

NUCLEAR REGULATORY COMMISSION

[NUREG-1600]

Policy and Procedure for Enforcement Actions; Policy Statement**AGENCY:** Nuclear Regulatory Commission.**ACTION:** Policy Statement; amendment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its General Statement of Policy and Procedure for Enforcement Actions (Enforcement Policy) to modify Supplement VI, "Fuel Cycle and Materials Operations," as well as to reflect recent NRC organizational changes. The Supplement VI amendment is warranted to reflect experience gained through fuel cycle enforcement actions and as a result of the Commission's recently designated responsibility for jurisdiction over the Gaseous Diffusion Plants (GDPs). The Enforcement Policy is also being amended to establish base civil penalties for GDPs. By a separate action published in this issue in the Federal Register, the Commission has issued a final rule amending the current regulations that govern GDPs. The revision to the Enforcement Policy reflects those amendments.

In addition, the Enforcement Policy is being amended to reflect recent NRC organizational changes. These changes redesignate which NRC officials are delegated the responsibility for performing certain enforcement functions. A clarification is also being made to remove ambiguity as to when the Commission is to be consulted prior to issuance of certain actions proposing civil penalties.

DATES: This amendment is effective on February 12, 1997. Comments are due on or before March 14, 1997.

ADDRESSES: Send written comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. ATTN: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

The Commission's Enforcement Policy was first issued on September 4, 1980. The Enforcement Policy is published as NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions (60 FR 34381; June 30, 1995)." The Enforcement Policy has been amended on a number of occasions, most recently on October 18, 1996 (61 FR 54461). As a result of experience gained through fuel cycle enforcement actions and amendments to 10 CFR part 76 being published today as a final regulation, an amendment to the Enforcement Policy is warranted to provide guidance on categorizing potential violations of 10 CFR part 76 and establish base civil penalties for violation of part 76. This amendment to the Enforcement Policy is being issued concurrently with the new rule.

Base Civil Penalties

Table 1A of the policy, which establishes base civil penalties for different types of licensees, is being modified to add GDPs to category "a." The amended table will provide that the base civil penalty for a Severity Level I violation of the Commission's requirements by a GDP will be at the statutory limit of \$110,000. In accordance with Table 1B, base civil penalties for Severity Level II and III violations are lesser amounts. In determining the proper civil penalty amount, the Commission considered the structures of these tables, which generally take 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 to workers receive higher civil penalties. In the case of GDPs, there are large numbers of workers at the sites, significant source term present (i.e., inventory of licensed material), and various chemical and toxic substances used as part of the GDPs operations. Therefore, in the event of an accident, there is the potential for significant radiological and non-radiological hazards to members of the public, including workers, and the environment.

With regard to the secondary factor of ability to pay, it is not the NRC's intention that the economic impact of a civil penalty be so severe that it puts the licensee or certificate holder out of business¹ or adversely affects a licensee's or certificate holder's ability

¹ Orders, rather than civil penalties, are used when the intent is to suspend or terminate licensed activities.

to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amount of penalties take into account a licensee's or certificate holder's ability to pay. In this case, issuing a civil penalty of less than \$110,000 to the Corporation for a significant violation would be disproportionate to the Corporation's significant revenues. In other words, a civil penalty of \$110,000 for a Severity Level I violation would be financially appropriate, but not financially crippling. In addition, a penalty based on this amount should get more attention from the Corporation and should have a greater deterrent effect.

Given the financial resources of GDPs, it is appropriate to utilize significant civil penalties to provide an effective deterrence from violating the Commission's requirements such that the likelihood of performance necessitating a shutdown order would be minimal. Accordingly, a base civil penalty of \$110,000 is appropriate in view of the potential consequences during an accident and the ability to pay. In addition, establishing the base civil penalty at the statutory limit would provide, at the outset, a clear message concerning the cost of noncompliance and additional motivation to maintain safety and compliance.

Severity Levels

The policy recognizes that regulatory requirements have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation, including both the technical significance and the regulatory significance, is evaluated as the first step in the enforcement process. In considering the significance of a violation, the staff considers the technical significance (i.e., actual and potential consequences) and regulatory significance. Supplement VI, "Fuel Cycle and Materials Operations," is being amended to provide additional examples for categorizing the severity levels of violations.

The changes are:

Severity Level I

1. Example A.5, which is being added to Supplement VI, is consistent with Supplement I guidance. This example is applicable for the Gaseous Diffusion Plants (GDPs) because other fuel facilities do not have Technical Safety Requirements (TSRs). Safety limits are those bounds within which the process variables must be maintained for adequate control of the operation and that must not be exceeded in order to protect the integrity of the physical

system that is designed to guard against the uncontrolled release of radioactivity.

2. Example A.6 is being added to Supplement VI to emphasize that a significant injury or loss of life due to a loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, whether radioactive material is released or not, is of very significant regulatory concern. This concern exists because an actual impact to the health and safety of the public or workers has occurred from activities related to the processing of radioactive material.

Severity Level II

1. Example B.4 is being added to Supplement VI to emphasize that, although less significant than Example A.3 in Supplement VI, the absence of all the criticality safety controls for a single anticipated or unanticipated nuclear criticality scenario is of very significant regulatory concern when the availability of fissile material makes a nuclear criticality accident possible.

2. Example B.5 is being added to Supplement VI to underscore that events which do not involve actual significant injuries or loss of life, but reasonably could have if circumstances had been different, are considered of very significant regulatory concern.

Severity Level III

1. Example C.5 is being modified in Supplement VI so that it is consistent with Supplement IV guidance. The NRC considers that a substantial potential for exposures, radiation levels, contamination levels, or releases (including releases of toxic material) caused by the failure to comply with NRC regulations or with procedures established to comply with license conditions to be a significant regulatory concern because it could have serious consequences to the public and licensee employees.

2. Example C.12 is being added to Supplement VI to emphasize that the failure of a certified facility to comply with a limiting condition for operation is considered a significant regulatory concern. This example is similar to Supplement I guidance and has been selected for the GDPs because other fuel cycle facilities do not have TSRs.

3. Example C.13 is being added to Supplement VI to emphasize that the loss of defense-in-depth over licensed or certified activities is considered a significant regulatory concern. This example is consistent with Supplement I guidance and is applicable to both fuel cycle and gaseous diffusion operations.

4. Example C.14, which is consistent with Supplement I guidance, is being added to Supplement VI. This example is generally applicable to the fuel cycle facilities.

5. Example C.15 is being added to Supplement VI. The failure to meet the requirements of 10 CFR 76.68 is significant because of the importance of certificate holders using the required process for maintaining and operating the facilities in accordance with the design and procedures described in their safety analysis report when there is uncertainty as to whether an unreviewed safety question is present. An after-the-fact evaluation that demonstrates that an unreviewed safety question was not involved would, in general, not mitigate the regulatory significance of failing to perform an appropriate evaluation prior to implementation of the change.

6. Example C.16 is being added to Supplement VI to emphasize that adequate control over vendors or contractors performing safety-related work or providing safety-related services is a significant regulatory concern. This example amplifies the NRC's concern that all safety-related activities, whether performed by the certificate holder or by one of its contractors, be conducted in accordance with the requirements in the application, TSRs and certificates.

7. Example C.17, which is consistent with the Supplement I guidance, is being added to Supplement VI. This example points out that equipment failures caused by inadequate or improper maintenance that substantially complicates recovery from a plant transient is a significant regulatory concern.

8. Example C.18 is being added to Supplement IV. This example indicates that the absence of all but one criticality safety control for a single anticipated or unanticipated nuclear criticality scenario is a significant regulatory concern when a critical mass of fissile material was present or reasonably available, because a nuclear criticality accident was possible.

Severity Level IV

1. Although less significant than the above examples, examples D.5 through D.8 are being added to Supplement VI to stress that such failures are more than a minor concern because they could lead to a more serious concern if left uncorrected.

Organizational Changes

In addition to the above changes, recent NRC organizational changes have redistributed certain staff functions

reporting to the Executive Director for Operations. Under the previous organization, the Deputy Executive Director for Nuclear Material Safety, Safeguards, and Operations Support (DEDS) was delegated the authority to approve and/or issue escalated enforcement actions associated with licensees of the Office of Nuclear Material Safety and Safeguards (NMSS). Similarly, the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research (DEDR) was delegated the authority to approve and/or issue escalated enforcement actions associated with licensees of the Office of Nuclear Reactor Regulation (NRR). Based on this distribution of functions, these two Deputy Executive Directors were designated as the principal enforcement officers of the NRC.

The NRC organizational changes have replaced the previous two Deputy Executive Director positions with three new Deputy Executive Director positions. Under the new organizational arrangement, the NRC Office of Enforcement (OE) reports to the Deputy Executive Director for Regulatory Effectiveness, Program Oversight, Investigations, and Enforcement (DEDO), and NMSS and NRR both report to the Deputy Executive Director for Regulatory Programs (DEDR). This change in reporting responsibilities consolidates the technical office oversight under the new DEDR, and redesignates a single deputy, the DEDO, as the NRC's principal enforcement officer.

Consistent with this change, the NRC Enforcement Policy is being modified to replace all previous references to either Deputy Executive Director with references to the DEDO. As such, the Enforcement Policy will designate the DEDO as having the authority to approve and/or issue escalated enforcement actions associated with either NRR or NMSS licensees. These changes will be reflected in the amendment to NUREG-1600.

Clarification

The Commission previously published (61 FR 65088, December 10, 1996) changes to the Enforcement Policy concerning consultation with the Commission prior to issuance of enforcement actions that proposed a civil penalty more than three times the Severity Level value shown in Table 1A for a single violation. The Commission is re-publishing that portion of the Policy (Section III.2) with slightly revised language to remove ambiguity and make clear that the requirement applies to a single violation or problem and not the total of multiple penalties

that may be proposed in one enforcement action. This is consistent with the Commission's original understanding and intent.

Paperwork Reduction Act Statement

This policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0136. The approved information collection requirements contained in this policy statement appear in Section VII.C.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a "major rule" and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

Accordingly, the NRC Enforcement Policy is amended by:

- a. Changing the first paragraph under Section III, "Responsibilities," by designating the principal enforcement officer of the NRC as "the Deputy Executive Director for Regulatory Effectiveness, Program Oversight, Investigations, and Enforcement (DEDO), hereafter referred to as the Deputy Executive Director," and deleting the references to the former Deputy Executive Director for Nuclear Material Safety, Safeguards, and Operations Support (DEDS) and the former Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research (DEDR).
- b. Revising all subsequent references to "the appropriate Deputy Executive Director" to read "the Deputy Executive Director."
- c. Revising Section III, "Responsibilities," Section VI, "Enforcement Actions," Subsection B., Table 1A, Category a., and Supplement VI, "Fuel Cycle and Materials Operations," as follows:

General Statement of Policy and Procedure for NRC Enforcement Actions

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III. Responsibilities

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Unless Commission consultation or notification is required by this policy, the NRC staff may depart, where warranted in the public's interest, from this policy as provided in Section VII, "Exercise of Enforcement Discretion." The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will also be provided notice the first time that discretion is exercised for a plant meeting the criteria of Section VII.B.2. In addition, the Commission will be consulted prior to taking action in the following situations (unless the urgency of the situation dictates immediate action):

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(2) Proposals to impose a civil penalty for a single violation or problem that is greater than 3 times the Severity Level I value shown in Table 1A for that class of licensee;

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VI. Enforcement Actions

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B. Civil Penalty

TABLE 1A—BASE CIVIL PENALTIES

| | |
|---|-----------|
| a. Power reactors and gaseous diffusion plants | \$110,000 |
| b. Fuel fabricators, industrial processors, and independent spent fuel and monitored retrievable storage installations | 27,500 |
| c. Test reactors, mills and uranium conversion facilities, contractors, vendors, waste disposal licensees, and industrial radiographers | 11,000 |
| d. Research reactors, academic, medical, or other material licensee ¹ | 5,500 |

¹ This applies to nonprofit institutions not otherwise categorized in this table, mobile nuclear services, nuclear pharmacies, and physician offices.

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Supplement VI—Fuel Cycle and Materials Operations

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

A. Severity Level I—Violations involving for example:

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3. A nuclear criticality accident;

4. A failure to follow the procedures of the quality management program, required by 10 CFR 35.32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient;

5. A safety limit, as defined in 10 CFR 76.4, the Technical Safety Requirements, or the application being exceeded; or

6. Significant injury or loss of life due to a loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, whether radioactive material is released or not.

B. Severity Level II—Violations involving for example:

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

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

4. A failure to establish, implement, or maintain all criticality controls (or control systems) for a single nuclear criticality scenario when a critical mass of fissile material was present or reasonably available, such that a nuclear criticality accident was possible; or

5. The potential for a significant injury or loss of life due to a loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, whether radioactive material is released or not (e.g., movement of liquid UF₆ cylinder by unapproved methods).

C. Severity Level III—Violations involving for example:

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

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5. A substantial potential for exposures, radiation levels, contamination levels, or releases, including releases of toxic material caused by a failure to comply with NRC regulations, from licensed or certified activities in excess of regulatory limits;

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10. A failure to receive required NRC approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of an RSO or replacement of an RSO with an unqualified individual; a change in the

location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance;

11. A significant failure to meet decommissioning requirements including a failure to notify the NRC as required by regulation or license condition, substantial failure to meet decommissioning standards, failure to conduct and/or complete decommissioning activities in accordance with regulation or license condition, or failure to meet required schedules without adequate justification;

12. A significant failure to comply with the action statement for a Technical Safety Requirement Limiting Condition for Operation where the appropriate action was not taken within the required time, such as:

(a) In an autoclave, where a containment isolation valve is inoperable for a period in excess of that allowed by the action statement; or

(b) Cranes or other lifting devices engaged in the movement of cylinders having inoperable safety components, such as redundant braking systems, or other safety devices for a period in excess of that allowed by the action statement;

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

(a) Not being able to perform its intended function under certain

conditions (e.g., safety system not operable unless utilities available, materials or components not according to specifications); or

(b) Being degraded to the extent that a detailed evaluation would be required to determine its operability;

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

15. A significant failure to meet the requirements of 10 CFR 76.68, including a failure such that a required certificate amendment was not sought;

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

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

18. A failure to establish, maintain, or implement all but one criticality control (or control systems) for a single nuclear criticality scenario when a critical mass of fissile material was present or reasonably available, such that a nuclear criticality accident was possible.

D. Severity Level IV—Violations involving for example:

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

3. Failure to follow the quality management (QM) program, including

procedures, whether or not a misadministration occurs, provided the failures are isolated, do not demonstrate a programmatic weakness in the implementation of the QM program, and have limited consequences if a misadministration is involved; failure to conduct the required program review; or failure to take corrective actions as required by 10 CFR 35.32;

4. A failure to keep the records required by 10 CFR 35.32 or 35.33;

5. A less significant failure to comply with the Action Statement for a Technical Safety Requirement Limiting Condition for Operation when the appropriate action was not taken within the required time;

6. A failure to meet the requirements of 10 CFR 76.68 that does not result in a Severity Level I, II, or III violation;

7. A failure to make a required written event report, as required by 10 CFR 76.120(d)(2); or

8. A failure to establish, implement, or maintain a criticality control (or control system) for a single nuclear criticality scenario when the amount of fissile material available was not, but could have been sufficient to result in a nuclear criticality.

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Dated at Rockville, Maryland, this 6th day of February, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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