

February 15, 2006

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - SECY-05-0234 - ADEQUACY OF
MEDICAL EVENT DEFINITIONS IN 10 CFR 35.3045, AND
COMMUNICATING ASSOCIATED RISKS TO THE PUBLIC

The Commission has approved the staff's recommendations to 1) retain the ± 20 percent delivered dose variation in 10 CFR 35.3045(a), as an appropriate threshold for medical event reporting for all medical use modalities except permanent implant brachytherapy; and 2) improve public understanding of the risks associated with medical events.

The Commission has disapproved the staff's recommendation to develop a rulemaking plan. Rather, the staff should forego the development of a rulemaking plan and proceed directly with the development of a proposed rule to modify both the written directive requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use to convert from dose-based to activity-based. The staff plan for developing the proposed rule should follow a path very similar to the activities associated with the effort for the training and experience rulemaking, with public input on the drafting of the proposed rule. The staff should develop whatever data is necessary to properly prioritize the activity, including consideration of the important Energy Policy Act-related rulemakings that have statutory deadlines, and include this activity in the next update to the Rulemaking Activity Plan.

The Commission acknowledges that changing circumstances may necessitate the need to revisit previous decisions. In general, the Commission strongly encourages the staff and ACMUI to continue their good efforts to review and improve upon existing Commission policy in this area. The staff and ACMUI are encouraged to periodically review existing policies and to suggest changes that both ensure public health and safety and reduce impediments to the safe and beneficial uses of radioactive material.

In addition to the four specific means by which staff intends to communicate the guiding principles for medical event definitions (article in NMSS Licensee Newsletter, Regulatory Information Summary, letters/discussions, and Event Summary footnotes), the staff should develop a Fact Sheet or Backgrounder for publication on NRC's website.

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR