

NOTATION VOTE

RESPONSE SHEET

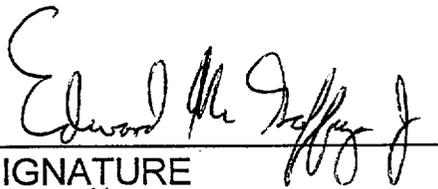
TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-99-201 - DRAFT FINAL RULE - 10 CFR PART 35,
"MEDICAL USE OF BYPRODUCT MATERIAL"**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments and edits.



SIGNATURE

November 24, 1999

DATE

Entered on "AS" Yes No

Commissioner McGaffigan's Comments on SECY-99-201

I approve completion of the final 10 CFR Part 35 rulemaking package using the draft final language provided in this paper subject to the comments below. My comments are based on the thorough staff paper and discussions with the staff, NRC's Advisory Committee on the Medical Use of Isotopes, the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors (CRCPD) during two recent public briefings of the Commission. I also approve notification of medical specialty boards at this time for the purposes of accepting requests for recognition of the boards before publication of the final rule. I offer the following comments and suggested edits.

Risk Assessment - First and foremost, I do not support delaying finalization of Part 35 for the purposes of conducting a formal risk assessment of the medical uses of byproduct material. Based on a two and a half-year exhaustive participatory process involving representatives of the medical community, OAS, CRCPD, and the public, the staff has developed a much more risk-informed and performance-based rule that will significantly reduce the regulatory burden for all NRC licensees. For example, licensees will no longer be required to submit their operating procedures at the time of license application, amendment or renewal. Rather, licensee procedures will only be reviewed by NRC during a reactive, not routine, inspection. Also, the controversial quality management program requirements have been reduced to two single elements--the use of written directives and patient identification verification. Further reduction of the regulatory burden has occurred in the diagnostic arena. For example, the rule no longer requires a Radiation Safety Committee for diagnostic use alone, dose calibrator test requirements have been reduced, radiation survey requirements rely solely on Part 20, and all training and experience requirements are much less prescriptive. I would also note that nothing in this rule prohibits the medical community or other stakeholders from conducting an independent formal risk assessment of the medical use of isotopes, and forwarding its analysis and recommendations for further modifications of Part 35 to NRC for its consideration.

Training and Experience - I fully support the less prescriptive and more performance-based proposed training and experience requirements for authorized user physicians, Radiation Safety Officers, physicists, and nuclear pharmacists. I commend the staff for identifying an orderly and fair solution to a complex issue that is generally acceptable to most if not all stakeholders. In particular, I strongly support retaining the current "80-hour" training requirement for physicians (primarily endocrinologists) who administer iodine-131 for diagnostic or therapeutic purposes, based on the extraordinarily low rate of misadministrations by this medical specialty. Therefore, as discussed below, I do not support and have serious concerns with the recommendation of the CRCPD Suggested Regulation committee (SR-6) that this category of user be required to meet the "700-hour" training requirement applicable to other categories of users.

Compatibility Level for Training and Experience Requirements - In the absence of a health and safety basis, I do not support the SR-6 committee recommendation that the Suggested State Regulations (SSRs) include increased training and experience requirements for endocrinologists. NRC's exhaustive rulemaking process involving stakeholders has resulted in a technically-sound, more risk-informed and performance-based rule that should be adopted by the Agreement States. It would be unfortunate, and I believe unnecessary from a health and safety perspective, if physicians who meet NRC's criteria are prevented by State regulation from using byproduct material at neighboring facilities located in certain Agreement States. To my

knowledge, NRC has no evidence to suggest that an adequate public health and safety basis exists to warrant increasing the current training and experience requirements for endocrinologists. This finding also applies to other categories of physician authorized users and other individuals including Radiation Safety Officers, physicists and pharmacists.

In fact, one could argue that State action to adopt more restrictive requirements could create a government-sanctioned restraint of trade against certain physicians or, at minimum, a disruption in the provision of medical services across state boundaries and increased costs to the national health care delivery system. Such an outcome would not be consistent with the fundamental goals of NRC's 1997 policy statements on adequacy and compatibility of Agreement State programs and the principles and policy for the Agreement State program (62 FR 46517). At the core of "compatibility," these policies place "uniformity and consistency in program areas having national significance. Such areas include those affecting interstate commerce, movement of goods and provisions of services and safety reviews for sealed source devices sold nationwide" (62 FR 46520). The last of these 3 areas is already explicitly covered by compatibility category B, as having "significant transboundary implications" (62 FR 46524).

Therefore, I believe that the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals should be changed from "C" to "B" to ensure that the provision of medical services nationwide is not disrupted by some Agreement States that might adopt significantly more restrictive criteria (e.g, 80 versus 700 hours). Requiring a more restrictive compatibility level would also be consistent with informal and formal comments received on the rule from some stakeholders during the rulemaking process and discussions during the recent Commission briefings.

Event Notification Requirements - While I recognize that most public comments do not generally support patient notification requirements, I continue to believe that written notification to patients of events is important and I support the current rule text for medical events and events involving the unintentional administration of byproduct material to an embryo, fetus or nursing infant. Therefore, I do not support inclusion of the "alternate text" provided by the staff that would eliminate the *written notification* element of the current rule and allow for *certification* by the licensee *that verbal notification had occurred*. Requiring patient notification is also consistent with "The Mammography Quality Standards Reauthorization Act" of 1998 (Pub. L. No. 105-248) which requires that patients who have received poor quality mammograms be notified in writing. NRC's notification requirement is also consistent with the Department of Veterans Affairs Handbook 105/1 which requires notification of patients who have been the subject of "unplanned clinical occurrences" such as administration of the wrong medication and other adverse events.

Reporting Threshold - I recognize the unique circumstances surrounding the intentional administration of byproduct material for medical purposes to women of child-bearing age, in particular that with such use comes an unavoidable risk. Therefore, I support the proposed *reporting threshold, not a dose limit*, of 5 rem for reporting such unintentional events since it is consistent with the NRC's Abnormal Occurrence (AO) criteria for reporting events to Congress and with recommendations of the National Council of Radiation Protection and American Association of Physicists in Medicine. I do not agree with the SR-6 committee recommendation to apply the 10 CFR Part 20 occupational worker gestational dose limit of 500 mrem to the

embryo/fetus and the 10 CFR Part 20 public dose limit of 100mrem/year to the nursing infant. Based on the information provided in the paper and discussions during the two recent Commission briefings, I believe that the SR-6 recommendation would have an unnecessary negative impact on the health care delivery system. Specifically, it appears that most diagnostic administrations would result in a dose to the embryo/fetus of 500 mrem or higher. As a result, physicians would be forced to perform a pregnancy test on virtually all women of child-bearing age for the sole purpose of avoiding an "unintentional" administration as defined by the regulator. This is particularly problematic in cases where the pregnancy is in such an early stage as to be undetectable at the time of administration. Thus, one could argue that an "unintentional" administration had occurred. I believe that NRC should avoid such intrusions into the practice of medicine and that the reporting threshold should be consistent with the AO criteria as suggested by the staff.

Patient Release - While I recognize that the current release limit of 500 mrem/year has resulted in an increased regulatory burden to some States to respond to radiation alarms at municipal landfills, I continue to support the current dose-based patient release criteria. This approach is consistent with most public comments received on this rule, and I believe that it provides adequate protection of public health and safety. It should also be noted that the patient release provisions continue to be supported by many States, and members of the medical community including RSOs and the Health Physics community. Also, while I am sensitive to the SR-6 committee concern that licensees provide appropriate instruction to the released patient to help to ensure that exposures to members of the public are as low as reasonably achievable, I do not agree with the SR-6 recommendation that licensees that have released patients in accordance with the regulations be held responsible for confirmed excessive exposures and releases of contaminated items to municipal landfills. I also support the proposed final rule which would allow housing in the same room two patients who are undergoing therapy procedures since the radiation dose that one patient contributes to the other represents an extremely small percentage of the administered dose received by each individual and such individuals should not be considered members of the public as suggested by the SR-6 committee.

CRCPD SR-6 Committee - As discussed throughout my vote, I am concerned that the SSRs may adopt certain provisions that are more restrictive than those proposed for Part 35 including training and experience criteria, patient release provisions, and event reporting thresholds. Therefore, I strongly encourage each Agreement State to consider the exhaustive and transparent process used by NRC to solicit input from all stakeholders which resulted in a technically-sound and more risk-informed and performance-based rule. I plan to keep abreast of the SR-6 committee's efforts to develop a final set of SSRs for medical use and I encourage all stakeholders to do the same.

Specific Edits -

1. Federal Register notice, page 360 - The comment and response sections appear inconsistent with regard to whether NRC is assigning a compatibility level C or D to certain provisions in 35.61, "Calibration of survey instruments." The language should be modified for clarity.

2. Federal Register notice, page 485 - Consideration should be given to modifying the 10 CFR 35.2 definition of *Address of use* to include the word, "prepared" for consistency with the 10 CFR 35.2 definition of *Area of use*.
3. Federal Register notice, page 512 - There is an inconsistency between items 10 CFR 35.63(b) and (c) regarding verifying patient dosages. Specifically, section (b) does not allow for direct measurement of "unit dosages" while section (c) allows for direct measurement of "other than unit dosages." It is my understanding that this was not the staff's intent; therefore, item (b) should be modified accordingly.
4. Federal Register notice, page 565 - The dosage record requirements contained in 10 CFR 35.2063(b) should be modified to add the date and time of dosage administration. In the absence of this information, it would be difficult if not impossible to determine if a medical event had actually occurred because the time lapse between dosage determination and dosage administration would not necessarily be documented.
5. Federal Register notice, page 567 - The staff should consider modifying the record requirements for decay-in-storage contained in 10 CFR 35.2092 to include the "name of the individual who performed the survey." This item could be substituted for the item requiring the "name of the individual who performed the disposal."

Other more minor edits to the Federal Register notice are indicated on the attached pages.

A handwritten signature in black ink, appearing to be 'E. M. G.', is located in the lower right quadrant of the page.

allowed the Agreement States is an important issue and should not be omitted from the discussion because information was not available in a timely manner.

Response. Supplement III of this document contains more detailed discussion of the comments that we received on the length of the comment period. As a result of public comment, we extended the comment period on the proposed rule from November 12, 1999 to December 16, 1999.

The proposed rule contained a brief explanation of the compatibility assignments that were made for the proposed rule. Subsequent to that publication, we received requests from Agreement State representatives to provide supporting documentation for how the assignments were made and to provide the essential objectives for each section. This information was made available to the Agreement States in an All Agreement States Letter. We asked that the States provide comment on the assignments by February 12, 1999.

We considered all comments received on the compatibility assignments and, where appropriate, made changes to either the assignment or to the rationale for the assignment. Supplement IV of this document contains a summary of the assignments. A more detailed compatibility chart which provides the essential objectives for each section and why particular designations were assigned is posted on the NRC Website at

X <http://www.HSRD.ORNL.GOV/NRC/HOME.HTML>.

not a correct web address. please correct.

Issue 4: How has NRC incorporated comments from the Agreement States on Agreement State issues?

Response. The assignment of a compatibility category C to this requirement is appropriate because the term transboundary applies to the use of byproduct material by licensees which operate in multiple locations. The category C designation provides a minimum level of safety, while providing some flexibility to Agreement States to be more restrictive.

Section 35.80, Provisions of mobile medical service.

Comment. A commenter did not agree with the our original basis for designating this section as D compatibility. They disagreed with the following statement: "since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity" the section is designated a D compatibility."

Other commenters commented on specific paragraph designations. A commenter stated that paragraph (a)(1) should not be a compatibility category H&S issue. Another commenter stated that paragraph (a)(4) should be compatibility category H&S issue^J but that the designation ~~was~~^J is inconsistent with the requirements for fixed facilities. (Note: Fixed facilities have to conduct surveys only for procedures requiring a written directive (§ 35.70)).

Response. The Agreement State representatives informed the NRC staff that not all Agreement States authorize mobile services and that there are a number of additional State professional and technical licensing issues which complicate this activity. The medical use of byproduct material (diagnostic or therapeutic) as a mobile service^h was been designated a compatibility category D for all Agreement States (not required for compatibility) and category D (H&S) for those Agreement States which authorize mobile services. This designation (D (H&S))

Comment. A commenter questioned the assignment of a compatibility category H & S to §§ 35.100 and 35.200 because they are very low risk procedures.

Response. Both requirements meet the two or fewer failure test scenario detailed in Management Directive 5.9. *for the assignment of compatibility category H&S.* These provisions assist in establishing a minimum level of safety in the medical use of agreement materials by reducing the likelihood of a medical event. X

Section 35.390, Training for use of unsealed byproduct material for which a written directive is required.

Comment. A commenter believed that Agreement States should have the option of adopting a higher standards for training even if it means the state would become "incompatible." X

Response. A compatibility category C was assigned to this requirement. This provides an appropriate level of safety while providing some flexibility to Agreement States to be more restrictive.

Section 35.432, Calibration measurements of brachytherapy sealed sources.

Comment. A commenter stated that this requirement should not be a compatibility category C.

X delete the reference to an ~~AMP~~^N. A medical use licensee is no longer required to amend its license before allowing anyone to work as an ANP if that individual meets the training and experience requirements in § 35.51(a), and the training and experience requirements were met within the 7 years preceding the date of the application. In addition, paragraphs (a) and (b) were reworded to clearly indicate the subject of each paragraph.

Paragraph (c) was revised to delete the requirement for a licensee to apply for a license amendment if the teletherapy physicist changes, provided the individual meets the requirements in §§ 35.51(a) and 35.59. This change is consistent with licensing requirements for AUs and AMPs.

The Commission recognizes that unusual conditions may arise when the RSO leaves a licensee with little to no advance warning. In this event, the licensee may want to consider using an AU or other individual qualified to be an RSO to fill the position, pending appointment of a new RSO. Under these conditions, the licensee must move expeditiously to permanently fill the position of RSO and should contact the appropriate NRC regional office and explain the situation.

Paragraph (d) was revised to require the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount or in a different form or it receives a different radionuclide than is authorized on the license. This change was made to clarify that the requirement is tied to a licensee's authorization to possess, not order, byproduct material and to clarify when an amendment is needed. For example, if a license authorizes possession of any byproduct material identified in §§ 35.100, 35.200, and 35.300, in

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user ~~or~~ as allowed by § 35.11(b)(1) shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.