

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

April 1, 1988

MEMORANDUM FOR: Victor Stello, Jr.
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON STATUS OF
PROPOSED RULEMAKING ON BASIC QA IN RADIATION
THERAPY AND RELATED ACTIVITIES, 2:00 P.M.,
TUESDAY, MARCH 22, 1988, COMMISSIONERS'
CONFERENCE ROOM, D.C. OFFICE (OPEN TO PUBLIC
ATTENDANCE)

The Commission was briefed by the staff on the status and public comments of rulemaking efforts for both basic and comprehensive quality assurance requirements for medical uses of radioisotopes.

The Commission made the following requests:

- Ø The staff should communicate with states, interested parties, and health care communities to identify opportunities for cooperation to foster improved programs for the medical use of isotopes.
- Ø The staff should contact the Agreement States to obtain any available data on medical misadministrations to supplement NRC's data base.
- Ø The staff should arrange for the Commission to be briefed by the NRC's Medical Advisory Committee and representative professional societies on positive steps that can be taken to improve quality assurance for medical use of isotopes.

(Subsequent to the meeting, the Commission scheduled a meeting with the NRC's Medical Advisory Committee and representative professional societies for April 7, 1988.)

- ø The staff should submit for Commission consideration an options paper on ensuring quality in the medical application of byproduct materials. The options should include performance based quality assurance requirements containing specific elements necessary for implementation. (Option 2, as presented in the briefing material.)
(EDO) (SECY Suspense: TBD)

Commissioner Bernthal requested the staff to provide the basis for staff's determination that some fraction of misadministrations reported as abnormal occurrences could likely result in adverse health effects. He also expressed concern as to whether the threshold implied by such a determination comports with that used elsewhere by the Commission to determine adverse health effects.
(EDO) (SECY Suspense: 4/22/88)

cc: Chairman Zech
Commissioner Roberts
Commissioner Bernthal
Commissioner Carr
Commissioner Rogers
OGC (H Street)
GPA
PDR - Advance
DCS - 016 Phillips