

Appendix A

NOTICE OF VIOLATION

Smith Kline/Accupath
2469 South King Street
Honolulu, Hawaii 96826

License No. 53-18280-01

As a result of the inspection conducted on February 5, 1982, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

- A. License Condition 12. states that licensed material shall be used by, or under the supervision of, Lynne Thornton or Dr. Robert C. Flair.

Contrary to the above, at the time of the inspection, February 5, 1982, licensed material was being used by four persons who were not under the supervision of Lynne Thornton or Dr. Flair.

This is a Severity Level IV Violation (Supplement VII).

- B. License Condition 10. states that licensed material shall be used only at 2828 Paa Street, #1140; Honolulu, Hawaii.

Contrary to the above, at the time of the inspection, February 5, 1982, licensed material (175 microcuries of iodine-125) was being used at 2469 S. King Street, Honolulu, Hawaii.

This is a Severity Level IV Violation (Supplement VII).

- C. 10 CFR 30.51(a) requires each licensee to maintain records showing the disposal of byproduct material. Also, 10 CFR 20.401 (c)(3) requires that records of disposals made pursuant to 20.303 to the sanitary sewer be maintained until the Commission authorizes their disposition.

Contrary to these requirements, at the time of the inspection, there were no records maintained by the laboratory of materials disposed to the sanitary sewer between the date of license issuance, January 5, 1979, and the date of the inspection, February 5, 1982.

This is a Severity Level V Violation (Supplement VII).

- D. 10 CFR 19.11(a) and (c) require that each licensee shall post current copies of the following documents: (1) the regulations in this part and in part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to the licensed activities; (4) Form NRC-3. 10 CFR 19.11(b) states

that if posting of a document specified in paragraph (a)(1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Contrary to the above requirements, at the time of the inspection, the above documents and Form NRC-3 were not posted in the laboratory, nor was there a notice which describes the documents and states where they may be examined.

This is a Severity Level VI Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Smith Kline/Accupath is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Under the authority of Section 182 of the Atomic Energy Act of 1954, as amended, this response shall be submitted under oath or affirmation.

dated FEB 22 1982

Original signed by
B. A. Riedlinger

B. A. Riedlinger, Radiation Specialist
Radiological Safety Branch

Tuesday
October 7, 1980

Part XII

**Nuclear Regulatory
Commission**

Proposed General Statement of Policy
and Procedure for Enforcement Actions

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

Proposed General Statement of Policy and Procedure for Enforcement Actions

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed general statement of policy.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has under consideration the following staff-proposed policy statement on enforcement policies and procedures. This proposed policy statement is intended to inform licensees and the public of the bases for taking various enforcement actions. It is intended that this policy, as finally adopted, be codified as Appendix C to Part 2 of Title 10 of the Code of Federal Regulations. Pending final adoption of the policy, the Proposed General Statement of Policy will be used as guidance to the NRC staff in taking enforcement actions.

DATE: Comments are due on or before December 31, 1980.

ADDRESSES: Send comments and suggestions to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Docketing and Service Branch. Copies of comments may be examined in the U.S. Nuclear Regulatory Commission Public Document Room, 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Dudley Thompson, Executive Officer for Operations Support, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-492-8487).

SUPPLEMENTARY INFORMATION: The criteria used by the Commission's staff to determine enforcement action and categories of noncompliance (referred to herefrom as "Criteria") were first published on October 17, 1972 (37 FR 21962). These Criteria were subsequently modified on January 3, 1975 (40 FR 820) and on December 3, 1979 (44 FR 77135). Since late 1979, the Commission has been considering the publication of a comprehensive statement of enforcement policy. Added urgency for the development of such a policy statement has arisen from the pendency, and now the enactment and approval of Pub. L. 96-295 (approved June 30, 1980), that, among other things, amended section 234 of the Atomic Energy Act to raise the maximum civil penalty from \$5,000 to \$100,000 and

eliminated the provision limiting the total civil penalties payable in any 30-day period to \$25,000.

The proposed statement of general policy set out below (Appendix C to Part 2) explains how the Commission will utilize its various enforcement authorities. The Commission is particularly interested in comments on the use of Table 2 (see Section IV, F).

Appendix C—General Policy and Procedure for NRC Enforcement Actions

The following statement of general policy and procedure explains the policies and procedures to be followed by the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions and by 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

I. Introduction and Purpose

The goals of the NRC's enforcement program are:

- to ensure "compliance with NRC regulations and license conditions";²
- to obtain "prompt correction of licensee weaknesses";³
- to deter "future noncompliance through strong enforcement measures";⁴ and
- to encourage improvement of licensee performance, thus enhancing the degree of protection of public health and safety, common defense and security, and the environment.

To help achieve these goals, the enforcement program "will emphasize prompt and vigorous enforcement" when dealing with persons "who are unable or unwilling to comply with NRC requirements" and, in any case, will "assure that a licensee will not benefit by violating NRC regulations."⁵ It is the Commission's intent that its enforcement program be marked by "an aggressive enforcement strategy that seeks more frequent use of stronger enforcement measures" and implementation that assures "that noncompliance is more expensive than compliance."⁶ These policies are intended to assure that the necessary

"meticulous attention to detail"⁷ and "high standard of compliance"⁸ will be achieved. Furthermore, "licensees who cannot achieve and maintain adequate levels of protection will not be permitted to operate."⁹

II. Legal Framework

The Commission's enforcement jurisdiction is drawn essentially from the Atomic Energy Act of 1954, as amended (sections 161, 186, and 234) and the Energy Reorganization Act (sections 206 and 223).

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and issue any orders that 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 a Commission regulation). However, licensees must be given an opportunity to demonstrate or achieve compliance before a license may be revoked or suspended (except in cases of willfulness or those in which the public health, interest, or safety require otherwise). Section 234 authorizes NRC to impose civil penalties for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and violations for which licenses can be revoked.

The Atomic Energy Act (Chapter 18) also authorizes NRC to obtain injunctions in response to violations of the Act (or any regulation or order issued under the authority of the Act). In addition, the Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of—

- (1) Sections 57, 92, 101, and 108;
- (2) Any other section of the Act or any regulation or order prescribed or issued under section 65 or subsections 161b, 161c, or 161d; and
- (3) The requirements set forth in the Act concerning the receipt, tampering, and disclosure of Restricted Data and trespass upon Commission installations.

Section 223 of the Atomic Energy Act also establishes criminal penalties

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

² Fiscal Years 1982-1986 Policy, Planning, and Program Guidance (PPPG), at para II.A.3.B.

³ *Id.*, at para II.B.2.I.

⁴ *Id.*

⁵ *Id.*, at para II.A.3.b.

⁶ *Id.*, at para II.B.2.I.

⁷ *In the Matter of X-Ray Engineering Co.*, 1 AEC 553, 555 (1960).

⁸ *In the Matter of Hamlin Testing Laboratories, Inc.*, 2 AEC 423, 428 (1964).

⁹ PPPG, at para II.A.2.a.

applicable to certain individuals of a firm constructing or supplying the components of any utilization facility licensed under section 103 or 104(b). Those individuals include any director, officer, or employee of such firms. Under the section, it would be a criminal offense if any of these individuals "by act or omission, in connection with such construction or supply, knowingly and willfully violates or causes to be violated, any section of this Act (i.e., the Atomic Energy Act of 1954, as amended) any rule, regulation, or order issued thereunder, or any license condition, which violation results, or if undetected could have resulted, in a significant impairment of a basic component of such a facility * * *."

A "basic component" is defined in section 223 generally along the lines of the definition in 10 CFR Part 21. Part 21 implements section 206 of the Energy Reorganization Act of 1974. Section 206 of the Energy Reorganization Act authorizes NRC to impose a civil penalty in an amount equal to that authorized by section 234 of the Atomic Energy Act for certain failures to report known safety defects in licensed facilities or activities. Section 206 has an approach similar to section 223, but section 206 does not provide for criminal penalties and is not as limited in scope as is the language in section 223.¹⁰

All alleged or suspected criminal violations of the Atomic Energy Act are investigated by the Federal Bureau of Investigation of the Department of Justice.

The Commission has implemented the enforcement provisions of the Atomic Energy Act and the Energy Reorganization Act by regulations set forth in 10 CFR Part 2 (§§ 2.201, 2.202, 2.204, and 2.205) and in 10 CFR Part 21. 10 CFR 2.201 governs the issuance of notices of violation. Sections 2.202 and 2.204 of Title 10 set forth procedures for, respectively,

- (1) *orders to show cause* why licenses should not be amended, suspended, or revoked or why such other action as may be proper should not be taken, and
- (2) *orders modifying licenses*.

Immediately effective ordering actions must be based on a finding that the public health, interest, or safety requires such actions, or that the basis for the action was a willful violation.

Section 2.205 sets forth procedures for assessing civil penalties.

Corrective enforcement actions may be taken in the absence of any violation

of NRC requirements; for example, when a safety problem not previously covered by a requirement is discovered. NRC imposes civil penalties, however, only on the basis of a violation of an existing requirement.

III. Severity of Violations

Regulatory requirements have varying degrees of safety, safeguards, or environmental significance. This policy statement categorizes all violations in terms of six levels of severity to show their relative importance. Severity Level I has been assigned to violations that are the most significant; Severity Level VI violations are the least significant.

Severity Levels I, II, and III comprise violations that are of significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. *Severity Level IV* violations include degradation of engineered systems or management control systems designed to assure proper plant construction or to detect, prevent, or mitigate an event. Although Severity Level IV violations in themselves are not cause for significant concern, they are the sort of violations that, if left uncorrected, could lead to matters of significant concern. *Severity Level V* covers other less serious violations that are of other than minor concern. *Severity Level VI* defines violations that are of minor concern.

Because of the considerable differences in the types of activities regulated by the NRC, violations of regulatory requirements have been scaled according to their relative importance within each of the following seven areas:

- (1) Reactor Operations (Supplement I),
- (2) Facility Construction (Supplement II),
- (3) Safeguards (Supplement III),
- (4) Health Physics (10 CFR 20 (Supplement IV)),
- (5) Transportation (Supplement V),
- (6) Fuel Cycle Operations (Supplement VI), and
- (7) Materials Operations (Supplement VII).

Detailed guidance is provided in Supplements I-VII for determining the appropriate severity level for violations in each of these seven areas of licensed activities. Violations not specifically identified by a severity level will be placed at the level best suited to the significance of the particular matter. Similarly, licensed activities not directly covered by one of the above listed seven areas; e.g., export license activities; will be placed in the activity area most suitable in light of the particular violation involved.

The NRC expects licensees and applicants 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 not reported. The severity level assigned to material false statements may be Severity Level I, II or III, depending on the circumstances surrounding the statement. Similarly, failure to make a required Part 21 report may be assigned Severity Level I, II or III.

IV. Enforcement Actions

This section describes the enforcement sanctions available to NRC and specifies the conditions under which each is to be used. The basic sanctions are notices of violation, civil penalties, orders of various types, and the less formal enforcement mechanisms such as bulletins and immediate action letters.

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 requires the licensee to provide a written statement, normally under oath, describing corrective actions taken (or planned), the results achieved, the date when full compliance will be achieved, and corrective action to prevent recurrence.

NRC uses the notice of violation as the standard method for formally recording the existence of a violation. The notice may be the only enforcement action taken, or it may be used as a basis for other enforcement actions, such as civil penalties and orders. Because the Commission wants to "encourage and support licensee initiative for self-identification and correction of problems," "NRC will not generally issue notices of violation for a violation that meets all of the four following tests:

- (1) It was identified by the licensee,
- (2) It fits in Severity Level V or VI,
- (3) It was reported, if required, and
- (4) It was or will be corrected within a reasonable time.

Licensees are not ordinarily cited for violations resulting from matters not within the control of the licensee, including its employees, that could not have been reasonably foreseen, such as, equipment failures that are not the result of personnel error or inadequate design, procedures, quality assurance,

¹⁰ The preceding descriptions are summaries of the basic enforcement provisions of the statutes; where important, the actual words of the statutes should be consulted.

¹¹ 10 CFR 2.206 Policy, Planning, and Program Guidelines, § 2.206 B.2.c.

fabrication, testing, maintenance, or communications.

A notice of violation may be issued to a licensed operator when a failure to comply with an operator's license contributes directly to violations of Severity Levels I, II, or III. In general, whenever a licensed operator is issued a notice of violation, the facility licensee also receives a notice of violation. For egregious single violations by licensed operators, or recurring operator involvement in Severity Level I, II, or III violations, suspension or revocation of the operator's license will be considered.

B. Civil Penalty

A *Civil Penalty* is a monetary penalty for violation of (a) certain specified licensing provisions of the Atomic Energy Act or supplementary Commission rules or orders, (b) any requirement for which a license may be revoked, or (c) reporting requirements under section 208 of the Energy Reorganization Act.

Civil penalties are generally imposed in the following situations:¹²

(1) Severity Level I, II, or III violations have occurred;

(2) Severity Level IV and V violations have occurred that are similar to violations discussed in a previous enforcement conference, and for which the enforcement conference was ineffective in achieving the required corrective action;¹³

(3) There are knowing and conscious¹⁴ violations of the reporting requirements of section 208 of the Energy Reorganization Act; or

(4) Willful violations of requirements have occurred.¹⁵

In determining the amount of a civil penalty to be applied, the Commission believes the gravity of the violation involved (i.e., severity level) is of paramount concern. However, when making this determination, NRC also considers the duration of the

noncompliance, how the problem was identified, the financial impact on the licensee of a given penalty, the good faith of the licensee, the licensee's prior enforcement history and whether the violation was willful.¹⁶

NRC imposes different levels of penalties on different classes of licensees. The base values of civil penalties ordinarily imposed are set

forth in Table 1. These distinctions are made primarily on the basis of potential public consequences. Licensee classes toward the top of the table are penalized more heavily because their operations generally involve greater nuclear material inventories and greater potential consequences to the health and safety of the public as well as licensee employees.

Table 1.—Base Civil Penalties

| Types of licensees | Severity levels of violations | | | | |
|--|-------------------------------|----------|----------|----------|---------|
| | I | II | III | IV | V |
| Power reactors (Other SNM licensees associated with Category I material for safeguard purposes only) | \$50,000 | \$30,000 | \$40,000 | \$15,000 | \$5,000 |
| Test reactors (Fuel facilities, Other SNM licensees for safeguard purposes only) | 40,000 | 40,000 | 20,000 | 7,500 | 2,500 |
| Research reactors (Critical facilities) | 18,000 | 18,000 | 8,000 | 3,000 | 1,000 |
| All other licensees and persons subject to civil penalties | 8,000 | 8,000 | 4,000 | 1,500 | 500 |

A secondary factor considered in Table 1 is the ability of various classes of licensees to pay the civil penalties. It is not the Commission's intention that the economic impact of a civil penalty be such that it puts a licensee out of business or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of NRC penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." As a general rule, the licensee classes toward the top of Table 1 represent larger firms, whereas those toward the bottom tend to be smaller. When determining the amounts of civil penalties for licensees for whom the table does not accurately reflect the ability to pay, NRC will consider necessary increases or decreases on a case-by-case basis.

The dollar values shown in Table 1 are those normally imposed for violations at the severity levels and for the types of licensees indicated. Because the NRC considers the potential for an event to be of similar seriousness as the occurrence of the event itself, the civil penalty amounts for Severity Level I and II violations are intentionally the same. However, in addition to civil penalties, an Order is generally issued for Severity Level I violations.

If, prior to NRC discovery, a licensee identifies, corrects, and (where required) reports a violation in a timely fashion, the civil penalty will be reduced by as much as 50 percent of the amounts shown in Table 1. This policy will

provide an incentive to licensees to find and correct problems on their own.

Civil penalties may be increased as much as 25 percent of the amounts shown in Table 1 if the licensee could reasonably have been expected to have taken effective preventive measures. For example, cases in which a licensee had knowledge of a problem as a result of a prior NRC inspection or licensee audit, or issuance of an order, bulletin, circular, information notice, generic letter, notice of violation, or other means, and still failed to comply despite such prior warning, the additive factor will apply. Particularly egregious cases, including cases involving willfulness, may result in penalties up to the statutory maximum. On the other hand, for those cases in which the NRC concludes that the licensee deserves special mitigation for "good faith," a civil penalty may be reduced by as much as 25 percent of the adjusted values resulting from reductions, if any, for special mitigation based on "self identification".

The "good faith" reduction will only be applied if, in addition to meeting the requirements for the 50 percent reduction, the licensee has taken extraordinarily prompt and comprehensive corrective action.

In the case of violations at Severity Levels I, II, or III, the amounts shown in Table 1 may be imposed for each violation. However, to emphasize the focus on the specific event(s) or problem(s) of concern, the cumulative total for all violations related to a specific event or problem will generally

¹² Orders may be issued in lieu of, or in addition to, civil penalties for these same situations.

¹³ In applying this guidance, NRC normally considers civil penalties only for violations that occur from the date of the last inspection or within two years, whichever is greater. NRC also considers the licensee's success in dealing with previously identified concerns. Enforcement conferences are normally conducted for all Severity Level I, II, and III violations as well as for Severity Level IV and V violations that are considered programmatic (rather than isolated) concerns.

¹⁴ The knowing and conscious standard is established by section 208(b) of the Energy Reorganization Act.

¹⁵ Willful violations include those involving careless disregard of requirements.

¹⁶ These factors are derived from the Conference Report on the FY 80 NRC Authorization Bill.

be the amount shown in Table 1.¹⁷ If the violations involve more than one specific event or problem, civil penalties may be assessed for each specific event or problem. The failure to make a required report of an event or problem is considered as a separate event.

A greater civil penalty is imposed if a violation continues for more than one day. Each of such violation may constitute a separate violation for the purpose of computing the applicable civil penalty. A continuing Severity III, IV or V violation which exceeds the maximum civil penalty for a single violation of the next higher severity level must be approved by the Commission, e.g., a continuing Severity Level III violation for a reactor exceeding \$100,000 must be approved by the Commission. A continuing Severity Level I or II violation which exceeds three times the maximum civil penalty for a single Severity I violation, i.e., \$300,000, must be approved by the Commission. Civil penalties in excess of the limits for each type of license will require specific Commission approval in accordance with guidance set forth in section V below.

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).

(1) *License Modification Orders* are issued when some change in the conduct of a licensed activity is necessary. These 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 modification is afforded. For cases in which the NRC believes a basis could reasonably exist for not modifying the license as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the license should not be modified in the proposed manner.

(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 and correction of an improperly constructed safety related system or component, or (ii) the licensee's quality assurance program implementation is not adequate and effective 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 correction action has been taken.

The policies governing immediately effective suspension orders and orders to show cause are the same as those previously described above for license modification orders.

(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,

(d) When a licensee does not pay a fee required by 10 CFR Part 170, or

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

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

D. Other Enforcement Actions

In addition to the formal enforcement mechanisms of notice of violations, civil penalties, and orders, NRC also uses informal mechanisms, such as enforcement conferences, bulletins, circulars, information notices, generic letters, notices of deviation, and immediate action letters as part of its enforcement and regulatory programs. NRC expects licensees to adhere scrupulously to any informal obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to make sure that expectation is realized.

(1) *Enforcement Conferences* are meetings held by NRC with licensee management to discuss safety, safeguards or environmental problems, licensee compliance with regulatory requirements, a licensee's proposed corrective measures (including schedules for implementation), and enforcement options available to the NRC.

(2) *Bulletins, Circulars, Information Notices and Generic Letters* are written notifications to groups of licensees identifying specific problems and calling for or recommending specific actions on their part. Responses to these notifications may be required to be under oath or affirmation.

(3) *Notices of Deviation* are written notices describing a licensee's or a vendor's failure to satisfy an informal commitment or failure to conform to the provisions of applicable codes, standards, guides, or accepted industry practices. The commitment, code, standard, practice or guide involved has not made a legally binding requirement, but it is a type of activity that a class of licensees has been encouraged to follow. The notice of deviation requests the licensee or vendor to provide a written explanation or statement describing corrective steps taken, the results achieved (or corrective steps that are planned), and the date when corrective action will be completed.

(4) *Immediate Action Letters (IALs)* are letters confirming a licensee's agreement to take certain actions to remove concerns about health and safety, safeguards, or the environment.

E. 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 and consideration of possible prosecution. 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.

F. Escalation of Enforcement Sanctions

NRC considers violations of Severity Levels I, II, or III to be very serious. If repetitive serious violations occur, NRC will consider issuing 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

¹⁷ All violations associated with a particular event or problem will be categorized at the same severity level, even though similar violations, if not associated with the event, might otherwise have been categorized at a lower severity level (e.g., the failure to post a radiation warning sign, which would normally be a Severity Level IV violation, would be categorized as a Severity Level II violation if it contributed to an actual overexposure exceeding 5 rems).

accordance with the criteria described in sections IV.B and IV.C. above.

Examples of enforcement actions that (could) (will normally) be taken for 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.

Table 2.—Examples of Progression of Escalated Enforcement Actions for 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 2 years (whichever is greater) | | |
|-----------------------|---|-----------|-----------|
| | 1st | 2d | 3d |
| I | a + b | c + b + c | d |
| II | a | a + b | a + b + c |
| III | a | a | a + b |

a = Civil penalty.
b = Suspension of affected operations until the Office Director is satisfied that there is adequate assurance that the licensee can operate in compliance with the applicable requirements, or modification of the license, as appropriate.
c = Allow change for modification or suspension of the license, as appropriate.
d = Further action, as appropriate.

Normally the progression of enforcement actions for repetitive violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on repetitive violations at an individual facility and not on repetitive violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations; repetitive violations may be charged even though the second violation occurred at a different facility and/or under a different license. For example, a physical security violation at Unit 2 of a dual unit plant that repeats an earlier violation at Unit 1 might be considered repetitive.

V. Responsibilities

The Director, Office of Inspection and Enforcement, as the principal enforcement officer of the Commission, has been delegated the authority to issue notices of violations, civil penalties, and orders.** The Director

* As indicated in the Supplemental Information Section of the Federal Register Notice, the Commission is interested in comments concerning the policy for the use of Table 2.

** The Directors of the Offices of Nuclear Reactor Regulation and Nuclear Materials Safety and Safeguards have also been delegated similar authority, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions necessary in the interest of the public health and safety but not to those involving a violation of any existing requirement. Similarly, it is expected that it will normally confine use of its authority to actions based on violations of existing requirements. The Director, Office of Administration, has been delegated the authority to issue orders where a licensee violate Commission regulations by mismanagement of license fees.

exercises judgment and discretion in determining the severity level of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, consistent with the general principles of this statement of policy and the technical merits of the case.

The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will be consulted prior to taking enforcement action in the following situations (unless the urgency of the situation dictates immediate action):

(1) An action affecting facility operations that requires balancing the public health and safety and common defense and security implications of not operating the facility with the potential radiological or other hazards associated with facility operation;¹⁹

(2) Proposals to impose civil penalties in amounts greater than the maximum values set forth in section IV.B;

(3) Any proposed enforcement action which the Commission asks to be consulted on; or

(4) Any action an Office Director believes warrants Commission involvement.

Supplement I.—Severity Categories Reactor Operations

A. Severity I—Violations involving:

1. A Safety Limit, as defined in the Technical Specifications, being exceeded;

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

3. An accidental criticality; or

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

B. Severity II—Violations involving:

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

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

C. Severity III—Violations involving:

1. A Technical Specification Limiting Condition for Operation being exceeded where the appropriate Action Statement was not satisfied;

2. A system designed to prevent or mitigate a serious safety event not being

able to perform its intended function under certain conditions (such as not operable unless offsite power is available);

3. Release of radioactivity offsite greater than the Technical Specification limit; or

4. Violation of 10 CFR 50.59 such that an amendment was not sought.

D. Severity IV—Violations involving:

1. Inadequate review or the failure to make a review in accordance with 10 CFR 50.59 or 10 CFR 21, that does not result in a severity level I, II, or III violation;

2. Any license limit, not covered by Severity Levels I, II, or III, being exceeded;

3. Failure to meet requirements not covered in Severity Levels I, II, or III, that measurably degrades the safety of operations, incident response, or the environment; or

4. Failure to make a required Licensee Event Report when the reported matter itself does not constitute a violation.

E. Severity V—Other violations, such as failure to follow procedures, that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Supplement II.—Severity Categories Facility Construction

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

B. Severity II—Violations involving:

1. A significant deficiency in quality assurance program implementation related to more than one work activity (e.g., structural, piping, electrical, foundations), as shown by multiple program implementation violations that were not identified and corrected until after installation (i.e., completion) and inspection by the quality assurance/quality control check points that are relied upon to identify such violations; or

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

C. Severity III—Violations involving:

1. Lack of quality assurance program implementation related to a single work activity (e.g., structural, piping, electrical, or foundations) as shown by multiple program implementation violations that were not identified and corrected by more than one quality assurance/quality control checkpoint relied upon to identify such violations;

* 10 CFR 82.29 Policy, Planning, and Program Guidance, para II A 2.4.

* This does not apply to instantaneous release limit.

2. Preoperational test program implementation in which the violations result in failing to confirm the design safety requirements of the structure or system; or

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

D. Severity IV—Violations involving:

1. Failure to follow one or more Quality Assurance Criteria not amounting to Severity Level I, II, or III violations; or

2. Inadequate review or the failure to make a review in accordance with 10 CFR Part 21.

E. Severity V—Other violations, such as failure to follow procedures, that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Supplement III.—Severity Categories *Safeguards**

A. Severity I—Violations involving:

1. Actual entry of an unauthorized individual into a vital area or material access area from outside the protected area that was undetected at the time of entry;

2. Actual theft, loss, or diversion of special nuclear material (SNM) or an act of radiological sabotage; or

3. Failure to promptly report an actual or attempted theft or diversion of SNM or an act of radiological sabotage.

B. Severity II—Violations involving:

1. Breakdown of security systems designed or used to prevent any unauthorized individual from entering a vital area or material access area from outside the protected area such that access could have been gained without detection;

2. Failure to operate the central (or secondary) alarm station;

3. Failure to respond to unauthorized or unanticipated security alarm annunciations;

4. Failure to establish or maintain safeguards systems designed or employed to prevent or detect the unauthorized removal of Category I SNM from areas of authorized use or storage; or

5. Breakdown of transportation security systems designed or employed to prevent the theft, loss, or diversion of SNM or acts of radiological sabotage.

C. Severity III—Violations involving:

1. Failure to provide protection or control of access into the protected area;

2. Failure to provide protection or control of access to a vital area or material access area;

3. Failure to provide protection or control of access to the transport vehicle or the SNM being transported; or

4. Failure to establish or maintain safeguards systems designed or used to detect the unauthorized removal of Category II SNM from areas of authorized use or storage.

D. Severity IV—Violations involving:

1. Failure to establish or maintain safeguards systems designed or employed to detect the unauthorized removal of Category III SNM from areas of authorized use or storage;

2. Failure of the security organization to follow procedures to cope with actual security incidents that are not covered by Severity Levels I, II, or III;

3. Failure of corporate or site security management to provide adequate direction or supervision of the security program that do not result in Severity Level I, II, or III violations; or

4. Inadequate review or the failure to make a review in accordance with 10 CFR Part 21.

E. Severity V—Other violations, such as failure to follow procedures or an approved security plan, that have other than minor safeguards significance.

F. Severity VI—Violations that have minor safeguards significance.

Supplement IV.—Severity Categories *Health Physics 10 CFR Part 20*

A. Severity I—Violations involving:

1. 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. 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 10 times the limits of 10 CFR 20.106;

4. A radiation level in an unrestricted area that exceeds 100 millirem/hour for a one-hour period;

5. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits of 10 CFR 20.303 or 20.304; or

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

B. Severity II—Violations involving:

1. 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. Exposure of a member of the public in excess of 0.1 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of 5 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. A radiation level in an unrestricted area that exceeds 50 millirem/hour for a one hour period;

6. Disposal of licensed material in quantities or concentrations in excess of 5 times the limits of 10 CFR 20.303 or 20.304; or

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

C. Severity III—Violations involving:

1. Exposure of a worker to levels in excess of those specified in 10 CFR 20.101 or 20.104;

2. A radiation level in an unrestricted area that exceeds 5 millirem/hour for a one hour period;

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 where such exposure or release does not occur (e.g., entry into high radiation area 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;

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

7. Exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103; or

8. Release for unrestricted use of contaminated material or equipment substantially in excess of NRC or license limits or the failure to decontaminate plant areas as required.

D. Severity IV—Violations involving:

1. Failure to follow requirements (e.g., inadequate survey, incomplete dosimetry, improper posting), not covered in Severity Levels I, II, or III, that substantially reduces the margin of safety;

2. A radiation level in an unrestricted area such that an individual may 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; or

4. Inadequate review or failure to make a review in accordance with 10 CFR Part 21.

E. Severity V—Violations involving:

*Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper (10 CFR 73.20) and a carrier (10 CFR 70.204). 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.

1. Failure to make a followup written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or

2. Any other matter, including failure to follow procedures, that has other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Supplement V.—Severity Categories

Transportation

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

1. Radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

2. Loss of package integrity resulting in surface contamination or external radiation levels in excess of ten (10) times the NRC or Department of Transportation (DOT) limits.

B. Severity II—Violations of NRC transportation requirements involving:

1. Loss of package integrity resulting in surface contamination or external radiation levels in excess of NRC or DOT requirements;

2. Surface contamination or external radiation levels in excess of three times NRC or DOT limits that did not result from a breach of package integrity; or

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

C. Severity III—Violations of NRC transportation requirements involving:

1. Breach of package integrity;

2. Surface contamination or external radiation levels in excess of, but less than a factor of three above NRC or DOT requirements, that did not result from a breach of package integrity;

3. Any noncompliance with labelling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

a. Improper identification of 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

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

D. Severity IV—Violations of NRC transportation requirements involving:

1. Any noncompliance involving package selection or preparation requirements which does not result in a breach of package integrity or surface contamination or external radiation levels in excess of NRC or DOT requirements.

2. Failure to follow procedures; or inadequate procedures, not covered in

Severity Level I, II, or III violations; that reduces the margin of safety; or

3. Inadequate review or failure to make a review in accordance with 10 CFR Part 21.

E. Severity V—Other violations, such as failure to follow procedures, that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Supplement VI.—Severity Categories

Fuel Cycle Operations

A. Severity I—Violations involving:

1. A nuclear criticality accident; or

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

B. Severity II—Violations involving:

1. A system designed to prevent or mitigate a serious safety event being inoperative;

2. Conduct of activities not authorized by the license that have a significant safety implication; or

3. Failure to make an immediate or prompt report required to be made by telephone or other electronic means.

C. Severity III—Violations involving:

1. A degraded system designed to prevent or mitigate a serious safety event (e.g., confinement barriers or criticality controls); or

2. Operation with a technically unqualified or unauthorized person resulting in a reduced margin of safety.

D. Severity IV—Violations involving:

1. Inadequate review or the failure to review activities in accordance with 10 CFR Part 21 or management reviews required by the license that are not performed or are performed inadequately but that do not result in a Severity Level I, II, or III violation;

2. Any operation limit not covered by Severity Level I, II, or III violations being exceeded;

3. Failure to follow requirements not covered in Severity Level I, II, or III violations, that reduces the margin of safety; or

4. Failure to make a required 30-day report.

E. Severity V—Other violations, such as failure to follow procedures, that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Supplement VII.—Severity Categories

Materials Operations

A. Severity I—Violations involving:

1. A technically unqualified or unauthorized person conducting a licensed activity that results in radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;

2. Use of unauthorized equipment that results in radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;

3. Possession or use of unauthorized materials requiring a license, that results in radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license;

4. Failure to perform required surveys, tests or evaluations, or to institute required safety precautions that results in radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license; or

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

B. Severity II—Violations involving:

1. A technically unqualified or unauthorized person conducting a licensed activity that results in radiation levels, contamination levels, or releases in excess of license limits;

2. Possession or use of unauthorized equipment or material in the conduct of licensed activities that results in radiation levels, contamination levels, or releases that exceed limits specified in the license.

3. Failure to perform required surveys, tests, or evaluations that results in radiation levels, contamination levels, or releases that exceed the limits specified in the license.

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

5. A system designed to prevent or mitigate a serious safety event being inoperative.

C. Severity III—Violations involving:

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;

3. Procurement of radioactive material for human use where such use is not authorized;

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

5. Failure to make required initial notifications associated with Severity Level III violations; or

6. Degradation of a system designed to prevent or mitigate a serious safety event.

D. Severity IV—Violations involving:

1. Failure to follow requirements not covered in Severity Level I, II, or III violations that reduce the margin of safety (e.g., failure to determine that a radiographic source is fully retracted after an exposure);

2. Failure to maintain patients containing cobalt-60, cesium-137, or iridium-192 implants hospitalized, to conduct required leakage or contamination tests, or use of improperly calibrated equipment; or

3. Inadequate review or the failure to review activities in accordance with 10 CFR Part 21 or management reviews required by the license that are either not performed or not performed adequately but that do not result in a Severity Level I, II, or III violation.

E. Severity V—Other violations, such as failure to follow procedures, that have other than minor safety or environmental significance.

F. Severity VI—Violations that have minor safety or environmental significance.

Dated at Bethesda, MD, this 1st day of October 1980.

For the Nuclear Regulatory Commission,
Victor Stello, Jr.,

Director, Office of Inspection and Enforcement.

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