7590-01-P

NUCLEAR REGULATORY COMMISSION

[NUREG - 1600]

NRC Enforcement Policy; Modification, Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy Statement: Modification.

SUMMARY: In conjunction with a major revision of 10 CFR Part 35, published in today's *Federal Register*, the Nuclear Regulatory Commission is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (Enforcement Policy). This change to the Enforcement Policy revises the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material; and to develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). These examples are used in the enforcement process to provide guidance for determining the significance or a particular violation.

DATES: Consistent with the rulemaking to revise 10 CFR Part 35, this action is effective [insert date 6 months after publication in the Federal Register]. Comments on this change to the

NRC's Enforcement Policy should be submitted not later than 30 days following the effective date and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Bill Borchardt, Director, Office of Enforcement, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

Background

In a separate action published in today's *Federal Register*, the NRC is revising its regulations in 10 CFR Part 35 governing the medical use of byproduct material to make the requirements risk informed and more performance based. Before this revision, 10 CFR 35.32 required a quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the physician who is the authorized user of the material under the NRC license. Among other things, the quality management program had to assure that, for certain medical uses, a written directive was

prepared and signed by the authorized user. The term “written directive” is defined in 10 CFR 35.2. Before this revision to the regulations, the term “misadministration” was used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. It was defined in 10 CFR 35.2.

In the revision of 10 CFR Part 35 published today, the requirement to use written directives has been moved to § 35.40. The terms “quality management program” and “misadministration” are no longer used. The term “medical event” is used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. This term is now defined in 10 CFR 35.2. The new § 35.41 requires that the licensee develop, implement, and maintain written procedures for medical uses that require a written directive. Among other things, the written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.

Minor conforming changes are being made to the examples in the NRC Enforcement Policy that formerly referred to the terms “quality management program” and “misadministration.” The examples are being changed to reflect the new terms “written procedures for administrations requiring a written directive” and “medical event.”

The last substantive change to the examples in the NRC Enforcement Policy that relate to errors in medical uses was published at 58 FR 17321 (April 2, 1993). At that time, the examples were changed to provide greater emphasis, and attach greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature.

Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events, such as failure to develop and implement adequate written procedures for administrations that require a written directive, failure to train personnel on the procedures, or failure to follow procedures that is more widespread than simple occasional human error. Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.

Conversely, the 1993 changes reflected a reduced severity level for individual violations that represent isolated mistakes involving human error made in the diagnosis or treatment of individual patients with byproduct material. The Commission continues to believe that the examples established in 1993 are appropriate, with minor modifications to conform to the terminology used in the newly revised 10 CFR Part 35.

The examples use the terms "substantial programmatic failure" and "programmatic weakness." To differentiate between these two terms, "substantial programmatic failure" applies in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. The failure could be due to a serious omission in the procedures required under 10 CFR 35.41 or to a failure to train employees to follow procedures. "Programmatic weakness" indicates that the failure is more widespread than simple occasional human error. For example, the term "programmatic weakness" would apply in a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions results in a medical event.

Paperwork Reduction Act

This final change to the NRC Enforcement Policy does not contain new or amended information collection requirements subject to the Paperwork Reduction Act fo 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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 to read as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

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SUPPLEMENT VI--FUEL CYCLE AND MATERIALS OPERATIONS

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A. Severity Level I - Violations involving for example:

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4. Failure to use a properly prepared written directive as required by 10 CFR 35.40; or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41; that results in a death or serious injury (*e.g.*, substantial organ impairment).

B. Severity Level II - Violations involving for example:

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3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that results in a medical event.

C. Severity Level III - Violations involving for example:

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5. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that does not result in a medical event. Failure to report a medical event. A programmatic weakness in the

implementation of written directives or procedures for administrations requiring a written directive, whether or not a medical event occurs.

D. Severity Level IV - Violations involving for example:

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3. Failure to use a properly prepared written directive as required by 10 CFR 35.40 or failure to follow procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures: (1) are isolated; (2) do not demonstrate programmatic weakness in implementation; and (3) have limited consequences if a medical event is involved.

Dated at Rockville, Maryland, this day of 2000.

For the Nuclear Regulatory Commission

Annette Vietti-Cook,
Secretary of the Commission