

March 20, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations
FROM: John C. Hoyle, Secretary /s/
SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057 MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

- (1) Focusing Part 35 on those procedures that pose the highest risk.
- (2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.
- (3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.
- (4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.
- (5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.
- (6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
- (7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.
- (8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(EDO - Program)
(EDO - Complete Rulemaking)

(SECY Suspense: 6/6/97)
(SECY Suspense: 6/30/99)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
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