February 16, 2000

COMMISSION VOTING RECORD

DECISION ITEM: SECY-99-201

TITLE: DRAFT FINAL RULE - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 16, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission, and the SRM of February 16, 2000.

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Annette Vietti-Cook
Secretary of the Commission

Attachments: 1. Voting Summary
2. Commissioner Vote Sheets
3. Final SRM

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

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VOTING SUMMARY - SECY-99-201

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. MESERVE | X | | | | X | 1/3/00 |
| COMR. DICUS | X | | | | X | 12/22/99 |
| COMR. DIAZ | X | | | | X | 12/16/99 |
| COMR. McGAFFIGAN | X | | | | X | 11/24/99 |
| COMR. MERRIFIELD | X | | | | X | 12/3/99 |

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on February 16, 2000.

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Commissioner Comments on SECY-99-201

## Chairman Meserve

I approve the staff's draft final rule language and draft responses to comments, subject to the observations below. The staff should strive to submit the revised final Part 35 rulemaking package and the Medical Policy Statement to the Commission within 3 months from the date of the SRM.

The following are my specific comments:

**Risk Assessment:** I agree with the staff recommendation that no additional risk assessment is necessary to support this rulemaking. The development of the draft final rule used a risk-informed approach and incorporates risk insights to focus licensee and regulatory attention on operational issues commensurate with their importance to health and safety. Also, the draft final rule represents a significant reduction in regulatory burden. Our action on this rule does not prohibit the medical community or other stakeholders from preparing a risk assessment relating to the medical uses of nuclear materials that could be considered by the Commission in connection with a petition for rulemaking.

**Training and Experience:** I approve the proposed training and experience requirements for authorized user physicians, RSOs, physicists, and nuclear pharmacists as proposed by the staff. I also agree with the concerns raised by the ACMUI regarding the need for a uniform national standard for training and experience. Therefore, I agree with Commissioners McGaffigan and Dicus that the compatibility level assigned to the T&E requirements be changed from "C" to "B" to ensure that the provision of medical services nationwide is not disrupted by some Agreement States imposing more restrictive training requirements.

**Event Notification:** I approve the alternative notification requirement proposed by the staff that would require verbal notification of the patient and a certification of that notification to NRC. However, I agree with Commissioners Merrifield and Diaz that there should be a copy of the notification placed in the patient's medical record. If the licensee is the patient's physician, the licensee should place a copy of the records required under 35.2045 in the patient's medical record. If the licensee is not the patient's physician, the licensee should, in addition to retaining a copy for 3 years, provide a copy of the records required under 35.2045 to the patient's physician with a request that the copy be included in the patient's medical record.

**Reporting Threshold for Unintended Exposure to an Embryo, Fetus, and Nursing Child:** I approve the establishment of a reporting threshold (not a dose limit) for unintended exposure to the embryo, fetus, or nursing child at 5 rem. I believe that the medical community has made a valid argument that a lower reporting threshold could significantly impact the practice of medicine because it might cause pregnancy testing in connection with many diagnostic procedures. This could result in desirable nuclear medicine procedures not being performed in some instances. In addition, I approve the staff's proposal to evaluate whether a rulemaking is needed to add a similar requirement in 10 CFR Part 20 or Parts 30, 40, and 70 for reporting an unintended exposure to an embryo, fetus, or nursing child that is not covered under 10 CFR Part 35. The staff should provide the Commission with either a rulemaking plan or a paper explaining why a rulemaking is unnecessary.

**Public Briefing:** I do not believe a public briefing on the draft final rule is necessary. However, if the staff perceives a significant demand for a briefing, I do not oppose such a briefing.

**Specialty Boards:** I approve the staff proposal to begin the process of recognition of the medical specialty boards before publication of the final rule.

## Commissioner Dicus

I commend the staff for an extremely well-written and concise summary of the concerns raised by various members of the public, the Agreement States, the medical community and the licensees. In particular, I would like to express my personal thanks for the NRC staff efforts to reach out and obtain feedback from the seven facilitated public workshops have been held since August 1997.

I have summarized my specific comments on each of the major issues as outlined below:

1. ***Formal risk assessment.*** I note that for the first time, the proposed final rule for 10 CFR Part 35 uses risk insights and operational experience to establish sound requirements that focus both licensee and regulatory resources on operational issues commensurate with their importance to health and safety. Accordingly, I agree with the staff to not perform a formal risk assessment at this time. To perform such an assessment would most likely be at a significant cost in terms of staff time and contractor dollars, as well as a potential delay of perhaps five years for the final rule. Considering that the revised rule is considerably more risk-informed than the current version, I believe that it would be more of a detriment to all stakeholders to delay at this time. I would, however, include additional information in the *Statements of Consideration* (see page 9 of the draft final *Federal Register* Notice, attached) which provides the many reasons why a formal risk assessment is not necessary (i.e., additional 5-year delay in the rulemaking, considerable staff and contractor costs, as well as the revised rule being risk-based).
2. ***Radiation Safety Committee (RSC)***. I support the requirement for an RSC to be required for two or more different types of uses under Subpart E, F and H, or two or more types of units under Subpart H. Licensee management should have the flexibility it needs to decide in how best to address the issues of concern in its radiation protection program.
3. ***Training and Experience (T&E) Requirements.*** Any increase to the T&E requirements for physicians (primarily endocrinologists) who administer I-131 for diagnostic or therapy, beyond 80 hours does not appear to be justified based on the lack of a history of radiation safety problems over the past 50 years in this area. The NRC focus should be on radiation safety and not the practice of medicine (i.e., clinical proficiency). Moreover, because the NRC has a responsibility for establishing a national program for these types of requirements, I believe that the training requirements should be consistent between NRC and the Agreement States, and accordingly, request that the compatibility level for this requirement be upgraded to Compatibility Level "B" (see item 4 below).
4. ***Compatibility Levels Regarding T&E Requirements ( 35.390).*** I do not agree with the SR-6 Committee plans to recommend to the States that they require a T&E requirements of 700 hours for endocrinologists. Historically, there has been no evidence to support a claim that this specialty of medicine has been less cautious in handling radioactive iodine than a radiologist or a nuclear medicine physician. I believe that a differing T&E requirement for endocrinologists would be problematic across the nation, and would most likely lead to additional medical

consultation, training and treatments by other physicians, ultimately affecting the medical treatment to the patient. The NRC staff has done an admirable job in bringing together the facts from all sides on this issue, and I believe that due to the transboundary issues associated with this discipline, it is imperative that the compatibility level be changed from Level "C" to "B" to ensure a consistent framework in the nation.

5. ***The Calibration of Sources and Instruments.*** I agree with the revisions made to 35.60, 35.62, and 35.432 which will require that licensees calibrate instrumentation in accordance with nationally recognized standards (per Public Law 104-113, *National Technology Transfer Act*) and address manufacturer concerns regarding the proper use and calibration of Sr-90 eye applicators. These changes make the requirements for instruments and sources more adaptable to new technology and are more performance-based.
6. ***Notification Following a Medical Event [ 35.3045(e)].*** I note that the majority of comments received from physicians, the ACMUI, and the Patient Rights Advocate request deletion of the requirement for licensees to notify and provide a written report to the patient or responsible relative after a medical event. As I have indicated before in SECY-98-128, I am on record as opposing Federally mandated requirements for notification of patients regarding misadministrations. I continue to believe that the proposed reporting levels for medical events cannot be justified on the basis of any real risk to either the patient(s) or the public. Reporting, in and of itself, implies that these events result in direct harm to the patient, when they often result in no effect on the patient. Because NRC's mission is to also ensure adequate protection of the public's health and safety, I believe that keeping a requirement in Part 35 for such notification is redundant to existing State laws and medical ethics, incorrectly allows intrusion by NRC into professional activities, and penultimately interferes with the doctor-patient relationship. It is for these reasons I believe there should be no NRC requirement for notification following a medical event.
7. ***Reporting Threshold for Unintended Exposure to an Embryo, Fetus and Nursing Child ( 35.3047).*** I agree with the staff's proposal to place this requirement in Part 35, and to raise the reporting threshold to 50 millisievert (mSv) (5 rem). The most important issue concerning this threshold is that the requirement is a *reporting* requirement, not a dose limit. I believe that the 50 mSv (5 rem) reporting threshold is justified for several reasons: (1) as stated in Report 54 of the National Council of Radiation Protection and Measurements, the risk to the embryo/fetus is "...considered to be negligible at 5 rad or less when compared to other risks of pregnancy..."; (2) there are no known deterministic effects of radiation exposure noted in the embryo, fetus, or nursing child at 5 mSv (500 mrem); and (3) the proposed lower threshold of 5 mSv (500 mrem) would likely require mandatory pregnancy tests for every woman of childbearing age who receives a diagnostic procedure, potentially negatively impacting the choice of treatment and the practice of medicine. As a final note, I believe that this requirement should be placed in Part 35, rather than Part 20, as was originally suggested, since Part 20 excludes the practice of medicine, or exposure from medical events.
8. ***Patient release criteria ( 35.75).*** While I can understand the issues many of the States face with regard to increasing responses to radiation alarms at municipal landfills, I continue to support the proposed final rule that establishes the current dose-based patient criteria of 5 mSv (500 mrem) per year. NRC has experienced great success in working with the licensee, local landfill operators, and regional offices to better understand, establish, and set appropriate levels and procedures for alarms on a case-by-case basis. If however, a State wanted to be more prescriptive in this area, there appears to be nothing in the proposed rule which would prevent them, for justified reasons, for setting more stringent limits. I am in agreement with Commissioner McGaffigan's position that while the SR-6 Committee believes that the licensee needs to provide adequate and appropriate instruction to the released patient to help ensure that exposures to members of the public are as low as is 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 release of contaminated items to municipal landfills.
9. ***Specialty Boards***. I agree with the staff's recommendations to notify specialty boards that we will begin accepting requests for recognition of such boards before publication of the final 10 CFR Part 35. It is a large step forward that Part 35 will no longer incorporate a listing of specialty boards whose diplomats automatically fulfill the T&E requirements for RSOs. This change represents a large burden reduction for medical licensees.
10. ***Medical Policy Statement***. I agree with the staff's recommendation to revise the Medical Policy Statement, consistent with the changes that this Staff Requirements Memorandum (SRM) conveys, and complete the final Part 35 rulemaking package to the Commission approximately three months from the date of that SRM.
11. ***Regional Inspector and License Reviewer Training.*** I support the staff's recommendation that NRC staff performing medical inspections will receive training in the final Part 35 as well as in any guidance documents associated with the rulemaking. I would expand this training to include license reviewers and regional managers, so that they too, become quite familiar with the significant revisions in Part 35. I would encourage the training to be completed in all of the regions as soon as Part 35 is finalized, just as was done for the Part 20 regional training sessions.
12. ***No Need for a Public Briefing***. I do not believe that there is a need for a public briefing on the draft final rule. I would rather the staff spend its limited resources on finalizing the rule, Medical Policy Statement, and corrections to the FRN so that this rule can be completed within the established timeframes.
13. ***Use of International System of Units.*** Per the final NRC Metrication Policy (effective on June 19, 1996), the final rule should be revised to consistently use the International System of Units (SI) first, with the English unit shown in brackets (see attachments for examples). Per this policy, even if the incoming comments are only in English units, the SI units should be in parentheses after that, encouraging the use and understanding of the metric units for radiation protection.
14. ***Changes to the FRN.*** In addition to the changes above, additional changes to the FRN are attached.

## Commissioner Diaz

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 EXIT 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 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.

## Commissioner McGaffigan

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.

## Commissioner Merrifield

First, I want to commend the staff for its credible and professional presentation of the issues in SECY-99-201, a task conducted under fairly stressful and contentious circumstances. The staff did an outstanding job of recommending proposed solutions and documenting public input both supporting and disagreeing with the staff proposed solutions. There are difficult and controversial decisions to be made in the revisions to 10 CFR Part 35. My vote on this complex paper is as follows:

**Risk Assessment:** I agree with the staff recommendation that no additional risk assessment is necessary to support this rulemaking. The draft final rule is risk informed and does significantly reduce regulatory burden in many areas. 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 approve the training and experience requirements as the staff has proposed in SECY-99-201. I recognize this is somewhat

of a controversial area even among the medical community (particularly for I-131). But I believe the staff has done a creditable job of justifying the specific training and experience recommendations for each area.

**Patient Notification:** I recognize that most public comments (including all comments from physicians, the ACMUI, and one patient's right advocate) are opposed to NRC regulations requiring notification to patients when a medical event occurs. The basic argument is that patient notification is part of the normal standards of conduct of an ethical doctor and that notification requirements are not necessary. However, there are others who do not have a complete level of confidence that all doctors are fully frank and forthcoming about medical decision making. I firmly believe there should be a requirement to both notify a patient, if medically appropriate, when a medical event occurs and to document the medical event in a manner which is accessible to the patient. However, I also believe that a requirement for patient notification and documentation can be done in such a manner as not to erode the doctor-patient relationship. Therefore as a reasonable compromise to the strong physician opposition, I approve, with modification as described below, the staff's proposed alternative wording for notification of a medical event. The alternative approach still requires patient notification and documentation but reduces some of the formality in the notification process. A doctor who follows the normal standards of conduct for ethical treatment of patients should have no problem achieving this requirement.

In the SRM directing the staff to propose an alternative notification requirement there were three conditions specifically mentioned: (1) verbal notification of the patient, (2) certification of the verbal notification to the NRC, and (3) documentation of the facts in the patient's medical record. The purpose of documenting the facts in the patient's medical record was to allow the patient to have access to the records at some future time, for what ever reason. In return for meeting these three criteria, the licensee or doctor would no longer be required to provide a written notification directly to the patient. The staff proposal achieves items (1) and (2), but it does not achieve (3). Instead, 35.2045 simply states that the licensee shall retain a record of certain facts concerning medical events for three years. The staff's logic is that the licensee is probably not the patient's physician and therefore is not likely to have access to the patient's medical file. However, the patient may or may not know about the separate file of the licensee, the patient may or may not have easy access to the information in the future, and the records would only be maintained for 3 years.

The final rule should be modified to state that if the licensee is the patient's physician, the licensee will place a copy of the records 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 records required under 35.2045 to the patient's physician with a request that they be included in the patient's medical record. As a point of clarification, the licensee should still be required to retain the records currently listed in 35.2045.

As a last issue to address under patient notification, I recognize that the modified alternative patient notification requirements (allowing a verbal notification) would make the medical reporting requirements different from the exposure reporting requirements of 10 CFR Part 20 (which require a written notification). I believe the difference in reporting requirements is justified for several reasons. First, Part 20 involves a worker-employer relationship whereas Part 35 involves a patient-doctor relationship. The physicians have made a reasonable argument that a mandatory written notification may have a detrimental effect on the doctor-patient relationship at a critical time in the patient's treatment plan. No such claim has been made for the worker-employer relationship. Second, worker exposures allowed under Part 20 are to be maintained as low as reasonable achievable and are not to exceed a set value. However, medical exposures are set at any value determined by the physician based on the patient's individual circumstances. Third, under Part 20, workers may be exposed to radiation on a daily basis. An overexposure may be the result of a single event or a result of cumulative exposures. However, medical exposures are conducted under controlled circumstances and are of limited duration. Based on these cumulative factors, I believe there is sufficient justification for the differences in required notifications under Part 20 and Part 35.

**Unintended Exposure:** I approve establishing a reporting threshold for unintended exposure to the embryo, fetus, or nursing child at 5 rem. This is a difficult decision for me. I am in no way implying that I authorize an embryo, fetus, or nursing child to intentionally receive 5 rem. I am only agreeing to the 5 rem standard as a reporting level. My personal preference is to maintain exposure to the embryo, fetus, or nursing child at the lowest level reasonably achievable. However, I am sufficiently persuaded by the argument that setting the reporting level for an unintended exposure under these circumstances at 500 mrem may have an impact on the practice of medicine. There are a number of routine diagnostic nuclear medicine tests that would produce an exposure to the fetus of between 500 mrem and 5 rem. If a patient was known to be with child, the doctor, in all probability, would intentionally prescribe the diagnostic test anyway as doctors do not consider an exposure of 5 rem or less as medically significant for an embryo, fetus, or nursing child. However, if a doctor were to unintentionally expose a embryo, fetus, or nursing child to greater than 500 mrem then, under the draft standards, the doctor would have to report it to the NRC as a medical event. Doctors may therefore prescribe mandatory pregnancy testing before administering nuclear medicine. However, there are circumstances in which pregnancy testing is not accurate. To avoid having to potentially require a pregnancy test or potentially report a medical event, doctors may choose to use another non-nuclear diagnostic, which may not be the best test for the patient under the medical circumstances. I would agree that such an action would be an unintentional intrusion into the practice of medicine. Therefore, since this section of the rule is a reporting requirement and not a dose standard, I will approve the reporting requirement to occur at 5 rem exposure.

In addition, I approve directing the staff to prepare a rulemaking plan to revise Part 20 or Parts 30, 40, and 70 to require reporting of unintended exposures under non-medical circumstances to an embryo, fetus, or nursing child.

**Speciality Boards:** The proposed revisions to 10 CFR Part 35 represent a significant reduction of burden on our medical licensees in a number of areas. Therefore I agree with the staff proposal to require implementation of the final rule within six months of its publication in the *Federal Register*. I also approve the recognition of speciality boards whose certification processes includes all of the requirements in a given section containing training and experience requirements. Because I support expeditious implementation of the final rule, I approve directing the staff to begin the process of recognizing speciality boards before the final rule is published.

**Medical Policy Statement:** I approve directing the staff to submit a revised Medical Policy Statement and complete the final Part 35 rulemaking package to the Commission four months from the date of the SRM on this paper.

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.