RULEMAKING ISSUE
NOTATION VOTE

December 20. 2000 SECY-00-0236

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: DRAFT RULEMAKING PLAN: EVENT REPORTING FOR UNINTENDED EXPOSURES TO AN EMBRYO/FETUS OR TO A NURSING CHILD UNDER NON-MEDICAL, NON-OCCUPATIONAL CIRCUMSTANCES

PURPOSE:

To provide the Commission with a draft rulemaking plan that includes an analysis of options for revising reporting requirements to capture unintended exposures to a nursing child or an embryo/fetus under non-medical circumstances, and to request a Commission decision on whether to proceed with such a rulemaking.

SUMMARY:

This paper discusses the issue of whether adequate reporting requirements are in place to ensure that NRC is receiving reports of unintended, non-medical radiation exposures to an embryo/fetus or to a nursing child and provides rulemaking options.

BACKGROUND:

By statute, the Commission is required to submit to the Congress, an annual report listing for the previous fiscal year any Abnormal Occurrences (AOs) at or associated with facilities licensed by the Commission.

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Section 208 of the Energy Reorganization Act of 1974, as amended, 42 U.S.C. § 5848; "Federal Reports Elimination and Sunset Act of 1995," Public Law No. 104-66.[1] The Commission has implemented this statute through issuance of an AO Policy Statement[2] which contains definitions and criteria to determine which incidents or events will be considered for reporting as AOs. For purposes of Section 208 and Section 2.(a) of the definitions portion of the Commission's AO policy statement, an "abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health and safety." 62 FR 18821. The AO policy statement criteria for reporting AOs include unintended radiation exposures.[3] Those criteria, set forth in Appendix A, "Abnormal Occurrence Criteria," of the AO policy statement distinguish between unintended exposures to adults (individuals 18 years of age or older), minors, and an embryo/fetus. For overexposures involving minors or an embryo/fetus, the threshold is an annual Total Effective Dose Equivalent of 50 millisievert (5 rem) or more (62 FR at 18823, Attachment 1).

The Commission approved publication of the Final Policy Statement in a Staff Requirements Memorandum (SRM) to SECY-96-193, "Abnormal Occurrence Reports: Implementation of Section 208, Energy Reorganization Act of 1974; Final Policy," November 7, 1996 (Attachment 2). In this SRM, the Commission directed the staff to report to the Commission on how NRC will identify unintended medical radiation exposures to an embryo/fetus or a nursing child. This issue was addressed during the revision of 10 CFR Part 35 and was discussed in SECY-99-201-Draft Final Rule-10 CFR Part 35, "Medical Use of Byproduct Material," August 3, 1999, and SECY-00-0118 - Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material, and 10 CFR Part 20, "Standards for Protection Against Radiation, May 21, 2000."

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[1] Section 208 requires that each AO report shall contain:
(1) the date and place of each occurrence;
(2) the nature and probable consequence of each occurrence;
(3) the cause or causes of each; and
(4) any action taken to prevent reoccurrence;

and that the Commission shall also provide wide dissemination to the public of the information specified in the above clauses.

[2] "Abnormal Occurrence Reports: Implementation of Section 208, Energy Reorganization Act of 1974; Revision to Policy Statement," 62 FR 18820, 18822 (April 17, 1997).

[3] The AO Policy Statement (62 FR at 18822), contains the following definition of "unintended radiation exposure:"

> (b) An "unintended radiation exposure" includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in 35.2) involving the wrong individual that exceeds the reporting values established in the regulations . . . . In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above the specified values.

In the SRM dated February 16, 2000 (Attachment 3), on SECY-99-201, the Commission approved the staff recommendation to modify the proposed rule for 10 CFR Part 35 to include a reporting threshold of 50 millisieverts (5 rems) to an embryo/fetus or nursing infant in cases where the radiation exposure was not intended. The Commission also directed the staff to "...prepare a rulemaking plan to revise either Part 20 or other parts of Title 10 to require reporting of unintended exposures under non-medical circumstances to an embryo, fetus, or nursing child. The rulemaking plan should discuss the pros and cons of each option, including a no action option if the staff believes a rulemaking is not necessary."

DISCUSSION:

The staff formed a Working Group to evaluate this issue. The Working Group was comprised of representatives from the Offices of Nuclear Material Safety and Safeguards; Enforcement; State and Tribal Programs; Nuclear Reactor Regulation; and the General Counsel. The Working Group reviewed the current regulations to determine if there are adequate reporting requirements in place regarding unintended exposures to an embryo/fetus or to a nursing child under non-medical circumstances to ensure that NRC is receiving reports of such exposures. The Working Group also reviewed the reports of these types of incidents that are contained in the Nuclear Material Events Database.

The Working Group found that:

1. A non-medical direct overexposure[4] to a nursing child is required to be reported to NRC as an overexposure to a member of the public, under 10 CFR § 20.2203.

2. Overexposures to an embryo/fetus from occupational exposure of a declared pregnant woman are reported to NRC under § 20.2203.

3. There are no specific reporting requirements for reporting unintended exposures to an embryo/fetus if a member of the public is pregnant and is exposed beyond the public dose limits, under non-medical, non-occupational circumstances.

4. A review of events in the Nuclear Materials Events Database (1995 to present) identified only 15 incidents resulting in overexposures to members of the public and one incident where there was a potential for an overexposure to a member of the public, which were reported to NRC. Of these, none reported an overexposure of an embryo/fetus or a nursing child. Based on the results of NRC's inspection program, the staff has no reason to believe that the database is inaccurate or incomplete with respect to overexposures to members of the public.

   In addition, in 1992, through an NRC investigation of a therapy misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania, NRC became aware that two non-radiation workers who were pregnant received unintended radiation exposures. As discussed later in this paper and in the draft rulemaking plan, the staff believes that

[4] Direct overexposure is distinguished from an overexposure in which a nursing child ingests breast milk from an overexposed mother who has ingested radioactive material.

NRC will learn of unintended exposures to an embryo/fetus as was the case with the incident in Indiana, Pennsylvania.

In addition to data on overexposures of members of the public, there were three reports of an overexposure to an embryo/fetus from medical administration of iodine-131 to the mother. There was also one reported overexposure of a nursing child from medical administration of iodine-131 to the mother that exceeded the AO criteria. The staff believes that, in the majority of cases, unintended, non-occupational overexposures to an embryo/fetus or nursing child are related to medical administrations to the mother.

The staff discussed this issue with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on November 9, 2000. The ACMUI believed that current reporting requirements in Part 20 are adequate and that a revision to the regulations is not needed.

The staff plans to include a statement in the AO report to reflect that events that are voluntarily reported to the NRC by NRC licensees or Agreement States and meet the AO criteria are included in the AO report. If NRC is voluntarily informed of an unintended, non-medical, non-occupational exposure to an embryo/fetus or to a nursing child, it will report it to Congress in the annual AO report if the event meets the AO criteria.

REGULATORY OPTIONS:

Based on the Working Group's findings, rulemaking options were developed to address two issues associated with non-medical, non-occupational radiation exposures to a nursing child or an embryo/fetus of a member of the public. These issues, associated options, and staff recommendations are listed below. A detailed discussion, including pros and cons for each rulemaking option, is provided in the attached rulemaking plan (Attachment 4).

Issue 1 - Nursing Child:

Options

1. Revise the definition of "member of the public" in 10 CFR § 20.1003 to clearly specify that a member of the public includes a nursing child,

2. Provide guidance to licensees that NRC considers the definition of "member of the public" in § 20.1003 to include a nursing child, or

3. No rulemaking action needed.

Issue 2 - Embryo/fetus:

Options

1. Revise 10 CFR § 20.2203(b) to include a specific reporting requirement that if a licensee is voluntarily informed of a pregnancy by a member of the public who received an exposure in excess of the public dose limits in § 20.1301, the licensee would then need to include that information in the report it submits to NRC about the overexposure. Reporting thresholds are detailed in the attached rulemaking plan.

2. Revise other parts of 10 CFR Chapter I to include a specific reporting requirement that if a licensee is voluntarily informed of a pregnancy by a member of the public who received an exposure in excess of the public dose limits in § 20.1301, the licensee would then need to include that information in the report it submits to NRC about the overexposure.

3. No rulemaking action needed.

Staff Recommendation:

The staff does not believe it is necessary to add specific reporting requirements in 10 CFR Part 20 or elsewhere in 10 CFR to require licensees to report to NRC any unintended radiation exposures to a nursing child or an embryo/fetus, under non-medical, non-occupational circumstances. The staff is recommending the "No Rulemaking Action" option for both Issues 1 and 2 for the following reasons:

1. Regulations are currently in place such that NRC will receive reports of overexposures to members of the public, which includes children. The staff is not aware of any situations where an embryo/fetus would receive an exposure where the mother would not receive essentially the same exposure. If the member of the public is pregnant or nursing a child, NRC may not receive that information unless she volunteers it. The staff believes that, in most cases, the woman will volunteer this information to the licensee or the NRC. As an example, in 1992, through NRC's investigation of a therapy misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania, NRC was made aware of two non-radiation workers who were pregnant and received unintended radiation exposures.

2. Any reporting requirement would have to be limited to situations in which the licensee was voluntarily informed of a pregnancy or nursing by a member of the public. This is consistent with the provisions of § 20.1208 regarding voluntary declaration of pregnancy by an occupational worker. The basis of a voluntary declaration is to avoid invasion of privacy issues.

3. A reporting requirement is not needed to maintain safety because there will be no change to the safety standards and dose limits currently in place, nor will it increase public confidence in NRC's ability to protect public health and safety. In addition, new reporting requirements may result in a slight increase in regulatory burden on licensees and require additional NRC staff time to review the reports. Any new reporting requirements will require review and approval by the Office of Management and Budget.

By statute (Section 208 of the Energy Reorganization Act of 1974, as amended, 42 U.S.C. § 5848; "Federal Reports Elimination and Sunset Act of 1995," Public Law No. 104-66), NRC is required to submit annual reports to Congress on any events which the Commission determines are significant from the standpoint of public health and safety. As discussed earlier in this paper, the Commission has implemented this statute through issuance of an AO Policy Statement which contains criteria to determine which incidents or events are considered significant for reporting to Congress and the public.

The final rule for 10 CFR Part 35 would require licensees to notify NRC of any exposure to an embryo/fetus that exceeds 50 millisieverts (5 rems) unless specifically approved, in advance, and any exposure to a nursing child that is greater than 50 millisieverts (5 rems) Total Effective Dose Equivalent, or has resulted in unintended permanent functional damage to an organ or a physiological system of the child. Without this revised rule, the staff realized that there would not have been a mechanism in place for NRC to receive reports of these exposures. Such exposures would not have triggered any other reporting requirement if the medical procedure was administered in accordance with the physician's direction.

For non-medical licensees, an unintended exposure to an embryo/fetus or to a nursing child (in the case of ingestion through the breast-milk) would occur only if the mother was exposed. If a member of the public, including a child, is exposed beyond the dose limits for members of the public in § 20.1301, the licensee has to report that overexposure to NRC in accordance with § 20.2203, as well as report the overexposure to the member of the public (§ 20.2205). The staff believes that an additional reporting requirement in Part 20 for a licensee to submit information about a member of the public being pregnant, even if it found out about the pregnancy through voluntary means from the woman, could involve invasion of privacy issues. As discussed elsewhere in this paper and in the draft rulemaking plan, staff believes that if a woman who was pregnant was notified of an overexposure, she would volunteer information regarding her pregnancy to the licensee, and that NRC would, in all likelihood, learn of the pregnancy. So, unlike Part 35, the staff believes that regulations are already in place such that NRC would learn of significant events involving unintended exposures to an embryo/fetus or nursing child under non-medical circumstances.

AGREEMENT STATE COMMENT ON THE DRAFT RULEMAKING PLAN:

This draft rulemaking plan has not been provided to the Agreement States for their comment. Under office procedures (NMSS Policy and Procedures Letter 1-63, Procedures for Preparation and Review of Rulemaking Packages, June 11, 1998), if a rulemaking plan is particularly controversial or involves a significant policy issue (as in this case), staff will send the rulemaking plan to the Commission before it is sent to the Agreement States. This allows Commission consideration of the staff's recommendation before seeking Agreement State review. If the Commission disapproves the staff's recommendation to terminate any further action on this rulemaking action, the draft rulemaking plan will be modified as needed to reflect the Commission's direction and provided to the Agreement States for a 45-day comment period.

If the staff goes forward with the subject rulemaking plan, the rule would be a Category C compatibility level. Agreement States would be required to adopt the essential objectives to avoid conflict, duplication, gaps or other conditions that would jeopardize an orderly pattern in the regulation of radioactive material on a nationwide basis.

RESOURCES:

If the Commission directs the staff to go forward with rulemaking, the resources would be approximately 0.5 FTE for NMSS and 0.1 FTE for other offices. These resources are available within the budget for fiscal years 2001 and 2002. The staff will need to evaluate the priority of the rulemaking, and other rulemaking activities, in accordance with the Planning, Budgeting, Program Management process.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed this paper for information technology and information management implications and has no objections.

RECOMMENDATION:

The staff recommends that:

1. The Commission approve the staff's recommendation to terminate any further action on this proposed rulemaking.

2. If the Commission directs further action on this rulemaking, approve dissemination of the rulemaking plan to the Agreement States for comment.

/RA/

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for Operations

Attachments: 1. AO Policy Statement
2. SRM dtd 11/7/96
3. SRM dtd 2/16/00
4. Draft Rulemaking Plan

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