IN RESPONSE, PLEASE
REFER TO: M930122
M930129C
M930208A
M930222

March 31, 1993

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

William C. Parler, General Counsel

FROM: Samuel J. Chilk, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON STATUS OF MEDICAL USE ACTIVITIES, 2:00 P.M., FRIDAY, JANUARY 22, 1993, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

BRIEFING BY AGREEMENT STATES ON THEIR ACTIVITIES IN MEDICAL USE AREA, 2:00 P.M., FRIDAY, JANUARY 29, 1993

BRIEFING BY IIT ON LOSS OF IRIDIUM-192 SOURCE AND THERAPY MISADMINISTRATION AT INDIANA REGIONAL CANCER CENTER, INDIANA, PA., NOVEMBER 16, 1992, 10:00 A.M., MONDAY, FEBRUARY 8, 1993

BRIEFING BY ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES, 9:00 A.M., MONDAY, FEBRUARY 22, 1993

The Commission was briefed (1) on January 22, 1993 by the NRC staff on the status of activities in the medical area, (2) on January 29, 1993 by the Organization of the Agreement States on their activities in the medical use area and by representatives of individual Agreement States concerning specific misadministration cases in their States, (3) on February 8, 1993 by the Incident Investigation Team (IIT) on the loss of an iridium-192 source and therapy misadministration at Indiana Regional Cancer Center, Indiana, PA, and (4) on February 22, 1993 by the Advisory Committee on the Medical Uses of Radioisotopes (ACMUI) on issues arising from the Cleveland Plain-Dealer articles on medical misadministration.

The matter of regulation of the medical use of radioactive materials has been the subject of continued and increasing attention by the Commission and the staff. The staff is requested to review its present tracking systems and compile an overall list of ongoing and planned medical action items and projects. The action items should be prioritized and categorized with an estimated date of completion.

(EDO) (SECY Suspense: 5/3/93)

The staff should review its updated list of action items to consider estimates of FTE and funding costs, and projected completion dates. The staff, in its report to the Commission, should factor in the resource implications of the existing staff requirements and those listed in the following paragraphs, the reduction in staff that will be applicable in FY 1994 and the following years, and recommend priorities and a schedule for the projects.

(EDO) (SECY Suspense: 7/30/93)

The staff should continue with currently scheduled efforts to review and reevaluate the NRC medical use regulatory program, i.e., the Medical Management Plan, the internal management review of current practices for implementing the medical use regulatory program and the external review of the program. The staff should continue to follow up on the findings in the IIT report and coordinate these actions with the review efforts. In these actions and in the following requirements the staff should, as appropriate, coordinate and consult with the Agreement States and the ACMUI. As part of this overall review the staff should:

1) Consider the advisability of establishing a national data base for tracking and evaluation of medical events within NRC and Agreement State jurisdiction.

2) Consider the potential for underreporting of misadministrations.

3) Consider possible NRC policies on patient followup.

4) Define the appropriate role and responsibilities of the medical consultant in NRC medical activities.

5) Consider NRC's role and scope of responsibilities versus that of the FDA and Agreement States in the review and approval of sealed sources and devices.

6) Consider what regulatory actions may be appropriate to better define the responsibilities and role of a Radiation Safety Officer (RSO) at medical institutions.

7) Proceed with clarifying amendments to 10 CFR 35, Regulatory Guide 10.8, and internal staff guidance memoranda to clarify the radiation safety requirements applicable to high dose rate remote afterloaders.

8) Consider the need for modifications or additions to the NRC Enforcement Policy to provide for notifying licensee Boards of Directors or Trustees in cases where escalated enforcement is undertaken by the NRC.

9) Consider potential mechanisms for tracking and notifying Agreement States and appropriate licensing/credentialing authorities of problem authorized users, including chronically careless practitioners as well as wrongdoers.

10) Consider the need to establish procedures under which local authorities including the coroner or medical examiner would be notified of misadministrations or other serious events including potentially significant exposures to radiation or radioactive materials.

The staff should report to the Commission on the progress and findings of the internal management review in early June.
(EDO) (Secy suspense: 6/15/93)

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
OIG
Office Directors, Regions, ACRS, ACNW (via E-Mail)
OP/SDBU/CR, ASLBP (via Fax)
PDR - Advance
DCS - P1-24