October 23, 2000

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0118

TITLE: FINAL RULES - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL" and 10 CFR PART 20, "STANDARDS FOR PROTECTION AGAINST RADIATION"

The Commission approved in part and disapproved in part the subject paper as recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of October 23, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette Vietti-Cook
Secretary of the Commission

Attachments: 1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

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VOTING SUMMARY - SECY-00-0118

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. MESERVE | X | | | | X | 8/16/00 |
| COMR. DICUS | X | | | | X | 8/10/00 |
| COMR. DIAZ | X | | | | X | 7/27/00 |
| COMR. McGAFFIGAN | X | | | | X | 8/4/00 |
| COMR. MERRIFIELD | X | X | | | X | 7/26/00 |

COMMENT RESOLUTION

In their vote sheets, the Commission approved a final rule which revises 10 CFR Part 35 to make it more risk-informed and performance-based, and to codify requirements for certain therapeutic devices. Also, 10 CFR Part 20 is being revised in response to a Petition for Rulemaking from the University of Cincinnati to allow a licensee the discretion to permit visitors to a hospitalized radiation patient to receive up to 5 millisievert (0.5 rem) in a year from exposure to the hospitalized radiation patient and provided some additional comments. Commissioners Dicus, McGaffigan, and Merrifield disapproved the staff request to develop a rulemaking plan that would provide the Commission options for adding requirements to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from another individual released under the provisions of 10 CFR 35.75 due to insufficient staff justification.

Instead, the Commission directed the staff to proceed with a proposed revision to Part 35 to require licensees to report situations they become aware of in which an individual receives a dose exceeding 50 mSv (5 rem) from a patient released under §35.3047. Commissioner Dicus provided the attached additional views related to this matter. Subsequently, the comments of the Commission were noted in an Affirmation Session SRM issued on October 23, 2000.

**Commissioner Dicus' additional views on SECY-00-0118:**

I cannot support the Commission's decision in this Staff Requirements Memoranda to instruct the staff to develop a proposed revision to Part 35 that will require a licensee to notify NRC no later than the next calendar day 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. Not only does this proposed direction specifically single out medical licensees for special requirements (unlike other types of licensees that we regulate), but it goes against our philosophy of developing regulations that are risk-informed and are intending to improve our heath and safety basis for regulating byproduct materials.

As I noted in my vote sheet on SECY-00-0118, the Commission has no historical nor inspection information to date to provide a supporting basis to justify the staff expending its limited resources in relatively short order to look further into the development of what would appear to be a rule for *potential* mistakes. While in theory, I might have been willing, for purposes of discussion, to consider a proposed rulemaking that would require licensees to notify us if they believed that the basis of a patient release under §35.75 may have been incorrect or the instruction inadequate, I cannot support directing the staff to develop a proposed rule for reporting a patient's failure to follow the physician's instructions. Not only would the licensee need to somehow determine "through voluntary means" that the patient did not follow directions given to them from a physician, but the proposed rule would require the licensee to submit a written report within 15 days of this finding not only to the NRC but to the individual(s) receiving the exposure, although by definition the licensee's knowledge of the individual(s) involved will be inconsistent and limited in nature. I see a host of practical difficulties in implementing such an unprecedented requirement and I fail to see any predictable benefit.

Rules of this type do not, in my opinion, make good regulatory sense nor are they an effective use of resources at a time when we are attempting to steer both NRC and Licensee resources in a risk-informed manner. I have firm belief in the NRC's materials inspection program, and would have thought that if this type of event were a problem amongst our licensees, our inspectors would have found such occurrences and provided a stronger basis for any proposed rulemaking in this area. Unfortunately, I am aware of no supporting data for this proposed rule.

Although the Commission's directions to the staff state that the proposed rule should indicate the Commission is not modifying its previous position that the NRC does not intend to enforce a patient's compliance with the licensee's instructions nor is it the licensee's responsibility to ensure compliance by patients once they leave the licensee's facility (Federal Register, Volume 62, Number 19, pages 4120-4133, January 29, 1997), one should question the reasoning of using staff resources to require reporting of individual's actions for which no licensee has regulatory responsibility.

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## Commissioner Comments on SECY-00-0118

### Chairman Meserve

I approve the staff recommendations, listed below, subject to the comments which follow:

1. Incorporation of the alternative rule text (Attachment 8) into the draft final Federal Register notice for Part 35 (Attachment 6);

2. Publication of the Final Rule (Attachment 6), with alternative rule text incorporated, in the Federal Register;

3. Publication of the "Notice of Change to Enforcement Policy" (Attachment 10) in the Federal Register;

4. Certification that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities and satisfies the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b);

5. Certification that this rulemaking will not negatively affect family well-being (Attachment 9); and

6. Development of a rulemaking plan that provides the Commission with options, including the "no-action" option, for revising Parts 20 or 35 to add a requirement for a licensee to report events in which an individual has received an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR 35.75.

I also approve the staff decision not to submit an inspection plan with the final rulemaking, as indicated in SECY-99-201, pending completion of the Medical Pilot Inspection Program that was approved by the Commission in SRM-SECY-00-0001. However, staff should, within 6 months of the completion of the pilot, report back to the Commission on the findings from the pilot and indicate how insights gained will be utilized to revise all medical inspection procedures so that they are more risk-informed and performance-based.

I note the following items from the Draft Final Federal Register Notice for Part 35 that need modification prior to publication:

a. Section VIII, "Consistency with Medical Policy Statement," indicates that the revised Medical Policy Statement (MPS) is being published [in the Federal Register] concurrent with publication of the final rule. In fact, the MPS will have been previously published; and

b. In § 20.1301(c), "Dose limits for individual members of the public," for consistency with the rest of Part 20, and in

line with the final NRC Metrification Policy, the SI units should consistently be in parentheses.

I commend the staff for its efforts in connection with this rulemaking. It has produced a high-quality product, with the benefit of extensive stakeholder involvement, on a demanding schedule. The result is a rule that reflects the Commission's commitment to pursue a risk-informed and performance-based approach to regulation.

## Commissioner Dicus

I commend the staff for another extremely well-written and complete Commission paper for the final revisions to 10 CFR Part 35. The staff has continued to perform in an outstanding manner in ensuring that the public's voice is heard and that issues raised are resolved and articulated in a final rule that embraces the Commission's vision for a new Part 35. I believe that the staff has succeeded in restructuring Part 35 to ensure that the final rule is consistent with our transition to making our regulations much more risk-informed. We should use this rule as an example for other areas of on-going regulatory improvement to remind us of how good the rulemaking process can be, when we go the extra mile, in obtaining stakeholder input and feedback into our regulatory process.

In summary, I approve:

1. The "Final Rule" (Attachment 6), and incorporation of the new alternative rule text for §§ 35.3045 and 35.3047 (Attachment 8) into this Final Rule, for publication in the Federal Register.

2. The "Notice of Change to Enforcement Policy" for publication in the Federal Register (Attachment 11).

3. The staff's assessment that this rule, when promulgated, will not have a negative economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

4. The staff's assessment that this rulemaking will not negatively affect family well-being (Attachment 10);

I do not approve the staff's request to develop a rulemaking plan for possibly revising 10 CFR Parts 20 or 35 to add a requirement for a licensee to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR § 35.75. Based on the historical and inspection information to date, there does not appear to be supporting data that would justify the staff expending resources to look further into the development of what would appear to be a proposed non risk-based rule. While there may be occurrences of individuals receiving an exposure of greater than 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR § 35.75, that in itself does not provide the justification for an additional rulemaking which would require licensees to report this type information.

In addition, specific editorial corrections for several of the Attachments to SECY-00-0118 are attached to this vote sheet.

## Commissioner Diaz

I approve, subject to my comments, publication of the Federal Register notice that revises Part 35 to make the medical regulations for the use of byproduct material more risk-informed and performance-based. I am pleased that the public, workers, and especially the patients will finally benefit from the extensive review and evaluation of NRC's medical use program that began in 1993 with an internal management review and culminated in the revision of both NRC's Medical Use Policy Statement (MPS) and the regulations for the medical use of byproduct material. The revised MPS and regulations provide a reasonable balance between NRC providing for the beneficial use of byproduct material in medicine and fulfilling its responsibility to protect the health and safety of the public, workers, and patients.

Like many people in life, I have dealt with the practice of medicine both personally and professionally and have encountered both its good and bad aspects. After deliberating on the full scope of the rule, my personal experiences, together with my professional training and actual use of radioactive material for both diagnosis and treatment of disease, have led me to focus my comments on the question: What will be the effect of the revised Parts 20 and 35 on patients?

Even though patients voluntarily choose to receive necessary radiation exposures, which could involve significant risk, NRC has a responsibility to protect patients from unnecessary exposures, and their consequences, if any. Therefore, one of the primary objectives of the final rule is to protect patients from unnecessary radiation exposures, e.g., the wrong patient receives the administration, or the wrong dosage or wrong byproduct material is administered. Although I believe the administration of medical radioisotopes is one of the safest procedures in the practice of medicine and efforts continue to be made to improve their safety, there are a few instances out of the millions of medical procedures each year when this is not the case, i.e., a "medical event" occurs. In these cases, I believe that patients have the right to be informed about the medical event, including being provided all of the information they need to assess any resulting health consequences. Since patients usually depend on their physicians to evaluate their medical information, it is extremely important that their physicians also be provided with the information necessary to evaluate the medical event and to make any recommendation on follow-up care. Therefore, I approve replacing the regulatory text in § 35.3045 with the staff's proposed alternative rule text that would require that the referring physician receives the same information that NRC receives to evaluate the medical event. The alternative text should also be inserted in § 35.3047, which requires that reports be provided to the referring physician following a dose to an embryo/fetus or a nursing child.

I approve the staff's recommendation to develop a rulemaking plan for revising Parts 20 or 35 to add a requirement for a licensee to report events when release of a patient results in another individual receiving an exposure in excess of the 5 mSv

(0.5 rem) in § 35.75. I believe that, on balance, § 35.75 benefits patients because it allows licensees to release from their control certain patients who have been administered unsealed byproduct material or implants containing byproduct material. Because of the dose limit set on release of these patients, they can return to the family environment and benefit from the support of family and friends, without posing an undue radiation risk to others that is beyond the risks encountered in everyday life. Development of a rulemaking plan would provide staff an opportunity to examine options and alternatives to determine if such a reporting requirement would have a positive impact on the health and safety of individuals who are exposed to the released patients. In conjunction with the above, I recommend that the SOC for § 35.75 be expanded to *encourage* licensees to provide *all* patients released in accordance with § 35.75 with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. In addition, the SOC should be expanded to encourage licensees to *voluntarily* report cases where the total effective dose equivalent to any individual from exposure to the released patient exceeds 5mSv (0.5 rem).

I want to reiterate my support for the amendment to Part 20 to allow licensees the discretion to permit visitors to receive up to 5 mSv (0.5 rem) from exposure to those patients that can not be released. Hospitalized patients, especially the young and elderly, emotionally benefit from visits from family and friends. Therefore, I agree with the staff's position that "the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the patient."

I also approve, subject to my comments, publication of the associated "Notice of Change to the Enforcement Policy," which revises the examples in NUREG-1600 (General Statement of Policy and Procedure for NRC Enforcement Actions), to make them consistent with the terms in the final rule.

In addition to the above comments, I have attached edits on the Draft Final Federal Register Notice for Part 35, as well as comments on the Draft Final Federal Register Notice for the Enforcement Policy, the Assessment of Federal Regulations and Policies on the Family), and the letter to the University of Cincinnati.

## Commissioner McGaffigan

I approve in part and disapprove in part the staff recommendations regarding Part 35 and offer the following comments for the staff's consideration. I commend the staff for their dedication and diligence in addressing a wide variety of stakeholder comments throughout this 3-year rulemaking process to develop a more risk-informed and more performance-based rule.

I approve issuance of the proposed final rule that revises Part 35 subject to inclusion of the alternate rule text, as provided in Attachment 8 to the paper, that would delete the recordkeeping requirements and revise the reporting requirements associated with medical events and unintended exposures to an embryo/fetus or nursing child. I also suggest that the alternate statements of consideration for sections 35.3045 and 35.3047, also provided in Attachment 8, be revised to explain why the proposed recordkeeping requirements in 35.2045 and 35.2047 were deleted in the final rule, i.e., licensee paperwork reduction.

I also approve the proposed final rule that revises Part 20, in response to a petition, to make clear the conditions under which the dose limits in Part 35, and not Part 20, may be applied to members of the public who visit patients undergoing diagnostic or therapeutic procedures. I also approve issuance and implementation of the revised enforcement policy.

I disapprove the staff recommendation to develop a rulemaking plan for revising Parts 20 or 35 to add a requirement for licensees to report events where an individual received an exposure in excess of 5mSv (500 millirem) from an individual released under 10 CFR 35.75. This approach is inconsistent with the intent of the Commission when promulgating the final rule on patient release (62FR 4120, January 29, 1997). Specifically, the Commission stated, "the NRC recognizes that the licensee has no control over the patient after the patient has been released," and that, "once the patient is released, the responsibility for following the instructions is entirely the patient's, not the licensee's." While the Commission recognized that it might be necessary to base the release decision on case-specific potential exposure scenarios (e.g., air travel by the patient), the Commission clearly stated that "the NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility," and that, "NRC would not penalize a licensee for the activities of the patient after release or if the patient were to leave against medical advice." Also, on page 219 of the proposed Federal Register notice (FRN) for Part 35, the staff states that "we have no documentation indicating that the exposure rates to the maximally exposed individual have exceeded the dose limit in 35.75." Finally, I believe that the resources that would be expended on such a rulemaking would be better spent on Part 35 implementation issues, e.g., developing and providing staff training on revised licensing and inspection guidance.

I offer the following comments for the staff's consideration on two issues discussed in the statements of consideration: 1) patient release; and 2) mobile medical service.

> *Patient Release* -- The Response to Issue 3 discussed on page 247 of the FRN regarding implementation of 10 CFR 35.75 needs to be revised. The proposed response does not appear to be consistent with the Commission's intent, regarding continued confinement of patients who are releasable under 35.75, when promulgating the final patient release rule (see 62 FR 4126). Specifically, in 1997, the Commission stated that there is no need for the licensee to keep the "released" patient under their control for radiation purposes if the patient remains hospitalized for other reasons; however, good health physics practice would be to continue to ensure that the doses to workers from the patient are kept as low as is reasonably achievable (ALARA). Keeping radiation doses to workers ALARA is very different from identifying a member of the nursing staff as the maximally exposed individual who might receive a dose in excess of 5 mSv (500 millirem) from a released patient. Furthermore, it is not clear why licensees that use the default value tables provided in NUREG-1556, to release patients without

further case specific analysis, would even need to specifically identify the maximally exposed individual since the default values were based on conservative assumptions to demonstrate that no one individual is likely to receive a dose in excess of 5 mSv (500 mrem) from the released patient. Also, if a licensee observes that one or more nurses are routinely exposed to patients released under 35.75 but still confined, they should take steps to ensure that the doses are ALARA as required by 20.1101, "Radiation protection programs." Therefore, I suggest that the staff revise the proposed response on page 247 of the FRN to ensure that it accurately reflects the Commission's intent when promulgating the final patient release rule.

*Mobile Medical Service* -- The Response to Issue 2 on page 221 of the FRN regarding mobile medical service needs to be revised. Specifically, the last sentence is unclear and could be interpreted to mean that byproduct material could be delivered to the client's address, if the material is secured against unauthorized removal, regardless of whether the client is an NRC or Agreement State licensee. Such an interpretation is not consistent with the preceding 3 sentences in the Response, the discussion on page 449 of the FRN or the proposed final 35.80(b). The staff should review the statements of consideration and the rule text to ensure that they consistently reflect the staff's position on whether, and under what conditions, byproduct material could be delivered directly to a client that is not a licensee.

Also, I note on pages 25-26 of the FRN that commenters apparently indicated that several States currently have no regulatory authority for naturally-occurring or accelerator-produced radioactive material (NARM). While I agree with the staff's proposed response, I suggest that, at minimum, these comments be brought to the attention of the Conference of Radiation Control Program Directors to avoid such gaps in the regulation of radioactive material and sources in medicine nationwide. I would also note that in 1997 while voting on Direction Setting Issue 7 and in early direction to the staff on this rulemaking, the Commission indicated its willingness to seek expansion of its statutory authority beyond Atomic Energy Act material to include NARM to make the national medical use program more uniform and consistent. The Commission did not pursue such legislation at that time so as not to divert resources from the Part 35 initiative. Now, that this rulemaking is finally concluding, I continue to believe that such legislation is a worthy goal and support efforts to this end.

Finally, I suggest specific edits to the FRN and attachments as indicated on the attached pages.

## Commissioner Merrifield

For the reasons described in the following paragraphs, I approve in part and disapprove in part the staff's recommendations in SECY-00-0118 for final rulemaking associated with 10 CFR Part 35 and 10 CFR Part 20. First, however, I want to specifically recognize, once again, the staff's tremendous efforts to develop final rules in the fairly controversial area of regulating the medical use of byproduct material. Unfortunately, the controversy will not end with issuance of the final regulations because the next phase, actually implementing the new regulations, will contain controversial issues of its own. I both encourage and support the staff's efforts in the next phase of this important activity.

I approve issuance of the proposed final rule that revises 10 CFR Part 35 subject to inclusion of the alternative text proposed by the staff. The alternative text addresses my basic concerns with patient notification issues in the rule and is acceptable since it also addresses a potential concern with OMB on record keeping and reporting requirements. I also approve the proposed final rule that revises 10 CFR Part 20 in response to a petition to make clear the conditions under which the dose limits in Part 35, and not Part 20, may be applied to members of the public who wish to visit patients undergoing diagnostic or therapeutic procedures. Finally, I also approve issuance and implementation of the revised enforcement policy.

I disapprove the staff request to develop a rulemaking plan which would provide the Commission options for adding requirements to report events where an individual receives an exposure in excess of 5 mSv (0.5 rem) from another individual released under the provisions of 10 CFR 35.75. The brief justification provided by the staff for this effort is insufficient to demonstrate that resources should be devoted to this potential rulemaking over using these resources in another area, such as the implementation of the revised Parts 20 and 35 under this rulemaking. One reason provided by the staff for a potential new reporting requirement was a situation where a licensee failed to follow 10 CFR 35.75 and an excessive exposure was received by a member of the public. In my opinion, this is a potential enforcement issue and not a reporting requirement issue. The second reason provided by the staff was the situation where a licensee fully complied with 10 CFR 35.75, but an exposure greater than 5 mSv still occurs to another member of the public. Although I was not a member of the Commission when the vote on patient release criteria occurred, a brief review of the Statement of Considerations for this rule change indicates that the Commission specifically did not attempt to control the patient once the patient was released from the hospital, which potentially would be an essential element of the proposed new rulemaking plan proposed by the staff in SECY-00-0118. Based on the justification provided to date and the need to be fiscally prudent with our limited resources, I do not believe it would be appropriate for the staff to devote additional efforts in this area at this time. If the staff strongly believes that rulemaking is needed in this area, I would not object to the staff providing, at their option, a new request, with additional justification beyond the information provided in this paper, to begin this proposed rulemaking effort at some time in the future.