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PDR
M. 29

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

OFFICE OF THE
SECRETARY

ACTION - Davis
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Felton
Philips
Besaw
Shelton

June 14,1985

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

FROM: for Samuel J. Chilk, Secretary

SUBJECT: SECY-84-485, PROPOSED REVISION OF 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

This is to advise you that the Commission (with all Commissioners agreeing) has approved SECY 84-485 subject to the following.

1. Modify Enclosure 1, page 30 by deleting the second paragraph under the heading, "§35.36 Radiation Safety Program Changes," and adding the following paragraphs:

> "The Commission notes that this change in the current licensing process under which all radiation safety program changes must be approved by license amendment, recognizes that, in the end, public health and safety is based on three features: (1) NRC regulates who may use byproduct material for medical use by listing authorized users on the license; (2) NRC regulates the degree of hazard, balanced with medical needs, by only allowing certain chemical and physical forms for medical use; and (3) NRC regulates where by product material may be used to allow for unannounced inspections of licensee radiation safety programs. This proposal would retain those regulatory features by requiring licensees to receive a license amendment before using material for new clinical methods of use not permitted by the license; before permitting new authorized users to use material; before receiving more material or different kinds of material than permitted by the license; and before using material at locations not listed on the license. These are major changes in a licensee's radiation safety program for which a license amendment would still be required (see §35.17). Under this proposal all other changes (such as selecting replacement equipment, re-arranging the nuclear medicine clinic, switching from one service contractor to another, or switching to an alternative equipment quality assurance procedure) would be minor changes.
>
> The Commission would appreciate comments on this major/minor dividing line or threshold. Is this dividing line clear and complete? Are there other features that should be considered as major changes, or are some of these major changes really not important to health and safety? Is there some other dividing line, either fixed or flexible, that would clarify which changes

are really not important to health and safety and may therefore be made by the licensee? Alternatively, should the Commission continue to require licensees to submit all radiation safety program changes for agency approval?

2. Modify Enclosure 1, page 30, by adding the following text after the heading and introductory paragraph "§35.37 Records and Reports of Misadministrations":

"Although the Commission has not revised its misadministration reporting and recordkeeping requirements, it would like to take this opportunity to ask for public comment on these requirements based on the experience gained since the requirements were first published in final form five years ago. For both diagnostic and therapeutic misadministrations, are the current requirements adequate to protect the public health and safety or should they be made more or less stringent? Should the regulations require prompt notification of the patient who received the misadministration? Do the regulations provide the public with a clear notice of the Commission's role when there is a misadministration? Should the Commission take enforcement action against licensees who misadminister byproduct material or radiation to patients? If so, what type of enforcement action should be taken?"

3. Delete the last paragraph under the heading "§35.30 ALARA program" in Enclosure 1, page 26, and insert the following:

"In this proposed rulemaking the Commission has not required non-institutional licensees, such as one or a few physicians in private practice, to have a formal ALARA program because, for those licensees, the physician authorized user is usually also the Radiation Safety Officer, management, and the line manager. Hence, any formal ALARA report requirement would consist of the physician reporting to himself. However, the Commission would appreciate comments as to whether all medical licensees should have a formal ALARA program. If so, should small licensees conduct an internal annual review or should that review be conducted by someone who is not associated with the licensee's program on a day-to-day basis? Commenters are reminded that the exhortation in 10 CFR 20.1(c) to make every reasonable effort to maintain radiation exposures and releases of radioactive materials ALARA applies to medical licensees. "

4. Modify Enclosure 1, page 3, by inserting a new sub-heading and text as the first subdivision under the heading "NRC's REGULATORY PROGRAM." (This modification was proposed in your memorandum to Mr. Hoyle, dated April 15, 1985.)

"Policy Regarding the Medical Use of Byproduct Material
In a policy statement published in 1979 (44 FR 8242), the NRC

noted that it regulates the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public, regulates the radiation safety of patients where justified by the risk to patients, and minimizes its intrusion into medical judgements affecting patients, and into other areas traditionally considered to be the practice of medicine. The NRC does have the authority to regulate the medical use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicted on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

"This revision retains NRC's current balance between adequate controls and avoidance of undue interference in medical judgements. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could result in the unwarranted or unsafe use of radiation."

The proposed rule should be modified as noted above and returned for signature and publication in the Federal Register.
(EDO/NMSS SECY suspense 7/12/85).

The staff is also requested to meet with the Advisory Committee on Medical Uses of Isotopes and determine what level of physician training is appropriate.

cc: Chairman Palladino
Commissioner Roberts
Commissioner Asselstine
Commissioner Bernthal
Commissioner Zech
OGC
OPE