and the corrective actions. However, a notice of violation will normally be issued for willful violations, if past corrective actions for similar violations have not been sufficient to prevent recurrence, or if the circumstances warrant increasing the severity of Level V violations to a higher severity level.

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 (a) certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders, (b) any requirement for which a license may be revoked, or (c) 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.

Civil penalties are proposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar² to previous violations for which the licensee did not take effective corrective action.

In applying this guidance for Severity Level III violations, NRC may, notwithstanding the mitigating and escalating factors in this section, refrain from proposing a civil penalty for violations that warrant the exercise of discretion under Section V.G. As to Severity Level IV violations, NRC normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act, and for any willful violation of any Commission requirement including those at any severity level.

NRC imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the basic civil penalties for various reactor, fuel cycle, and materials programs. 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 such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed

² The word "similar," as used in this policy, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amount of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, NRC will consider as necessary an increase or decrease on a case-by-case basis.

NRC attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, NRC intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$100,000 per violation, per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

NRC reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances, adjustments to these values may be made for the factors described below:

1. Identification and Reporting

Reduction of up to 50% of the base civil penalty shown in Table 1 may be given when a licensee identifies the violation and promptly reports the violation to the NRC. In weighing this factor, consideration will be given to, among other things, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required

report. No consideration will be given to a reduction in penalty if the licensee does not take immediate action to correct the problem upon discovery. On the other hand, the base penalty may be increased by as much as 50% if the NRC identifies the violation provided the licensee should have reasonably discovered the violation before the NRC identified it.

2. Corrective Action To Prevent Recurrence

Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may result in up to a 50% increase or decrease in the base civil penalty shown in Table 1. For example, very extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 50% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action—such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

3. Past Performance

Reduction by as much as 100% of the base civil penalty shown in Table 1 may be given for prior good performance. On the other hand, the base civil penalty may be increased as much as 100% for prior poor performance.

In weighing this factor, 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 prior performance including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty. For purpose of assessing past performance, violations within the past two years of the inspection at issue or the period within the last two inspections whichever is longer will be considered.

4. Prior Notice of Similar Events

The base civil penalty may be increased as much as 100% for cases where the licensee had prior knowledge of a potential problem as a result of a licensee review, a specific NRC or industry notifications or other reasonable indication of a potential problem, and had failed to take effective preventive steps. Prior notice may include findings of NRC, the licensee, or industry made at other facilities of the

licensee where it is reasonable to expect the licensee to take action to prevent similar problems at the facility subject to the enforcement action at issue.

5. Multiple Occurrences

The base civil penalty may be increased as much as 100% where multiple examples of a particular violation are identified during the inspection period.

6. Duration

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

(1) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

(2) If a licensee (a) is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or (b) had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

(3) Alternatively, whether or not a licensee is aware or clearly should have been aware of a violation that continues for more than one day, the base civil penalty may be increased as much as 100% to reflect the added significance resulting from the duration of the violation.

7. Maintenance-Related Cause

The base civil penalty may be increased as much as 50% for cases where a cause of a maintenance-related violation at a power reactor is a programmatic failure. For the purposes of application of this factor, a cause of the violation shall be considered to be maintenance-related if the violation could have been prevented by implementing a maintenance program consistent with the scope and activities defined by the Revised Policy Statement on the Maintenance of Nuclear Power Plants. In assessing this factor, consideration will be given to, among other things, whether a failure to perform maintenance or improperly performed maintenance was a programmatic failure. The degree of the programmatic failure will be considered in applying this factor.

The above factors are additive. However, in no instance will a civil penalty for any one violation exceed \$100,000 per day.

The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted, if an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if

viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required

report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

TABLE 1A—BASE CIVIL PENALTIES

	Plant operations, construction, health physics and EP	Transportation		Type A quantity or less *
		State guards	Greater than type A quantity †	
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 ‡	25,000	* 100,000	25,000	5,000
e. Mills and uranium conversion facilities	10,000		5,000	2,000
f. Industries users of material §	10,000		5,000	2,000
g. Waste disposal licensees	10,000		5,000	2,000
h. Academic or medical institutions ¶	5,000		2,500	1,000
i. Independent spent fuel and monitored retrievable storage installations	25,000	100,000	25,000	5,000
j. Other material licensees	1,000		2,500	1,000

* Includes irradiated fuel, high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.
 † Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.
 ‡ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.
 § This amount refers to Category 1 licensees (as defined in 10 CFR 75.2). Licensed fuel fabricators not authorized to possess Category 1 material have a base penalty amount of \$50,000.
 ¶ Includes industrial radiographers, nuclear pharmacies, and other industrial users.
 ** This applies to nonprofit institutions not otherwise categorized under sections "e" through "g" in this table.

TABLE 1B—BASE CIVIL PENALTIES

Severity Level	Base Civil Penalty Amount
	(Percent of amount listed in Table 1A)
I	100
II	80
III	50
IV	15
V	5

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 and 2.204). Orders may be issued as follows. Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate.

(1) License Modification Orders are issued when some change in licensee equipment, procedures, 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 a licensee does not respond to a notice of violation where a response was required;

(d) When a licensee refuses to pay a fee required by 10 CFR Part 170; 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 licensee on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by NRC that such activity is unauthorized.

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 cause why the order should not be issued in the proposed manner.

D. Escalation of Enforcement Sanctions

NRC considers violations of Severity Level I, II, or III to be serious. If serious violations occur, NRC will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. NRC carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections V.B and V.C.

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. However, 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 + d	a + b + c	d
II	a	a + d	a + b + c
III		a	a + d

- 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. Show cause for modification or revocation of the license, as appropriate.
 d. Further action as appropriate.

E. 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 will normally be taken only when there is little doubt 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, 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.

Examples of situations which could result in enforcement actions against individuals include, but are not limited to, violations which involve:

- Recognizing a violation of procedural requirements and willfully not taking corrective action.
- Willfully performing unauthorized bypassing of required reactor safety systems.
- Willfully defeating alarms which have safety significance.
- Unauthorized abandoning of reactor controls.
- Inattention to duty such as sleeping, being intoxicated while on duty, or otherwise not meeting requirements for fitness for duty.
- Willfully taking actions that violate Technical Specification Limiting Conditions for Operation (enforcement action for a willful violation will not be taken if the operator meets the standards of 10 CFR 50.54(x), i.e., unless the operator acted unreasonably considering all the relevant circumstances surrounding the emergency.)
- Falsifying records required for NRC regulations or by the facility licensee.
- Willfully failing to take "immediate actions" of emergency procedures.
- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel.

Any proposed enforcement action against individuals must be done with the concurrence of the Deputy Executive Director for Regional Operations. The opportunity for an Enforcement Conference with the individual will usually be provided.

Examples of sanctions that may be appropriate against NRC-licensed operators are:

- Issuance of a letter of reprimand to be placed in the operator's license file.

- Issuance of a Notice of Violation, and

- Suspension for a specified period, modification, or revocation of the license.

The sanctions are listed in escalating order of significance.* The particular sanction to be used should be determined on a case-by-case basis.

In addition, NRC may take enforcement action 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, enforcement action 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 individual, an Order modifying the facility license to require the removal of the individual from all nuclear-related activities for a specified period of time or indefinitely may be appropriate.

F. 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 Deputy Executive Director for Regional Operations.

G. Exercise of Discretion

Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, NRC may exercise discretion as follows:

* 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 for violations on "any person." "Person" is broadly defined in section 115 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.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. NRC may refrain from issuing a notice of violation for a violation described in an inspection report or official field notes that meets all of the following criteria:

- a. It was identified by the licensee.
- b. It is normally classified at a Severity Level IV or V.
- c. It was reported, if required.
- d. It was or will be corrected, including measures to prevent recurrence, within a reasonable time, and
- e. It was not a willful violation or a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

2. The NRC may refrain from issuing a notice of violation or a proposed civil penalty for violations described in an inspection report or official field notes that meet all of the following criteria:

- a. (i) The NRC has taken significant enforcement action based upon a major safety event contributing to an extended shut-down of an operating reactor or a material licensee (or a work stoppage at a construction site), or the licensee is forced into an extended shutdown or work stoppage related to generally poor performance over a long period; (ii) the licensee has developed and is aggressively implementing during the shutdown a comprehensive program for problem identification and correction; and (iii) NRC concurrence is needed by the licensee prior to restart;

b. Non-willful violations are identified by the licensee as the result of its comprehensive program, or as a result of an employee allegation to the licensee. If NRC identifies the violation, the NRC should determine whether enforcement action is necessary to achieve remedial action;

c. The violations are based upon activities of the licensee prior to the events leading to the shutdown; and

d. The violations would normally not be categorized as higher than Severity Level III violations under the NRC's Enforcement Policy.

3. The NRC may refrain from proposing a civil penalty for a Severity Level III violation not involving an overexposure or release of radioactive material that meets all of the following criteria:

- a. It was identified by the licensee and reported;
- b. Comprehensive corrective action has been taken or is well underway within a reasonable time following identification;
- c. It was not a violation that either (i) was reasonably preventable by the licensee's action in response to a previous regulatory concern identified

within the past two years of the inspection or since the last two inspections whichever is longer or (ii) reasonably should have been corrected prior to the violation because the licensee had prior notice of the problem involved; and

d. It was not a willful violation or indicative of a breakdown in management controls.

4. The NRC may refrain from proposing a civil penalty for a Severity Level III violation involving a past problem, such as in engineering, design, or installation, that meets the following criteria:

- a. It was identified by a licensee as a result of a licensee's voluntary formal effort such as a Safety System Functional Inspection, Design Reconstitution Program, or other program that has a defined scope and timetable which is being aggressively implemented and reported;
- b. Comprehensive corrective action has been taken or is well underway within a reasonable time following identification; and
- c. It was not likely to be identified by routine licensee efforts such as normal surveillance or QA activities.

5. If the NRC issues an enforcement action for a violation at a Severity Level III violation and as part of the corrective action for that violation, the licensee identifies other examples of the violation with the same root cause, the NRC may refrain from issuing an additional enforcement action. In determining whether to exercise this discretion, the NRC will consider whether the licensee acted reasonably and in a timely manner appropriate to the safety significance of the initial violation, the comprehensiveness of the corrective action, whether the matter was reported, and whether the additional violation(s) substantially change the safety significance or character of the regulatory concern arising out of the initial violation.

Notwithstanding paragraphs 2, 3, 4, and 5 above, a civil penalty may be proposed when judgment warrants it on the basis of the circumstances of the individual case. For example, civil penalties may be warranted where multiple Severity Level III violations are discovered or where the violation is willful. In addition, as provided in Section VIII, Responsibilities, the Deputy Executive Director for Regional Operations may refrain from issuing a civil penalty or a notice of violation for a Severity Level 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 circumstances, if any, that 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.

H. Related Administrative Actions

In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, NRC also uses administrative mechanisms, such as bulletins, information notices, generic letters, notices of deviation, notices of nonconformance, and confirmatory action letters to supplement its enforcement program. 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 licensees to make sure that such commitments are met.

(1) Bulletins, Information Notices, and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

(2) 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.

(3) Confirmatory Action Letters are letters confirming a licensee's or a vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(4) Notices of Nonconformance are written notices describing non-licensee failure 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.

I. Referrals to 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 for

investigation. Referral to the Department of Justice does not preclude the NRC from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Department of Justice to the extent practicable.

VI. Inaccurate and Incomplete Information

A violation of the regulations on submitting complete and accurate 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 III "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. A licensee official for purposes of application of the Enforcement Policy means a first line supervisor or above as well as a licensed individual, radiation safety officer, or a person listed on a license as an authorized user of licensed material. 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 citation 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, 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 in not correcting or providing

information raise questions about its commitment to safety or its fundamental trustworthiness, the Commission may exercise its authority to issue orders modifying, suspending, or revoking the license. The Commission recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described above.

VII. Public Disclosure of Enforcement Actions

In accordance with 10 CFR 2.790, all enforcement actions and licensee responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Level I, II, or III, press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

The Deputy Executive Director for Regional Operations (DEDRO), as the principal enforcement officer of the NRC, has been delegated the authority to issue notices of violations, civil penalties, and orders.⁸ Regional Administrators may also issue notices of violation for Severity Level IV and V violations and may sign notices of violation for Severity Level III violations with no proposed civil penalty and proposed civil penalty actions with the concurrence of the DEDRO. In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, the DEDRO or the Regional Administrator must exercise judgment and discretion 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 such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances.

⁸ The Director, Office of Enforcement, acts for the Deputy Executive Director for Regional Operations in the latter's absence or as directed. The Directors of the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, and Special Projects have also been delegated authority to issue orders, but it is expected that normal use of this authority by NRR, NMSS, and OSP will be confined to actions necessary in the interest of public health and safety. The Director, Office of Administration and Resources Management, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license fees.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. 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) Refraining from taking enforcement action for matters meeting the criteria of Section V.G.2.

(6) Any action the Office Director believes warrants Commission involvement; or

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

IX. Vendor Enforcement

The Commission's enforcement policy is also applicable to non-licensees (vendors). 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 are 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 of reactor and materials licensees and Part 71 licensees are subject to the requirements of 10 CFR Part 21 regarding reporting of defects in basic components.

The NRC conducts inspections of reactor licensees to determine whether they are ensuring that vendors are meeting their contractual obligations with regard to quality of products or services that could have an adverse effect on safety. As part of the effort of ensuring that licensees fulfill their obligations in this regard, the NRC inspects reactor vendors to determine if they are meeting their obligations. These inspections include examination of the quality assurance programs and their implementation by the vendors through examination of product quality.

The NRC may also inspect vendors, including suppliers of Part 71 and materials licensees, to determine whether they are complying with Part 21. When inspections determine that violations of NRC requirements have occurred, or that vendors have failed to fulfill contractual commitments 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 including Part 21. Notices of Violation will be issued for vendors which violate Part 21. Civil penalties will only 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.

Supplement I—Severity Categories

Reactor Operations

A. Severity I—Violations involving for example:

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

2. A system⁴ designed to prevent or mitigate a serious safety event not being able to perform its intended safety function⁵ when actually called upon to work;

3. An accidental criticality; or

4. Release of radioactivity offsite greater than ten (10) times the Technical Specifications limit.⁶

B. Severity 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; or

2. Release of radioactivity offsite greater than five (5) times the Technical Specifications limit.

C. Severity III—Violations involving for example:

1. A significant violation of a Technical Specification Limiting Condition for Operation where the appropriate Action Statement was not satisfied within the time allotted by the Action Statement, such as:

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

3. Dereliction of duty on the part of personnel involved in licensed activities;

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

5. Release of radioactivity offsite greater than the Technical Specifications limit;

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

7. Licensee failure to conduct adequate oversight of vendors resulting in the use of products or services which are of defective or indeterminate quality and which have safety significance; or

8. 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 IV—Violations involving for example:

1. A less significant violation of a Technical Specification Limiting Condition for Operation where the appropriate Action Statement was not satisfied within the time allotted by the Action Statement, 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. Failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation;

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

4. Failure to make a required Licensee Event Report.

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

Supplement II—Severity Categories

Part 50 Facility Construction

A. Severity I—Violations involving a structure or system that is completed⁷ in such a manner that it would not have satisfied its intended safety related purpose.

B. Severity 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). Such 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 III—Violations involving for example:

1. A deficiency in a licensee quality assurance program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). Such 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. Failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

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

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

Supplement III—Severity Categories

Safeguards

A. Severity I—Violations involving for example:

1. An act of radiological sabotage or actual theft, loss, or diversion of a formula quantity of special nuclear material¹⁰ in which the security system did not function as required; or

2. Actual undetected entry of an unauthorized individual¹¹ into a vital area¹² from outside the protected area who represents a threat.

B. Severity II—Violations involving for example:

1. Actual theft, loss or diversion of special nuclear material of moderate strategic significance¹³ in which the security system did not function as required;

2. Failure or inability to control access such that an unauthorized individual could easily gain undetected access¹⁴ into a vital area from outside the protected area; or

3. Failure to have a security system designed or used to prevent the theft, loss, or diversion of SNM of moderate strategic significance or greater amounts or acts of radiological sabotage.

C. Severity III—Violations involving for example:

1. Failure to conduct an adequate search at the access control point that results in the introduction to the protected area of items that may be useful in radiological sabotage or theft of SNM;

2. Failure or inability to control access such that an unauthorized individual could easily gain undetected access into a vital area from inside the protected area or to the protected area from outside the protected area;

3. Significant failure of the safeguards systems designed or used to prevent or detect the theft, loss, or diversion of SNM or radiological sabotage;

4. Failure to properly secure or protect classified or other sensitive safeguards information which would significantly assist an individual in an act of radiological sabotage or theft of special nuclear material;

5. Significant failure to take compensatory measures for a known security situation that would easily allow unauthorized and undetected access to a protected or vital area;

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

7. Breakdown in the security system 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 IV—Violations involving for example:

1. Failure of a safeguards system designed or used to prevent or detect the theft, loss, or diversion of SNM or radiological sabotage;

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

3. Failure to implement 10 CFR Parts 25 and 95 and information addressed under Section 142 of the Act, and the NRC approved security plan relevant to those parts;

4. Failure to make, maintain, or provide log entries in accordance with 10 CFR 73.71 (c) and (d);

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

6. Failure to properly secure or protect classified or other sensitive safeguards information which would not significantly assist an individual in an act of radiological sabotage or theft of special nuclear material;

7. Failure to control access such that an opportunity exists that could allow unauthorized and undetected access into the protected area or from the protected area into a vital area but which was not easily exploitable;

8. Inadequate compensatory measures for a known security situation that could allow unauthorized and undetected access;

9. Failure to properly test a security system; or

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

E. Severity V—Violations that have minor safeguards significance such as:

1. Isolated failure to log a security event in accordance with 10 CFR 73-71(c); or

2. Other violations that have minor safeguards significance.

Supplement IV—Severity Categories

Health Physics 10 CFR Part 20¹⁵

A. Severity I—Violations involving for example:

1. Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or

5. Exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity II—Violations involving for example:

1. 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. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;

4. Failure to make an immediate notification as required by 10 CFR 20.403(a)(1) and 10 CFR 20.403(a)(2);

5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303; or

6. Exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity III—Violations involving for example:

1. 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. 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. Substantial potential for an exposure or release in excess of 10 CFR 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;

¹⁵ Personnel overexposures and associated violations, incurred during a lifesaving effort, will be treated on a case-by-case basis.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

10. Improper disposal for licensed material not covered in Severity Levels I or II.

11. Exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103.

12. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program.

13. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection.

14. Conduct of licensee activities by a technically unqualified person.

15. Significant failure to control licensed material, or

16. 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 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. Failure to make a 30-day notification required by 10 CFR 20.405;

4. Failure to make a followup 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 V—Violations that have minor safety or environmental significance.

Supplement V—Severity Categories

Transportation¹⁶

A. Severity I—Violations of NRC transportation requirements involving for example:

1. Annual whole body radiation exposure of a member of the public in excess of 2.5 rems of radiation;

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 II—Violations of NRC transportation requirements involving for example:

1. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

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

¹⁶ 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.

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

C. Severity III—Violations of NRC transportation requirements 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. Significant failure to identify the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls; or

c. Substantial potential for personnel exposure or contamination, or improper transfer of material;

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

5. 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 IV—Violations of NRC transportation requirements involving for example:

1. 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. Failure to register as an authorized user of an NRC-Certified Transport packages;

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

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

6. 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 V—Violations that have minor safety or environmental significance.

Supplement VI—Severity Categories

Fuel Cycle and Materials Operations

A. Severity 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; or

3. A nuclear criticality accident.

B. Severity II—Violations involving for example:

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

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

C. Severity III—Violations involving for example:

1. 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. Medical therapeutic misadministration or the failure to report such misadministration;

7. Multiple errors of the same or similar root cause that results in diagnostic misadministrations over the inspection period, or a recurrent violation from the previous inspection period that results in a diagnostic misadministration; or

8. 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.

9. Failure, during radiographic operations, to have present or use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by part 34.

D. Severity IV—Violations involving for example:

1. 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. Medical diagnostic misadministration or a failure to report such a misadministration.

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

D. Severity IV—Violations involving for example:

1. 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. Medical diagnostic misadministration or a failure to report such a misadministration.

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

Supplement VII—Severity Categories

Miscellaneous Matters

A. Severity I—Violations involving for example:

1. Inaccurate or incomplete information¹⁷ 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 which 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

¹⁷ In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference also should be made to the guidance in Section VI.

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

public health and safety or the common sense 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 30.7 or similar regulations against an employee; or
5. A knowing and intentional failure to provide the notice required by Part 21.

6. Failure to substantially implement the required fitness-for-duty program.*

B. Severity II—Violations involving for example:

- 1. Inaccurate or incomplete information which 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 which 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, (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. Action by plant management above first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee; or
5. A failure to provide the notice required by Part 21.

- 6. Failure to remove an individual from escorted access who has been involved in the sale, use, or possession of illegal drugs within the protected area or to take action for a duty misuse of alcohol, prescription drugs, or over-the-counter drugs;
7. Failure to test for cause when observed behavior within the protected area or credible information concerning activities within the protected area indicates possible fitness for duty based on drug or alcohol use; or
8. Deliberate failure of the licensee's Employee Assistance Program to notify licensee's management when EAP's staff is aware that an individual's condition may adversely affect safety related activities.

C. Severity III—Violations involving for example:

- 1. Incomplete or inaccurate information which 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 which the NRC requires be kept by a licensee

which 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. Failure to provide "significant information identified by a licensee" to the Commission and not amounting to a Severity Level I or II violation;
4. Action by first-line supervision in violation of 10 CFR 50.7 or similar regulations against an employee; or
5. Inadequate review or failure to review such that, if an appropriate review had been made as required, a Part 21 report would have been made.

6. 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 such denials such that, as a result of the failure, a person previously denied access for fitness-for-duty reasons was improperly granted access.

7. 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. Failure to ensure, as required, that contractors or vendors have an effective fitness-for-duty program; or

9. 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.

D. Severity IV—Violations involving for example:

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

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

3. Inadequate review or failure to review under Part 21 or other procedural violations associated with Part 21 with more than minor safety significance.

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

5. Failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.10.

E. Severity V—Violations of minor procedural requirements of Part 21.

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

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

3. Minor procedural requirements of Part 21.

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

Supplement VII—Severity Categories

Emergency Preparedness

A. Severity 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 II—Violations involving for example:

1. In a site area 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. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

C. Severity III—Violations involving for example:

1. 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); or

2. Licensee failure to meet or implement one emergency planning standard involving assessment or notification.

D. Severity IV—Violations involving for example:

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

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

* The examples for violations for fitness-for-duty relate to violations of 10 CFR Part 26.