NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-99-201 - DRAFT FINAL RULE - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"**

Approved XX with comments Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

SIGNATURE

12.16.99

DATE

Entered on "AS" Yes ✓ No ____

**COMMISSIONER DIAZ'S COMMENTS ON SECY-99-201 - DRAFT FINAL RULE FOR 10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL**

The long awaited revision to 10 CFR Part 35 is one of the most important actions that NRC can take as a regulatory agency. Part 35 deals with the administration of radiation for health reasons. As frequently stated, it is customary to avoid unnecessary radiation exposure and significant exposure to radiation. Medical uses of radiation result in necessary exposures, many insignificant risk-wise, and some quite significant. Whether acknowledged or not, each of us brings his or her own life experience as a factor to consider when making our decisions. In this case, my experience both professional and personal -- I have worked and trained at Vanderbilt University Hospital, Mount Sinai Hospital, etc., and like most of us of "a certain age," I have been a patient in a nuclear medicine department -- has given me a profound respect for the dedication of nuclear medical professionals as well as the understanding and forebearance of the American patient. Suffice it to say, we at the NRC will discharge our duties well if we keep in mind that we are affecting individuals' lives, as well as their families. This experience leads me to consider Agreement State compatibility and the notification of medical events issues with a different perspective.

I strongly believe that decisions that affect people's lives are best made locally, especially when involving patient-physician relationships. On the other hand, I know that transboundary concerns should be addressed at the national level. I believe that the Commission achieved the proper balance between the above interests when it approved the Policy Statement on Adequacy and Compatibility of Agreement State Programs on June 30, 1997 (62 FR 465217). Moreover, the staff has correctly applied the policy for the requirements included in 10 CFR Part 35. Specifically, the compatibility category proposed by the staff for training and experience requirements, compatibility C designation, is correct as it ensures that there will not be conflicts, duplications, or gaps in regulatory programs. I do not believe that there are concerns specific to the medical use of isotopes that would support assigning a compatibility B designation for these requirements. I do encourage Agreement States to consider the NRC's justification for the training and experience requirements included in the rule, to consider the comments received by NRC on this issue, as well as to consider the transboundary implications of establishing more stringent requirements. In addition, if some Agreement States wish to pursue requirements that differ from NRC's, I urge them to seek public input, whether called for in their State procedures or not. Although not required by the Administrative Procedures Act to conduct workshops with the public, NRC has found such meetings in circumstances such as 10 CFR Part 35 to be beneficial.

Part 35 affects the public directly. Whether receiving diagnostic tests as part of health maintenance or undergoing therapeutic treatment procedures covered under Part 35, a patient and his/her family are at a heightened stage of anxiety. Thus, with the patient in mind, I believe that requiring verbal notification of a medical event[1] would lead to better patient understanding

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[1] Being a proponent of clarity in communications, I had hoped that the term "misadministration" would have been replaced with more descriptive terms, e.g., "undertreatment," "overtreatment," or any other terms proposed by the stakeholders. However, since the term "medical event" was agreed to by the majority of the stakeholders, I can support it.

and appreciation of the event and its ramifications, if any. Since a verbal notification provides an opportunity for the patient to ask clarifying questions, I find that it is preferable to a written notification that is simply handed to the patient. I am not of the opinion that verbal notification takes away an existing "right" for a written document that is available to the patient. Therefore, I propose that the patient also be informed that a record of the verbal notification -- and ensuing dialogue -- will be made part of the patient's medical record and available to the patient if requested. The medical professionals are responsible -- and accountable -- for timely patient notification that is responsive to the risk of the medical event. I strongly believe that this considers patients and their families as people, not records.

The following are my recommendations on the draft final rule:

Medical Policy Statement - I approve the staff to submit the revised Medical Policy Statement to the Commission with the final 10 CFR Part 35 rulemaking package.

Licensing Guidance - The staff should submit the final licensing guidance with the final 10 CFR Part 35 rulemaking package.

Recognition of Specialty Boards - I approve the staff to begin the process to recognize specialty boards prior to publication of the final rule.

Patient Notification - As already discussed, the staff should modify the rule language in § 35.3045 to require verbal notification of the individual affected by the medical event. The notification should require that the patient be informed that a record of the notification is available upon request. In addition, the recordkeeping requirements in § 35.2045 should be modified to require a record of the patient notification, including clarifying statements, if any. I also agree with Commissioner Merrifield's recommendation that the licensee be required to place a copy of the record required under § 35.2045 in the patient's medical record. If the licensee is not the patient's physician, the licensee is to provide a copy of the record to the patient's physician with a request that they include it in the patient's medical record. The licensee should still be required to retain the records currently listed in § 35.2045.

Training and Experience Requirements - I approve the training and experience requirements provided in the draft final rule with one exception. To ensure that authorized users have an appropriate mix of both formal training and experience, the staff should modify the wording in §§ 35.290(c)(1) and 35.390(b)(1) as follows:

> "... Has completed 700 hours of **an appropriate combination of both** training and experience in ..."

Reporting Unintended Exposures to Embryo, Fetus, or Nursing Child - I approve the reporting threshold for unintended exposures to the embryo, fetus, or nursing child at 5 rem. In addition, I approve the staff recommendation to prepare a rulemaking plan for requirements for reporting unintended exposures to an embryo, fetus, or nursing child that would not be covered under 10 CFR Part 35.

The following specific comments are provided on the draft Federal Register Notice (FRN):

- Section 35.652 of the draft FRN language requires licensees to make surveys as defined in the sealed source and device (SSD) registry. However, there is no requirement for NRC or Agreement States to include specific information, including survey information, in registration certificates. Therefore, this information may not be available. The staff should modify § 35.652 to require licensees to perform surveys of the device and compare the results of the surveys with documented information on the expected radiation levels. The licensee could then rely on comparison with the SSD registry, if available, or initial surveys performed by the device manufacturer.

- In lieu of using sources or devices that are included in the SSD registry, the draft final rule would allow licensees to use sources or devices in research in accordance with an Investigative Drug Exemption accepted by FDA (§§ 35.400 and 35.600). The staff should consider whether this provides adequate assurance of safety since the NRC and Agreement State evaluations focus on radiation safety, not clinical proficiency.

- The staff should consider whether it is necessary to have licensees perform acceptance testing of therapy-related computer systems (§§ 35.457 and 35.657). In doing so, the staff should consider whether these requirements are duplicative of FDA requirements and whether licensees should be able to rely on the product manufacturer's testing. The staff should also consider whether licensees should be able to rely on the manufacturer's relative helmet factors instead of determining the relative helmet factors before the first use of the unit (§ 35.635).

- The staff should modify its response to the issue of "deemed" status of individuals (page 39 of the draft FRN language) to clearly indicate the nexus between the current and new terminology for status of individuals (e.g., noting whether teletherapy physicist are equivalent to an AMP for 35.600, whether AUs for §§ 35.392 and 35.394 are equivalent to AUs for §§ 35.932 and 35.934) or should indicate that licensing guidance will clearly address this issue.

- A commentor requested (page 255 of the draft FRN language) the inclusion of a definition of "nationally recognized bodies" since certain determinations must be made using protocol accepted by "nationally recognized bodies." The staff should either include a definition for "nationally recognized bodies" in the rule or provide additional justification, in response to the comment, why a definition is not necessary.

- Page 372 of the draft FRN language indicates that the rule includes definitions of "gamma stereotactic radiosurgery unit" and "radioactive drug." However, these are not included in the rule language. The staff should determine whether these definitions are necessary and either include them in the rule language or make the appropriate correction to page 372.

I want to thank the staff and the many stakeholders for their dedication to developing a rule for medical use of byproduct materials that is responsive to the health and well-being of patients and workers.