

N McElroy

APR 15 1985

MEMORANDUM FOR: John C. Hoyle, Acting Secretary

FROM: William J. Dircks
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS - DISCUSSION OF PROPOSED
REVISIONS TO PART 35, 10:00 A.M., WEDNESDAY,
MARCH 20, 1985, COMMISSIONERS' CONFERENCE
ROOM, D.C. OFFICE (OPEN TO PUBLIC ATTENDANCE)
(SECY-84-485)

This is in response to your memorandum of March 29, 1985 (M850320A) that forwarded the Commission's request for additional information concerning the revision of 10 CFR Part 35, "Medical Use of Byproduct Material."

In response to the request that the statement of considerations include a summary of NRC's regulatory role as it affects the patient, the staff proposes to insert the following paragraph on page 3 of SECY 84-485, Enclosure 1 (the Federal Register notice), as the first subdivision under the heading "NRC'S REGULATORY PROGRAM":

Policy Regarding the Medical Use of Byproduct Material

In a policy statement published on February 9, 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 judgments 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 predicated 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 judgments. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could result in the unwarranted or unsafe use of radiation.

8509230393 850906
PDR PR
35 50FR30616 PDR

OFFICE

SURNAME

John C. Hoyle

-2-

In response to the request that the staff clarify the definition of "minor change" by characterizing a representative cross-section of "minor changes" that have required license amendments in the past, the staff submitted an analysis of license amendments in a memorandum to Mr. Chik from me dated April 3, 1985.

(Signed) William J. Dircks

William J. Dircks
Executive Director
for Operations

DISTRIBUTION - 850320

NMSS r/f
FCML r/f
FC Central File
NLMcElroy
VLMiller
RECunningham
JGDavis
WJDircks
BClausser
PPAS/NMSS
NMSS 850320
DBMausshardt
EDO r/f
GCunningham
Roe
Rehm
Stello
WGKerr
JTaylor

*see previous concurrence

ELD
TDorian
4/16/85

OFFICE	FCML	FCML	FC	FC	NMSS	NMSS	EDO
SURNAME	NLMcElroy/pj	VLMiller	DRChapell	RECunningham	DBMausshardt	JGDavis	WJDircks
DATE	04/10/85	04/08/85*	04/ /85	04/11/85	04/11/85	04/11/85	04/11/85

*no by direction
by phone
mlm*