

PLEASE
M910612B

IN RESPONSE,
REFER TO:

June 19, 1991

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations
William C. Parler, General Counsel
Harold R. Denton, Director
Governmental and Public Affairs

FROM: Samuel J. Chilk, Secretary /S/

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION/DISCUSSION
AND VOTE, 11:30 A.M., WEDNESDAY, JUNE 12,
1991, COMMISSIONERS' CONFERENCE ROOM, ONE
WHITE FLINT NORTH, ROCKVILLE, MARYLAND
(OPEN TO PUBLIC ATTENDANCE)

I. SECY-91-166 - Joint Motion to Stay or Vacate License
Issuance by Petitioners in Shoreham Proceeding

The Commission, by a 4-0 vote, approved an order responding to a request by the Shoreham-Wading River Central School District and the Scientists and Engineers for Secure Energy to, among other issues, stay issuance of LILCO's requested "possession only" license amendment for the Shoreham Nuclear Power Plant pending completion of on-going litigation in the New York Court of Appeals.

The Order denies the petitioners request. The Commission also approved the staff's recommendation that it be allowed to issue a possession only license without prejudice to petitioners rights to pursue a hearing before the Licensing Board.

(Subsequently, on June 12, 1991, the Secretary signed the Order.)

II. SECY-91-130 - Final Amendments to 10 CFR Parts 2 and 35 on Quality Management Program and Reportable Events

The Commission, by a 4-0 vote, approved publication of final amendments to 10 CFR Parts 2 and 35 requiring applicable Part 35 licensees to implement quality management programs to provide high confidence that byproduct material will be administered as directed by an authorized user physician.

The Commission approved the final rule as proposed by the staff in SECY-91-130 subject to: 1) keeping the present 24 hour time period for notifying the referring physician and patient in the event of a misadministration, and 2) retaining the use of the term "misadministration" for those events which are reportable to the Commission under these amendments. Commissioners Rogers and Remick would have also made additional changes to the regulations to limit the use of the term "misadministration" to those events which are subject to enforcement action.

The Federal Register Notice should be revised as noted in 1) and 2) above and the attached editorial changes should be incorporated. The final Federal Register Notice should be reviewed by the Regulatory Publications Branch, ADM, and forwarded for signature and publication.

(EDO) (SECY Suspense: 6/28/91)

The staff should complete in a timely manner the considerations of how best to ensure notification and assessment of pregnancy and nursing status associated with diagnostic and therapy medical procedures and advise the Commission of the results.

(EDO) (SECY Suspense: 12/2/91)

After the rule is published the staff should continue with implementation activities associated with the rule, including:

1) Revision of the staff's guidelines for selecting medical misadministration events for Abnormal Occurrence Reporting in Manual Chapter Appendix 0212, Part II to conform the guidelines to the new QM and misadministration rule, including consideration of modifications to the existing NRC policy statement for determination of abnormal occurrence to include specific medical abnormal occurrence criteria.

(EDO) (SECY Suspense: 12/31/91)

2) Conforming revisions to staff's guidance for NRC inspectors on the types of information they should collect following potential misadministrations, in response to the SRM dated November 15, 1990, on COMKC-90-21.

(EDO) (SECY Suspense: 9/30/91)

- 3) Follow-through on the staff's commitment in SECY-91-120 to provide the Commission with an assessment of the effectiveness of the QM rule at the annual briefing on medical uses of byproduct material three years after the rule becomes effective, including recommendations on the need for a rulemaking on comprehensive quality management and on the status of the ANPR.
(EDO) (SECY Suspense: 2/94)

GPA and EDO staff are requested to develop and implement procedures for receiving and analyzing misadministration data from the Agreement States, who regulate two-thirds of the medical licensees in the U.S. The Commission believes that it needs to systematically collect and assess the misadministration data that it receives from Agreement States to fulfill its national oversight responsibilities and to follow through on its request for the information and decision on the level of compatibility. As in the past, these data may indicate generic problems that can best be addressed through rulemaking to ensure the medical uses of byproduct material continue to provide adequate protection of the public health and safety.

(GPA/EDO) (SECY Suspense: 12/91)

The Commission commends the staff on NRC's Medical QA Team who participated in the Quality Assurance Pilot Program and the many workshops with interested parties on the proposed quality assurance rule. The process of discussing and resolving concerns with the proposed rule was arduous, but well worthwhile given the quality of the final QM rule. Staff's diligent efforts on the QM rule have also provided invaluable experience and insights into how to improve NRC's process for developing rules and regulatory policies on controversial issues.

Attachment:
As stated

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
ACRS
PDR - Advance
DCS - P1-24

IF INTERESTED IN ATTACHMENT, PLEASE REFER TO THE SRM