August 27, 2002

# COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0111

TITLE: PROPOSED RULE TO AMEND 10 CFR PART 35 TO REQUIRE LICENSEES TO NOTIFY NRC OF AN INDIVIDUAL RECEIVING A DOSE EXCEEDING 50 MILLISIEVERTS (5 REM) FROM A PATIENT RELEASED UNDER 10 CFR 35.75

The Commission (with Commissioners Dicus, McGaffigan, and Merrifield agreeing) disapproved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 27, 2002. Chairman Meserve and Commissioner Diaz approved the paper.

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

Annette L. 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

# VOTING SUMMARY - SECY-02-0111

## RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. MESERVE | X | | | | X | 8/22/02 |
| COMR. DICUS | | X | | | X | 8/2/02 |
| COMR. DIAZ | X | | | | X | 6/27/02 |
| COMR. McGAFFIGAN | | X | | | X | 7/22/02 |
| COMR. MERRIFIELD | | X | | | X | 8/7/02 |

## COMMENT RESOLUTION

In their vote sheets, Commissioners Dicus, McGaffigan, and Merrifield disapproved the staff's recommendation. Chairman Meserve and Commissioner Diaz approved the paper and would have preferred to publish the rule for public comment prior to making a decision on the rulemaking. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on August 27, 2002.

**Commissioner Comments on SECY-02-0111**

Chairman Meserve

In SECY-02-0111 the staff requests Commission approval to proceed with a proposed rulemaking to require licensees to notify the NRC if the licensee becomes aware that a member of the public has received or is estimated to have received a dose exceeding 5 rem (50 mSv) from a patient released under 10 C.F.R. § 35.75. Although I recognize that a majority of the Commission has voted to disapprove this rulemaking, I have some concerns with the Commission's action.

The failure to pursue this rulemaking will perpetuate an inconsistency in the Commission's rules. Under Part 20 of our regulations, a dose to a member of the general public above the public dose limit of 100 mrem (1 mSv) must be reported in writing to the NRC within 30 days. 10 C.F.R. § 20.2203(a)(2)(iv).[1] And any such exposure must be reported to the exposed individual no later than the transmittal to the Commission. Id. § 20.2205. Thus, our generally applicable radiation regulations serve to ensure that the NRC and affected members of the public are provided information about doses that have been incurred in excess of regulatory requirements. The Part 20 requirements do not apply to exposures of patients for the purpose of medical diagnosis or therapy or to the circumstance at issue here, exposures of other individuals from those administered radioactive materials for medical purposes. Id. § 20.1002; see also id. § 20.1301(a)(1). But even Part 35 provides for reporting in circumstances other than those covered by the proposed rulemaking; for example, reporting to both the NRC and the patient is required for doses above certain limits arising from the misadministration of byproduct material. Id. § 35.3045; see also id. § 35.3047. Insofar as I am aware, the only circumstance in which the reporting of an exposure in excess of our dose limits is not required would be corrected by the proposed rulemaking.

As a result of not moving forward with this proposed regulation, the NRC will lose the insight into compliance with our regulations that the reporting requirements provide. We will thus not have this tool as a means to assess the effectiveness of our regulatory program. By failing to have a rule, we also sacrifice the discipline for compliance that a reporting requirement serves to reinforce.

Perhaps even more important, members of the public who may have received involuntary doses from the release of patients will never be informed of their exposure. Although some might dismiss this concern on the basis that the resulting dose is unlikely to exceed a few hundred millirem and thus does not present a meaningful risk, this approach ignores the intense public sensitivity to and concern about radiation matters. The public demands a right to know about involuntarily incurred risks, particularly radiation-related risks. As noted above, the NRC has recognized this right in every other arena. We should not dismiss this public sensitivity so swiftly here.

Finally, I am concerned about the impact of not providing the general public with the opportunity to comment on the proposed rule. One of our performance goals is to increase public

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[1] Immediate notification must be provided if the dose exceeds 25 rems (0.25 Sv) and 24-hour notification must be provided if the dose exceeds 5 rems (0.05 Sv) in any 24-hour period. 10 C.F.R. § 20.2202.

confidence in our actions. Although the Commission has considered the comments from the medical community (through the Advisory Committee on the Medical Use of Isotopes) and the Agreement States, the Commission has not heard from the general public on this matter. We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process. The resources needed to allow the public to comment on the proposed rule are not large (1.2 FTE). SECY-02-0111 at 4. And I believe that building public confidence in our actions requires that we hear from all stakeholder groups. Thus, before concluding that the reporting and notification requirements are unnecessary, we should hear from the public.

In light of these considerations, I would proceed with the publication of a proposed rule. Because an informal staff analysis has suggested that exposures above 5 rem (50 mSv) are very unlikely, I believe that the proposed rule should be revised to ask for comment on a notification requirement that is directly connected to the relevant dose limit. Section 35.75 allows the release of patients when the dose to another individual is not likely to exceed 0.5 rem (5 mSv). As the staff originally suggested in SECY-00-0118 (at 6), I would support consideration of a proposed rule that would establish a reporting requirement that is triggered when the licensee becomes aware that a member of the public has received a dose in excess of this limit. Reporting of involuntary exposures arising from the release by medical patients would then be addressed in the same fashion as the reporting required by Part 20, in which the reporting of doses above the relevant regulatory limit are required.

Commissioner Dicus

As I stated in my vote on SECY-00-0118, and in my additional views when the Commission previously voted on the revisions to 10 CFR Part 35, I do not approve of the staff's request to publish a proposed requirement for a licensee to report events where an individual receives an exposure in excess of 50 mSv (5 rem) from an individual released in accordance with 10 CFR § 35.75. In discussions with the staff, there appears to be no known exposure scenario, involving any radioactive isotope, in which an individual could receive in excess of 5 rem from exposure to a released patient in accordance with 35.75. Not only does this proposed rule specifically single out medical licensees for special requirements (unlike other types of licensees that we regulate), it goes against the NRC philosophy of developing regulations that are risk-informed and are intended to improve our heath and safety basis for regulating byproduct materials.

As the staff has observed, when we look at whether or not this proposed rule would increase the Agency performance goals in any of the following areas: (1) maintaining public health and safety; (2) increasing effectiveness, efficiency, and realism; (3) increasing public confidence; or (4) reducing unnecessary regulatory burden, the answer is a simple "No." Rules of this type do not 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 believe that if the NRC issues this proposed rule at this time, it would only serve to increase the tension between NRC and the medical stakeholder organizations (i.e., ACR and SNM/ACNP) which we are currently trying to work with on the development of diagnostic and therapeutic guidance documents for the new Part 35. I have confidence in both the NRC and Agreement State materials inspection programs and believe that any violation of patients released under 10 CFR Part 35.75 will be ascertained by these inspectors and appropriately dealt with during the enforcement process.

Commissioner Diaz

I approve, subject to the comments below, publication of the proposed rule to amend 10 CFR Part 35 to require licensees to notify NRC of an individual receiving a dose exceeding 50 millisieverts (5 rem) from a patient released under § 35.75. As I noted in my vote on SECY-00-0118, I strongly support the use of § 35.75, which benefits patients by allowing them to return to the family environment and receive the support of family and friends, without posing an undue radiation risk to others that is beyond the risks encountered in everyday life. Therefore, I believe it is important to solicit public comment on this rulemaking in order for the Commission to make an informed decision.

I continue to strongly agree with the right of exposed individuals to be provided with all of the information they need to assess any resulting health consequences. However, I am concerned with the proposed § 35.75(e), as drafted, because receipt of a copy of the report to NRC could be both confusing and alarming to an exposed individual. The text in the proposed paragraph (e) should be deleted and the proposed text below should be added to paragraph (d). This text would be consistent with the reporting requirements in the new §§ 35.3045(e) and 35.3047(e).

> (d)"The licensee . . .of this section." To meet the requirements of this paragraph, the notification may be made to the individual's responsible relative or guardian, when appropriate. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description, if requested.

The SOC should note that, if requested, the written description should be provided to the exposed individual, or appropriate responsible relative or guardian, and/or the individual's physician. Because individuals usually depend on their physicians to evaluate any medical information, it is extremely important that, if requested, physicians also be provided with the information necessary to evaluate the exposure and to make any recommendation for follow-up, if appropriate.

I also note that the following addition should be made to § 35.3075(c)(vi) to make it consistent with my suggested change to paragraph (d) above.

> (c)(vi) Certification . . . exposed individual(s) (or the individual's responsible relative or guardian).

Commissioner McGaffigan

I disapprove the staff's recommendation to publish a proposed requirement for licensees to report events where an individual received an exposure in excess of 5 rem from an individual released under 10 CFR 35.75.

As I stated in my vote on SECY-00-0118, this proposal is inconsistent with the intent of the Commission when promulgating the original final rule on patient release (62FR 4120, January 29,

1997) which has not changed with the most recent revisions to Part 35. 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."

In addition, in the proposed Federal Register notice (FRN) for the original Part 35, the staff stated that "we have no documentation indicating that the exposure rates to the maximally exposed individual have exceeded the dose limit in §35.75." The staff has recently indicated that there are very few credible scenarios in which someone who is released by the medical facility under the §35.75 dose limit (no more than 0.5 rem to another individual), and who *does not* follow the instructions provided by the licensee, could expose another individual to more than 5 rem. Therefore, I believe the likelihood of this occurring is very low.

Even if the licensee does have an indication that someone did not follow the instructions, it is not clear what actions the NRC would expect the licensee to perform. How much investigation would the licensee need to perform to deny or confirm the individual's compliance with the directions? If a patient states to the licensee "that it was sometimes difficult to follow the instructions" is the employee that hears that statement going to be required to begin an investigation? What actions would NRC expect the licensee to take against an employee who hears this statement and does not begin an investigation? What if the licensee suspects in advance that an individual will not follow the instructions, would they be required to actively investigate the situation? This rulemaking obviously has no basis in safety, and there are too many open issues associated with its implementation.

I also do not see that this rulemaking meets any of the agency's strategic goals. Since this amendment only requires a notification after an exposure has happened, it does not increase the protection of the public health and safety or the environment. Since the staff has no evidence that the dose limit in §35.75 of 0.5 rem has been exceeded, continuing to put resources into completing this rulemaking would not make NRC's activities more effective, efficient or realistic. The agency's goal of reducing unnecessary regulatory burden would not be met by implementing a rulemaking such as this, which is plainly not necessary or helpful. And finally, in the current environment of heightened security if NRC were to spend valuable time and resources focusing on this issue, when there are clearly more important issues the public would like us to address, it would not increase the public's confidence in the agency.

Based on the above arguments, I believe that the staff's time and resources would be better spent on other more important issues rather than wasting any more time going forward with this rulemaking effort.

Commissioner Merrifield

I disapprove the issuance of the proposed rule in SECY-02-0111 and the staff does not need to take further action in this area. I am fully supportive of the patient release criteria in 10 CFR Part

35 and I acknowledge that some State officials object to these specific provisions. When we issued a major revision to Part 35, one side issue raised was the potential of a significant exposure to a member of the general public by a patient released under the NRC release criteria. Due to the multitude of issues under consideration at that time for revising Part 35, we did not have significant time to resolve the issue as part of that rulemaking. The proposal by the staff was to develop a rulemaking plan to address this issue, which could have included a “no action” proposal. I believed that this was an important decision to address; and that if rulemaking was necessary, I would rather go directly to the proposed rule stage vice having the additional delay by developing a rulemaking plan, particularly since the issue had already been discussed at the Commission level. The proposed rule developed by the staff and discussed with both the ACMUI and the Agreement States has allowed a reasonable discussion of the relevant facts. Based on these discussions, I believe there are significant implementation problems with the proposed rule and that it would not significantly protect public health and safety, would not increase effectiveness of our regulations, and would not increase public confidence in our regulations. The proposed rule would increase the regulatory burden without a significant benefit. Therefore, I now believe the issue should be closed without additional rulemaking.