February 16, 2000

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary /s/

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

The Commission approved draft final rule language and responses to public comments subject to the comments provided below and the changes listed in the attachment. The staff should incorporate these changes and submit the final Part 35 rulemaking package, including the guidance document and the revised Medical Policy Statement to the Commission. The Commission does not believe that a briefing on the final rule package is necessary.

(EDO) (SECY Suspense: 5/31/00)

1. Training and Experience. The staff should revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.

2. Event Notification. The Commission approved the alternative language for the notification requirement proposed by the staff with modifications. Specifically, the alternative language proposed by the staff should be revised as follows:

   A. Replace the alternative section §35.3045(e) with the following:

      e. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. 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 written description if requested.

   B. Replace the alternative section §35.3045(g) with the following:

      g. A licensee shall retain a record of a medical event in accordance with § 35.2045. A copy of the records required under §35.2045 shall be provided to the referring physician if other than the licensee.

   C. Replace alternative section 35.2045(b) with the following:

      b. The record must include --

         1. The licensee's name;

         2. Names of the individuals involved;

         3. The social security number or other identification number if one has been assigned of the individual who is the subject of the medical event.

         4. A brief description of the event and why it occurred;

         5. The effect, if any, on the individual;

         6. The actions, if any, taken or planned to prevent recurrence; and

         7. Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

   The staff should consider: 1) making conforming changes to § 35.2047 and § 35.3047; and whether the rule should specify when the record required under § 35.2045 must be provided to the referring physician.

3. Medical Specialty Boards. The Commission approved 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.

4. Use of International System of Units. Per the final NRC Metrication Policy, the final rule should be revised to consistently use both the International System of Units (SI) and non-SI units. If referencing an existing rule where non-SI units are listed first (i.e., 10 CFR Part 20), the SI units should be in parentheses.

5. Surveys. 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.

6. Acceptance Testing. The draft final rule (§§ 35.457 and 35.657) requires acceptance testing of therapy-related computer systems. The staff should reconsider the need for this requirement. 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).

7. CRCPD SR-6 Committee. The Commission encourages the CRCPD to use a transparent process similar to that used by NRC. Some Agreement States may contemplate adopting certain provisions that are different from those promulgated for Part 35. Accordingly, the staff should encourage each such State to consider the exhaustive and transparent process used by NRC to solicit input from all stakeholders in the formulation of a risk-informed, performance-based rule. The staff should provide a copy of this final SRM to the CRCPD SR-6 committee, keep abreast of the committee's efforts to finalize the Suggested State Regulations, and informally provide the Commission with updates on this issue.

8. Risk Assessment. The Commission approved the staff recommendation that no additional risk assessment is necessary to support this rulemaking. The draft final rule is risk informed and significantly reduces regulatory burden in many areas. Nothing in the NRC's regulations 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 Commission consideration. The staff should include additional information in the *Statements of Consideration* (see page 9 of the draft final Federal Register Notice) 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-informed).

9. Patient Release Criteria (§35.75). While understanding the issues many of the States face with regard to increasing responses to radiation alarms at municipal landfills, the Commission continues to support the proposed final rule that establishes the current dose-based patient criteria of 5 mSv (500 mrem) per release. The Commission continues to believe that the current dose-based release criterion of 5 mSv (500 mrem) per release adequately protects public health and safety.

   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, the Commission does 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.

10. Event Reporting. The Commission approves the staff recommendation to modify Part 35 to include a reporting threshold, not a dose limit, of 5 rem to an embryo/fetus or nursing infant in cases where the radiation exposure was not intended. Additionally, the staff should prepare a rulemaking plan to revise either Part 20 or other Parts of Title 10 to require reporting of unintended exposures under non-medical circumstances to an embryo, fetus, or nursing child. The rulemaking plan should discuss the pros and cons of each option, including a no action option if the staff believes a rulemaking is not necessary.

(EDO) (SECY Suspense: 10/27/00)

Attachment: Editorial Changes to Federal Register Notice in SECY-99-201

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA

Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

ATTACHMENT

Editorial Changes to Federal Register Notice in SECY-99-201

1. On page 7, paragraph 3, revise line 4 to read ' ... each type of risk **as they are viewed in the regulation of medicine**.'

2. On page 7, paragraph 4 (1st indented paragraph), revise line 2 to read ' ...patient, public, **or** ~~and~~ worker **s**.'

3. On page 8, 2nd full paragraph, revise line 3 to read ' **One** ~~The~~ commenter noted that most ....' Revise line 4 to read ' **This** ~~The~~ commenter believed that ....'

4. On page 8, 3rd full paragraph, revise line 1 to read ' ... overspending on ~~the~~ low risk activities.'

5. On page 8, last paragraph, revise line 2 to read ' ... landfill alarms **as a result of disposal of** ~~to~~ short-lived, low-activity ....'

6. On page 19, paragraph 2 should include mention of decreasing inspection frequency for good performance.

7. On page 26, the 1st paragraph in the 'Response' should discuss Public Law 104-113 on Federal agency use of consensus standards and should discuss how these standards are incorporated in the guidance.

8. On page 39, the staff should modify its response to the issue of "deemed" status of individuals 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.

9. On page 59, revise line 2 from the top to read 'NUREG-1556, Vol. 9 **, "Program-Specific Guidance About Medical Use Licensees"**.'

10. On page 63, in the last line after 'proposed rule', cite the Federal Register reference.

11. On page 66, line 2 from the top, insert an additional space after the end of the sentence and capitalize 'The' at the start of the next sentence.

12. On page 68, last paragraph, in line 2, a 'master materials licensee' is not defined in the regulations, only in the guidance documents. Reference should be made to NUREG-1556, Volume 10.

13. On page 73, 1st full paragraph, revise line 2 to read ' ... individuals using only **I-131** ~~iodine-131~~ in quantities that ....'

14. On page 79, in the paragraph labeled 'Response', revise line 3 to read ' ... clarify the specific requirements **of the AEA**.'

15. A commenter requested (page 255 of the draft FRN language) an explanation of the meaning of "nationally recognized bodies" since certain determinations must be made using protocol accepted by "nationally recognized bodies." The staff should expand the response in the FRN to provide additional guidance on what is meant by "nationally recognized bodies."

16. On page 356, next to the last paragraph, the Website address needs to be corrected.

17. On 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.

18. On page 363, 2nd paragraph under 'Comment', revise line 4 to read ' ... designation ~~was~~ is inconsistent with ....'

19. On page 363, last paragraph, revise line 4 to read ' ... as a mobile service **has** ~~was~~ been designated ....'

20. On page 365, paragraph 2 (Response), revise line 2 to read ' ... Management Directive 5.9 **for the assignment of compatibility category H&S**.'

21. On page 365, paragraph 3 (Comment), line 2, delete the 's' at the end of 'standards'.

22. On page 372, 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.

23. On page 376, revise lines 1 and 2 from the top to read ' ... ~~delete~~ **add** the reference to an AMP. A medical use ... to work as an AMP ~~ANP~~ if that individual ....'

24. On 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*.

25. On page 503, paragraph (a), revise line 2 to read ' ... of an authorized user ~~or~~ as allowed by ....'

26. On 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.

27. On page 565, the dosage record requirements contained in 10 CFR 35.2063(b) should be further reviewed to ensure that enough information is retained to determine if a medical event had actually occurred. As part of this review, the staff should consider the possible time lapse between dosage determination and dosage administration. As appropriate from this review, the staff should consider revising the record keeping requirements in the final rule.

28. On page 567, the staff should consider modifying the record requirements for decay-in-storage contained in 10 CFR 35.2092 to substitute the "name of the individual who performed the survey" for the "name of the individual who performed the disposal."