

June 25, 1992

MEMORANDUM FOR: James M. Taylor  
Executive Director for Operations

Barry A. Siegel, Chairman  
Advisory Committee on the Medical Uses of  
Isotopes

FROM: Samuel J. Chilk, Secretary /s/

SUBJECT: SECY-92-171 - ADMINISTRATION OF BYPRODUCT  
MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL  
TO PATIENTS WHO MAY BE PREGNANT OR NURSING

The Commission (with all Commissioners agreeing) has approved the development of a performance-based rule and a modified regulatory guide which addresses the administration of byproduct material or radiation from byproduct material to patients who may be pregnant or nursing.

(EDO) (SECY Suspense: 12/24/92)

In preparing the rulemaking package, the staff should consider the following:

- 1) the precautions which are already in use to guard against improper administration of nonradiological drugs, chemicals or other procedures to patients who are pregnant or nursing and the feasibility of simply mandating their use for radiological procedures,
- 2) the philosophies espoused by NCRP and ICRP for addressing the radiation safety concerns associated with administration of radiation or radioactive materials to patients who may be pregnant or nursing,
- 3) consistency with the information on radioactive drugs available from the U.S. Pharmacopeia for the health professional and for the patient,

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SRM

- 4) consultation with Oak Ridge Associated Universities to establish an appropriate dose threshold for reporting unintended exposures to embryos, fetuses, and nursing infants from diagnostic administrations,
- 5) a second independent study to be done by a qualified, disinterested party to assist in preparing the regulatory analysis, and
- 6) developing a sound regulatory analysis that quantifies, to the extent available data permits, the risks and benefits, in order to have confidence that the solution being recommended is consistent with the problem being addressed.

The staff should continue to interact closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the development of the proposed rule and regulatory guide.

The Commission (with all Commissioners agreeing) requests that the ACMUI formulate recommendations on how the ACMUI could develop and document its views for the staff and Commission on major policy issues and provide an estimate of the resources required to carry out the recommendations. The staff should advise the ACMUI to present its recommendations at the July 31, 1992 briefing.

(ACMUI)

(SECY Suspense:

7/31/92)

cc: The Chairman  
Commissioner Rogers  
Commissioner Curtiss  
Commissioner Remick  
Commissioner de Planque  
OGC  
OCAA  
OIG