Closeout of items in SRM-SECY-99-201
Not Addressed in Final Register Notice

Staff Requirements - SECY 99-201, Draft Final Rule - 10 CFR Part 35, "Medical Use of Byproduct Material" directed staff to consider several issues when preparing the final Part 35 rulemaking package. The following discussion documents staff's consideration of these issues where staff's consideration would not be readily identifiable in the Federal Register notice for the final rule.

Items from the Body of the Staff Requirements Memorandum

Item 2 - The Commission directed that staff make specific changes to § 35.2045, "Records of medical events," and § 35.3045, "Report and notification of a medical event." As a result of these changes, the Commission stated that "The staff should consider: 1) making conforming changes to §§ 35.2047 and 35.3047 and 2) whether the rule should specify when the record required under § 35.2045 must be provided to the referring physician"

Response: We made conforming changes between §§ 35.2047 and 35.3047 to make them as consistent as possible. This consistency benefits both NRC staff and licensees because it makes the rule easier to use. These conforming changes also reduce the regulatory burden on licensees had the proposed rule text not been modified.

We revised the rule text (§ 35.3045(g)) to reflect that a copy of the record required under § 35.2045 shall be provided to the referring physician, if other than the licensee, within 15 days after the discovery of the medical event. We believe that this change is needed to ensure that the referring physician has all the available documented information about the medical event to support any decisions about remedial or prospective health care of the patient. The 15-day time period to provide the referring physician with a copy of the record is based on § 35.3045 (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

As noted in the Commission paper, we have also developed alternative rule text for Commission consideration (See Attachment 8) which deletes the recordkeeping requirements in §§ 35.2045 and 35.2047. This implements the Commission's direction that the referring physician be provided with documentation of the medical event and minimizes the recordkeeping burden on licensees.

Item 6 - "The staff should reconsider the need for [the draft final rule to require acceptance testing of therapy-related computer systems]. 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."

Response: We have maintained the requirement for licensees to perform acceptance testing of therapy-related computer systems. The FDA does not test the output of software-based treatment planning systems as part of their approval for marketing process, rather they verify that the developer/vendor documents that industry accepted standards were used to develop, test, and verify the software's function and accuracy. Licensees should not be allowed to rely on the product manufacturer's testing to meet this requirement. Most software-based treatment planning systems are designed for general purpose use and often require the correct input of various source parameters by the user in order to obtain accurate treatment plan results. User acceptance testing serves not only to verify that the underlying treatment planning system software is producing the correct results but also verifies the accuracy of the user entered source parameters. American Association of Physicists in Medicine (AAPM) Report of the Therapy Committee Task Group 56, "Code of Practice for Brachytherapy Physics," was used in developing the components of acceptance testing.

Regarding helmet factors, the measurement of the helmet factors is inherent in patient dosimetry. Therefore, for the same reasons cited above, we have included this requirement in the final rule. The performance objectives for the tests required in § 35.635 are based on recommendations in AAPM Report No. 54, "Stereotactic Radiosurgery." For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user.

Item 7 - "The staff should provide a copy of the final SRM to the SR-6 committee, keep abreast of the Committee's efforts to finalize the SSR, and informally provide the Commission with updates on this issue."

Response: A copy of the final SRM was provided to the Agreement States under Agreement State Letter No. SP-00-18, March 3, 2000. In addition, the staff will keep knowledgeable of the SR-6 Committee's efforts to finalize the Suggested State Regulation and informally provide the Commission with updates on this issue.

Items from the Attachment to SECY-99-201

Item 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."

Response: We reviewed the recordkeeping requirements in § 35.2063, "Records of dosages of unsealed byproduct material for medical use." We considered the possible time lapse between dosage determination and administration for diagnostic and therapeutic administration. In the case of diagnostic procedures (written directive is not required), it is extremely unlikely that this time difference would result in a situation where the dose difference would exceed the threshold

for a medical event identified in 35.3045 because the byproduct material has a short half life and low activities are administered. Therefore, we do not believe that a prescriptive requirement to record the time of dose administration can be justified in a risk-informed, more performance based rule.

In the case of therapeutic administrations (written directive is required), it is possible that a significant time difference between dosage determination and administration could result in a medical event. We do not believe however, that a requirement for recording the time of administration should be added to the rule. Licensees are required by § 35.41 to develop implement, and maintain written procedures to provide high confidence that ". . . each administration is in accordance with the written directive." Compliance with this performance-based requirement should provide NRC with sufficient information to establish whether an administration was in accordance with a written directive and did not result in medical event.