

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

April 22, 1988

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

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON PROPOSED  
BASIC QA RULE WITH REPRESENTATIVES OF NRC  
ADVISORY COMMITTEE ON THE MEDICAL USES OF  
ISOTOPIES AND INDUSTRY SCIENTIFIC COMMITTEES,  
2:00 P.M., THURSDAY, APRIL 7, 1988, COMMIS-  
SIONERS' CONFERENCE ROOM, D.C. OFFICE (OPEN  
TO PUBLIC ATTENDANCE)

The Commission\* met with the NRC Advisory Committee on the Medical Uses of Isotopes, representatives of the industry's scientific communities and the staff to discuss rulemaking initiatives for quality assurance in medical uses of radioactive isotopes.

Presentations by representatives of the medical profession and the Advisory Committee on the Medical Uses of Nuclear Isotopes were made by the following:

- Ø Carol S. Marcus, Ph.D., M.D.  
Los Angeles County Harbor-UCLA Medical Center
- Ø Glenn L. Tonnesen, M.D.  
Fairfax Hospital
- Ø Otha Linton  
American College of Radiology
- Ø Faiz Khan, Ph.D.  
American Association of Physicists in Medicine
- Ø Richard E. Gross  
Center for Devices and Radiologic Health of the FDA
- Ø Vincent P. Collins, M.D.

Private Practitioner, Houston, Texas

- ø Melvin L. Griem, M.D.  
University of Chicago

\* Commissioner Rogers was not present.

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- ø David H. Woodbury, M.D.  
Westland Medical Center', Westland, Michigan
- ø Peter R. Almond, Ph.D.  
University of Louisville

The Commission made the following requests of the staff:

ø Consistent with the directives outlined at the March 22, 1988, Commission briefing on the same subject matter, submit for Commission consideration an options paper providing alternatives for rulemaking on quality assurance requirements for medical application of radioactive isotopes. These alternatives should include (but need not be limited to):

- 1) the positive elements from the previously published NPR, incorporating suggestions and comments received from the public, where appropriate;
- 2) a non-prescriptive approach. Requirements should be performance based and should allow licensees to either develop or adopt QA programs tailored to specific clinical environments; and
- 3) some combinations) of 1) and 2), above.

As part of the options paper, the staff should outline a pilot program to be conducted during the public comment period for a performance based rule. The results of the pilot program along with the analysis of public comments should be addressed in recommending a final rule for Commission consideration.

In light of the discussion during the meeting, the staff should also review whether the term "misadministration" itself, as well as its definition should be revised as part of the rulemaking.

(EDO) (SECY Suspense: 5/31/88)

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Ø Insure that the appropriate medical and scientific communities are kept currently informed of medical misadministration events.

(EDO)

(SECY Suspense: 5/31/88)

Ø Explore alternatives to establish better communication channels between NRC and the medical and industry scientific communities.

(EDO)

(SECY Suspense: 5/31/88)

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