



OFFICE OF THE  
SECRETARY

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

December 21, 1992

RELEASED TO THE PDR

1/7/93

date

initials

MEMORANDUM FOR: James M. Taylor  
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary *HC*

SUBJECT: COMIS-92-026 - REVIEW OF THE REGULATION OF  
THE MEDICAL USE OF BYPRODUCT MATERIAL

The recent and most serious therapy misadministration incident in Indiana, Pennsylvania, in addition to other recent events and circumstances, has served to highlight the importance of assuring that NRC's medical licensing program is properly designed and effectively implemented to provide adequate assurance of public health and safety.

1. The Commission requests that you nominate for Commission approval, a senior NRC manager to perform a management review of the existing medical use regulatory program. This review should focus on whether our existing programs, including oversight of the Agreement state program, is being effectively implemented. The review should be coordinated with the management plan (September 8, 1992 Bernero to Taylor memorandum) which is under development, and with any recommendations from the IIT. The senior manager should identify any recommendations to correct deficiencies in implementation of our existing program.
2. To complement this implementation review, the Commission is also interested in an in-depth review of the basic regulatory rules, policies, practices and procedures to assess whether our current framework for medical use of byproduct material is appropriate to fulfill our statutory responsibilities for public health and safety. The Commission therefore requests that you propose, for Commission approval, a charter and proposed members for an outside group to conduct such a review. The group's membership should provide a balanced representation of interested and affected parties including some drawn from the medical licensing community. The goal of the group is to develop an assessment of the adequacy and appropriateness of the framework, and to identify specific recommendations for Commission review and action.

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3. In performing tasks one and two, the senior NRC manager and the review group should solicit the views of ACMUI.

The Commission asks that you afford both of these efforts a high priority.

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