Draft Rulemaking Plan

Event Reporting for Unintended Exposures to an
Embryo/Fetus or to a Nursing Child Under Non-Medical Circumstances

REGULATORY PROBLEM OR ISSUE

Are regulatory requirements currently in place to assure that unintended exposures under non-medical circumstances to an embryo/fetus or to a nursing child are reported to NRC?

BACKGROUND

By statute, the Commission is required to submit to the Congress, an annual report listing for the previous fiscal year "any abnormal occurrences" (AO) at facilities licensed by the Commission. 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]. This statute has been implemented by the Commission through issuance of an Abnormal Occurrence 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 Abnormal Occurrence 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 AO's include any "unintended radiation exposures."[3]

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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 Abnormal Occurrence (AO) Policy (62 FR 18820, April 17, 1997, on page 18820), 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.

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 18820, page 18823, Attachment 1).

The Commission approved publication of the Final Policy Statement in Staff Requirements Memorandum (SRM), SECY-96-193 - "Abnormal Occurrence Reports: Implementation of Section 208 Energy Reorganization Act of 1974; Final Policy," November 7, 1996. It 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 and describe the staff's experience with voluntary reporting. The SRM also directed the staff to "address whether the final AO Policy criteria should be revised to omit reference to these types of incidents, if the staff does not recommend a mechanism to 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. The proposed rule for 10 CFR Part 35 contained separate reporting requirements for unintended exposures of an embryo/fetus or nursing child. For the embryo/fetus, a licensee would be required to notify NRC of any dose greater than 5 millisieverts (500 millirems), unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user. For a nursing child, a licensee would be required to report to NRC any dose, regardless of intention, greater than 5 millisieverts (500 millirems). In response to numerous comments from stakeholders on these reporting requirements, the staff discussed two options in SECY-99-201, "Draft Final Rule - 10 CFR Part 35, "Medical Use of Byproduct Material," dated August 3, 1999. Option 1 would have placed the requirements in 10 CFR Part 20, "Standards for Protection Against Radiation." Under Option 2, the requirements would be in 10 CFR Part 35, "Medical Use of Byproduct Material," and the reporting threshold would be raised to 50 millisieverts (5 rems). The staff proposed that it was more appropriate to go forward with Option 2 because the majority of incidents that would warrant reporting occur during medical use. The staff stated it would further evaluate whether or not rulemaking is needed to add a similar requirement to 10 CFR Part 20, or Parts 30, 40, and 70 to address a non-medical exposure to an embryo/fetus or a nursing child.

In a SRM dated February 16, 2000, SECY-99-201 - Draft Final Rule - 10 CFR Part 35, "Medical Use of Byproduct Material," 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. 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 rulemaking is not necessary."

EXISTING REGULATORY FRAMEWORK

10 CFR Part 20 contains occupational dose limits for adults (10 CFR § 20.1201), minors (§ 20.1207); and declared pregnant women (§ 20.1208); as well as dose limits for individual members of the public (§ 20.1301). If these specified dose limits are exceeded, licensees are

required by § 20.2203 to report such overexposures to NRC, and are required by § 20.2205 to provide same to the affected individual. Each report required by §20.2203(c) must describe the extent of the exposure to individuals, including the estimates of each individuals dose.
10 CFR §20.2203(b).

In addition, §§ 20.2201 and 20.2202, respectively, require licensees to immediately report to NRC "... under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas;..." or when an incident occurs "... that may have caused or threatens to cause ... an individual to receive ..." a specified radiation dose, e.g., five times the occupational dose limit for an adult. The text of each of these requirements (or relevant portions) is provided below.

Section 20.2201, "Reports of theft or loss of licensed material," requires, in part, that

(a) Telephone reports

(1) each licensee shall report by telephone as follows:
(i) immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
(ii) within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to Part 20 that is still missing at this time.

(Note: The telephone report must be followed by a written report within 30 days, and must include, in part, information regarding exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas.)

Section 20.2202, "Notification of incidents," requires, in part, that

(a) ... each licensee shall immediately report any event involving byproduct, source or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions -

(1) An individual to receive
(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or
(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or
(iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

(2) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake . . . .

(b) ... Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours -
(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or
(ii) A lens dose equivalent exceeding 15 rems (0.15 SV); or
(iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv);

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake. . . .

Section 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits." requires, in part, that

(a) *Reportable events*. In addition to the notification required by 10 CFR § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:
(i) The occupational dose limits for adults in § 20.1201; or
(ii) The occupational dose limits for a minor in § 20.1207; or
(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or
(iv) The limits for an individual member of the public in § 20.1301

(Note: Such reports must describe the extent of the exposure of individuals to radiation and radioactive material, including, as appropriate, estimates of each individual's dose; the levels of radiation and concentration of radioactive material; the cause of the elevated exposures, dose rates, or concentrations; and corrective steps to prevent a recurrence.)

Section 20.2205, "Reports to individuals of exceeding dose limits." requires, in part, that

When a licensee is required, pursuant to the provisions of 10 CFR § 20.2203, ... to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Commission to the individual. This report must be transmitted at a time no later than the transmittal to the Commission.

EXPOSURE CATEGORIES

The staff has identified several different categories in which an embryo/fetus or nursing child could receive an unintended radiation exposure under non-medical circumstances. These categories are discussed below.

1. Nursing Child - Specific Licensees:

The staff reviewed the regulations to determine if there is a reporting requirement in place for unintended radiation exposures under non-medical circumstances to a nursing child. A "member of the public," by definition in 10 CFR § 20.1003, means "any individual except when that individual is receiving an occupational dose." A nursing child is considered to be a member of the public. NRC regulations require licensees to report unintended, non-medical exposures to a nursing child under § 20.2203 if that exposure exceeded the dose limits for a member of the public.

2. Embryo/fetus - Specific Licensees:

The staff reviewed the regulations to determine if there is a reporting requirement for unintended exposures under non-medical circumstances to an embryo/fetus. The staff determined that there are 3 potential situations in which an unintended radiation exposure under non-medical circumstances to an embryo/fetus could occur:

(1) Occupational workers who are pregnant and have declared their pregnancy in accordance with 10 CFR § 20.1208

For women who have declared their pregnancy, the licensee must ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure, does not exceed 5 millisieverts (500 millirems). If the limit for the embryo/fetus of a declared pregnant woman is exceeded, the licensee must submit reports to NRC and to the individual as required by §§ 20.2203 and 20.2205, respectively.

(2) Occupational workers who are pregnant and have chosen not to declare their pregnancy

Occupational workers who are pregnant are not required to declare their pregnancy and may choose not to do so. The dose limits for these women would be controlled by the regulations in 10 CFR § 20.1201, Occupational dose limits for adults. If a dose limit is exceeded for an occupational worker, the licensee must submit a report to NRC as required by § 20.2203. (NOTE: The definition of unintended exposure in the AO Policy specifically excludes unintended exposures to the embryo/fetus of occupational workers who have chosen not to declare their pregnancy (62 FR 18822)).

(3) Members of the public that are pregnant

The dose limits in 10 CFR § 20.1301, Dose limits for members of the public, apply to members of the public that are pregnant. The annual dose limit for members of the public is 1 millisievert (100 millirems), total effective dose equivalent, exclusive of other dose contributions noted in that section. If a member of the public receives an exposure beyond that limit, licensees are required to submit reports of that overexposure in accordance with §§ 20.2203 and 20.2205. Additionally, § 20.2202 requires licensees to notify NRC of incidents in which it is possible for individuals to exceed specified dose limits, all of which fall within the AO criteria.

The staff believes that a woman who is pregnant and was notified of an overexposure would volunteer information regarding her pregnancy to the licensee. If a member of the public is overexposed, NRC would likely learn about an exposure to an embryo/fetus, if the woman volunteered that information to the licensee.

3. Embryo/fetus and Nursing Child - General Licensees:

In most cases, general licensees are required to comply with 10 CFR §§ 20.2201 and 20.2202. The staff does not believe that it is necessary to add a specific reporting requirement for general licensees to notify NRC of an unintended exposure to an embryo/fetus or a nursing child (i.e. a member of the public). Devices licensed under a general license are designed to be inherently safe, even under accident conditions, so that persons receiving no radiation safety training can safely operate the device. For example, a device manufactured under § 32.51 for transfer to persons generally licensed under § 31.5 must meet the following criteria (§ 32.51(a)(2)(ii) and (iii)):

(1) it is unlikely that any person will receive in one year a dose in excess of 10 percent of the limits in § 20.1201(a), that is, 5 millisieverts (500 millirems), and

(2) under accident conditions, it is unlikely that any person would receive an external dose or dose commitment in excess of 150 millisieverts (15 rems) whole body, 2 Sieverts (200 rems) to the extremities or localized areas of the skin averaged over areas no larger than 1 square cm, and 500 millisieverts (50 rems) to other organs.

The staff believes that the likelihood of an event occurring at a level such that the AO criteria would be met is low. If there was an accident involving a generally licensed device, or if a device was lost or stolen, NRC would be aware of the incident due to current reporting requirements. The staff believes that there will be enough media attention and public notice that members of the public would be aware of potential overexposures and come forward to the licensee expressing any concerns as to exposure of an embryo/fetus or nursing child.

STAFF REVIEW OF NUCLEAR MATERIALS EVENT DATABASE:

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 involved 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 NRC's 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.

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.

RULEMAKING OPTIONS

Rulemaking options have been addressed under two separate categories: Issue 1 - Unintended Exposures under Non-medical, Non-occupational Circumstances to a Nursing Child; and Issue 2 - Unintended Exposure under Non-medical, Non-occupational Circumstances to an Embryo/Fetus. There does not appear to be a need for further consideration of unintended, occupational radiation exposure of an embryo/fetus or a nursing child. Each issue has multiple options for consideration. These options are discussed below.

Issue 1 - Unintended Exposures under Non-medical, Non-occupational Circumstances to a Nursing Child

Option 1. Revise the definition of "individual member of the public" in 10 CFR § 20.1003 to clearly specify that a nursing child is a member of the public and that a licensee shall report any exposure to a nursing child if the public dose limits in § 20.1301 are exceeded.

Pro:
- Revising the definition would eliminate any question that a nursing child is a member of the public.

Cons:
- A nursing child is a member of the public. Therefore, this rulemaking is not necessary.
- The NRC is not aware of any cases of an overexposure to a nursing child as a result of an overexposure to the mother that was not related to a medical administration. There is no reason for the staff to believe that such exposures are occurring and are not being reported to NRC.
- This issue of an overexposure of a nursing child under non-medical, non-occupational circumstances appears to be very narrow in scope and the expenditure of resources for such a rulemaking cannot be justified by the scope of the issue.

Option 2. Provide guidance to licensees that NRC considers the definition of "member of the public" in 10 CFR § 20.1003 to include a nursing child.

Pro:
- Providing guidance will help ensure that licensees are aware that a nursing child is considered a member of the public.

Con:
- Developing guidance will utilize resources for an issue that may already be understood and could best be used for higher priority projects.

Option 3. No rulemaking action needed.

A third option is to take no action to impose a new reporting requirement.

Pros:
- A nursing child is a member of the public and therefore the issue is already addressed.
- Saves the expenditure of resources associated with a rulemaking and allows the resources to be applied to higher priority rulemaking efforts.

Cons:
- A licensee may not realize that a nursing child is a member of the public and; therefore, may not be reporting unintended radiation exposures to a nursing child.
- Is not consistent with the regulatory approach for medical use requiring licensees to report to NRC certain exposures either to an embryo/fetus or nursing child. It is also not consistent with the regulatory approach articulated in SRM dated October 23, 2000, SECY-00-0118, in which the Commission directed the staff to develop a proposed revision to Part 35 that will require a licensee to notify NRC after it becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75. SECY-00-0118 - Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material, and 10 CFR Part 20, "Standards for Protection Against Radiation," Attachment 6 at 640-42; SRM-00-0118, October 23, 2000.
- The Commission may not receive information on incidents or events which it considers significant from the standpoint of public health and safety, and which the Commission uses to comply with Section 208 of the Energy Reorganization Act. (That is, licensees reporting unintended radiation exposures are not explicitly required to provide information to the NRC which they may learn through voluntary means as to the pregnancy or nursing status of a member of the public.) This information regarding whether or not an unintended radiation exposure involved a nursing child would not be available for the Commission to evaluate the safety significance of the event and to report fully in its AO report on the nature and consequence of the exposure.

Recommended Option for Issue 1: Option 3, "No rulemaking action needed"

The staff does not believe that revising the definition of member of the public in 10 CFR §20.1003 to explicitly state that a nursing child is a member of the public is necessary. 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 is exposed, including a child, 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). 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. Such a rulemaking would not increase public confidence or maintain safety beyond the reporting requirements that are already in place and would

expend resources that could best be used for higher priority rulemaking. Furthermore, there is no data to indicate that additional specificity or clarification is necessary.

Issue 2 - Unintended Exposure under Non-medical, Non-occupational Circumstances to an Embryo/Fetus

In reviewing the following options, note that any reporting requirement would have to be limited to situations during which the licensee, through no investigation or assumptions of its own, is voluntarily informed of a pregnancy by a member of the public. Voluntary reporting of a pregnancy is consistent with the provisions of 10 CFR § 20.1208 regarding voluntary declaration of pregnancy by an occupational worker.

Option 1. Revise 10 CFR Part 20

Revise 10 CFR § 20.2203(b) to add 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 dose limits, the licensee would be required to include that information in the report it submits to NRC. The requirement would only apply to a member of the public who was overexposed and has voluntarily informed the licensee that she was pregnant. This reporting threshold could be established at either 5 millisieverts (500 millirems) or 50 millisieverts (5 rems).

(a) A licensee would be required to report to NRC a dose to an embryo/fetus of 5 millisieverts (500 millirems) or more.

Pros:

- This reporting threshold would be the same reporting threshold as in § 20.2203 that sets forth the dose limits for an embryo/fetus of a declared pregnant worker in § 20.1208.

- This reporting of information voluntarily provided by a member of the public to the licensee would be consistent with the regulatory approach articulated in the SRM dated October 23, 2000, SECY-00-0118 - Final Rules - 10 CFR Part 35, “Medical Use of Byproduct Material” and 10 CFR Part 20, “Standards for Protection Against Radiation”

- The Commission would receive information on incidents or events which it considers significant from the standpoint of public health and safety, and which the Commission uses to comply with Section 208 of the Energy Reorganization Act. (That is, licensees reporting unintended radiation exposures are not explicitly required to provide information to the NRC which they may learn through voluntary means as to the pregnancy or nursing status of a member of the public.) This information regarding whether or not an unintended radiation exposure involved a nursing child would not be available for the Commission to evaluate the safety significance of the event and to report fully in its AO report on the nature and consequence of the exposure.

Cons:
- This reporting threshold would be inconsistent with the reporting threshold in the final revision to Part 35.
- An additional reporting requirement may result in a slight increase in unnecessary regulatory burden on licensees.
- An additional reporting requirement does not appear to improve public confidence because, in the event of an incident, a woman who is notified of an exposure can always inform the licensee or the NRC if she is pregnant.

(b) A licensee would be required to report to NRC a dose to an embryo/fetus of 50 millisieverts (5 rems) or more.

Pros:
- This threshold is the same as the AO criteria and information about the event would be available to include in NRC's report to Congress. Licensee's report would provide to the Commission information on incidents or events which it considers significant from the standpoint of public health and safety, and which the Commission uses to comply with Section 208 of the Energy Reorganization Act. (That is, licensees reporting unintended radiation exposures would be required to provide information to the NRC which the may learn through voluntary means to the pregnancy status of a member of the public). This information regarding whether or not an unintended radiation exposure involved an embryo/fetus would not be available for the Commission to evaluate the safety significance of the event and to report fully in its AO report on the nature and consequence of the exposure.
- This reporting of information voluntarily provided by a member of the public to the licensee would be consistent with the regulatory approach articulated in the SRM dated October 23, 2000, SECY-00-0118 - Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material" and 10 CFR Part 20, "Standards for Protection Against Radiation"
- This reporting threshold would be consistent with the reporting threshold in the final revision to Part 35.

Cons:
- This reporting threshold is a factor of 10 times greater than the current reporting requirement in § 20.2203 that refers to the limits for an embryo/fetus of a declared pregnant worker in § 20.1208.
- An additional reporting requirement may result in a slight increase in unnecessary regulatory burden on licensees.
- An additional reporting requirement does not appear to improve public confidence because, in the event of an incident, a woman who is notified of an exposure can always inform the licensee or the NRC if she is pregnant.

Option 2. Revise Other Parts of Title 10

Revise other Parts of Title 10 to add 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 dose limits, the licensee would be required to include that information in the report it submits to NRC. The requirement would only apply to a member of the public who was overexposed and has voluntarily informed the licensee that she was pregnant. This reporting threshold could be established at either 5 millisieverts (500 millirems) or 50 millisieverts (5 rems). The reporting thresholds are discussed in Option 1 above.

Pro:
- Currently, the regulations in other parts of Title 10 CFR, Chapter I (besides Part 35) do not establish limits for reporting of exposures exceeding the dose limits. If a reporting requirement was added to each Part, then the licensee subject to that Part would clearly understand that unintended exposures would need to be reported.

Cons:
- This duplication could lead to inconsistencies in the regulations, due to potential errors in cross-referencing.

- Current reporting requirements for overexposures are in Part 20. Licensees are required to comply with Part 20. It is easier for licensees if all reporting requirements of overexposures are located within the same Part of 10 CFR Chapter I.

Option 3. No rulemaking action needed.

A third option is to take no action to impose a new reporting requirement.

Pros:
- Due to potential privacy issues, NRC would not want to require a licensee to determine if a member of the public was pregnant at the time of an exposure. The staff believes that a pregnant woman who is notified of an overexposure would volunteer information on her pregnancy status to the licensee or NRC. If a member of the public is overexposed, NRC would likely learn about an exposure to an embryo/fetus, if the woman volunteered that information to the licensee or to the NRC directly.

- This option has the advantage of saving the resources needed to develop a rulemaking that may only minimally increase the information that licensees are already required to provide in 10 CFR 20.2203(b)(1) as to the extent of exposure of individuals number of reports above what NRC already receives.

Cons:
- There is the chance that NRC would not receive a report of an unintended exposure to an embryo/fetus, and NRC would not necessarily know about the event so that it could review the circumstances during the next inspection and focus the licensee on improving its radiation safety program and report fully in AO reports as to the nature and consequence of each occurrence.

- Is not consistent with the regulatory approach for medical use requiring licensees to report to NRC certain exposures either to an embryo/fetus or nursing child. It is also not consistent with the regulatory approach articulated in SRM dated October 23, 2000, SECY-00-0118, in which the Commission directed the staff to develop a proposed revision to Part 35 that will require a licensee to notify NRC after it becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75. SECY-00-0118 - Final Rules - 10 CFR Part 35, "Medical Use of Byproduct Material, and 10 CFR Part 20, "Standards for Protection Against Radiation," Attachment 6 at 640-42; SRM-00-0118, October 23, 2000.

Recommended Option for Issue 2: Option 3, "No rulemaking action needed"

After evaluating this issue, the staff does not believe that it is necessary to add a specific reporting requirement for licensees to report to NRC an unintended exposure to an embryo/fetus. 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. A pregnant woman who is notified of an overexposure would likely volunteer information about her pregnancy to the licensee or to the NRC. 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). 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.

Recommended Action

No rulemaking action. However, the staff plans to revise the AO report to reflect: 1) the voluntary nature of information submitted by licensees on unintended, non-medical, non-occupational exposures to an embryo/fetus or to a nursing child, and 2) that if NRC is informed of any such exposures, it will report those exposures to Congress in the annual AO report if the event meets the criteria.

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, was 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 raise invasion of privacy issues. As discussed elsewhere in this 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 exposure to an embryo/fetus or nursing child under non-medical circumstances.

OGC Analysis of Legal Sufficiency

The purpose of this draft rulemaking plan is to consider, as the Commission has directed, whether to revise either 10 CFR 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.

By statute, NRC is required to submit an annual report to Congress and widely disseminate to the public information on unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., an abnormal occurrence (AO). Section 208, Energy Reorganization Act of 1974, 42 U.S.C. § 5848; "Reports Elimination Act," Public Law 104-66. Appendix A of the AO policy statement contains the criteria upon which the Commission relies to determine whether an event or incident is an AO within the purview of Section 208. 62 Fed. Reg.18822-23. Those criteria distinguish between unintended radiation exposures to an adult (any individual 18 years of age or older) and such exposures to a minor (an individual less than 18 years of age) or embryo/fetus. The annual total effective dose equivalent (TEDE) threshold for adults is 250 mSv (25 rem), while for a minor or embryo/fetus, the annual TEDE is 50 mSv (5 rem). 62 Fed. Reg. 18823. As stated in the AO policy statement, an "unintended radiation exposure" is "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 specified values." Id., at 18822.

In the occupational or medical contexts, the current or proposed regulations contain specified dose limits or reporting thresholds, as the case may be, for minors, an embryo/fetus of a declared pregnant woman, or a nursing child. For the occupational exposure of a declared pregnant woman, licensees are required by 10 CFR §§ 20.2203 to report to the Commission and to the individual doses in excess of the values in §§ 20.1208. 10 CFR §§ 20.2203 and

20.2205. As noted by the Commission in the regulatory history of 10 CFR § 20.1208, requiring licensees to make this determination could raise potential personal privacy and discrimination issues regarding occupational dose limits for pregnant women. "Standards for Protection Against Radiation," 56 Fed. Reg. 23360, 23373 (May 21, 1991). Section 35.3047 of the draft final rule to revise 10 CFR Part 35, "Medical Use of Byproduct Material," contains separate requirements for licensees to report administrations of byproduct material, or radiation therefrom, to a pregnant or nursing female that results in a dose to an embryo/fetus or nursing child above 50 mSv (5 rem), unless the administration was specifically approved, in advance, by an authorized user. SECY-99-201, "Draft Final Rule - 10 CFR Part 35, 'Medical Use of Byproduct Material,' " Attachment 7, at 579-80 (August 3, 1999); SRM, SECY-00-0118, October 23, 2000. However, that rule would not specify dose limits for such administrations nor require licensees to ascertain the pregnancy or nursing status of a female patient before administering the byproduct material. Id.; at 343. The rationale for not imposing the latter requirement is that it is the standard of practice for authorized users to assess the pregnancy or nursing status of their patients before the medical administration of byproduct material. Id.

As directed by the Commission, this rulemaking plan considers whether there are mechanisms for NRC to identify unintended radiation exposures to an embryo/fetus or nursing child (exposed by ingesting breast milk) in the non-occupational, non-medical setting. Section 20.1301 contains dose limits for individual members of the public, which, according to the staff, includes direct, unintended radiation exposure to a nursing child (i.e., not exposed through its mother's breast milk). Reporting requirements are in place for unintended occupational and/or medical exposures, as described above. For other unintended radiation exposures not covered by those requirements, the staff states that based on past NRC experience, there would not be very many such exposures in the first place and individual members of the public or the licensee would likely voluntarily report such unintended exposures to the NRC even in the absence of a specific regulatory requirement. 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). 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. The staff has presented bases, which in its view, distinguish these unintended radiation exposures from the unintended medical exposures required to be reported in new § 35.3047.

One can conclude that there are no legal impediments to the staff's recommendation of no rulemaking action. The no rulemaking action option would not raise any environmental, backfit, small business, Paperwork Reduction Act, technology transfer or other issues associated with rulemaking.

There is, however, a policy question whether there is sufficient basis to distinguish the need for reporting requirements for unintended, non-medical, non-occupational radiation exposures. New § 35.3047 is based on the need for NRC to obtain the information on incidents or events which it considers significant from the standpoint of public health and safety, as required by Section 208 of the Energy Reorganization Act. SECY-99-201, Attachment 7, at 460-61. In that

rulemaking the Commission considered two alternatives: revise the AO criteria (to delete the requirement to inform Congress of medical events involving unintended radiation exposure of a nursing child or embryo/fetus) or develop a reporting requirement that would provide the information needed by the Commission to comply with Section 208. Id., at 461. The Commission rejected the first alternative, noting that the AO criteria had been recently revised. Id., at 462. As to the second alternative, the Commission stated that it was not convinced that it would be inappropriate to report such exposures to Congress or that the new reporting requirement would be overly burdensome or unwarranted. Id., at 341. Whether the same conclusions can be made here is the question of policy before the Commission.

In conclusion, OGC has determined that there are no known bases for legal objection to the staff's recommended course of action.

Backfit Analysis

This rulemaking plan is related to reporting requirements only and will, therefore, not require a back fit analysis.

Paperwork Reduction Act

The Office of the Chief Information Officer (OCIO) has reviewed the rulemaking plan for information technology and information management implications and concurs with the plan. However, if the staff goes forward with rulemaking, the rule will have additional reporting requirements that will require review by the OCIO for information collection requirements.

Agreement State Implementation Issues

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 for 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.

Supporting Documents

If the Commission directs the staff to go forward with rulemaking, a Regulatory Impact Analysis, an Office of Management and Budget clearance package, and Regulatory Flexibility Certification will need to be developed in support of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

If there is rulemaking, it would not constitute a major rule under the Small Business Regulatory Enforcement Fairness Act. This position will be confirmed through consultation with OMB.

Resources

If there is rulemaking, it is estimated that the resources required will be 0.5 FTE for NMSS and 0.1 FTE for other offices.

EDO or Commission Issuance

If the Commission directs the staff to go forward with rulemaking, it will be forwarded to the Commission for approval because it involves a significant question of policy concerning reporting thresholds and potential privacy issues.

Lead Office Staff and Staff from Supporting Offices - Concurring Official

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Cardelia Maupin, STP	Paul Lohaus, STP
Patricia Milligan, NRR	Samuel Collins, NRR
Harriet Karagiannis, RES	Ashok Thadani, RES

Public Participation

If the Commission directs the staff to go forward with rulemaking, the staff will discuss the draft rulemaking plan with the Advisory Committee on the Medical Uses of Isotopes during public meetings. Additionally, the staff plans to interact with the Nuclear Energy Institute during its routine public meetings with NRC. The rulemaking will also be placed on NRC's Rulemaking Website to enhance input from the public.