



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

NOV 08 1990

AD43-2

MEMORANDUM FOR: Darlene Huyer, Chief  
NUDOCS/IRM

FROM: Anthony Tse, RDB/DRA/RES

SUBJECT: REGULATORY HISTORY DOCUMENTS FOR AN INTERIM FINAL RULE ON  
PREPARATION AND USE OF RADIOPHARMACEUTICALS (10 CFR Parts 30  
and 35)

Enclosed are copies of the subject documents for the NUDOCS. As requested by Micheal Lesar of the Regulatory Publications Branch/ADM, each document was marked "AD43-2," those documents that can be made available to the public were marked "PDR," and those documents that cannot be made available to the public were marked "CF."

Also enclosed for your information is a copy of the index of the above mentioned documents. Please let me know if you have any questions.

A handwritten signature in cursive script, appearing to read "A Tse".

Anthony Tse  
Rulemaking Section  
Regulation Development Branch  
Division of Regulatory Applications  
Office of Nuclear Regulatory Research

Enclosures:  
1. Index  
2. Copies of documents

cc (w/encl. 1):  
M. Lesar, ADM

9011190290 901108  
PDR PR  
30 55FR34513 PDR

## REGULATORY HISTORY FOR AN INTERIM FINAL RULE (10 CFR PARTS 30 AND 35)

AUTHORIZATION TO PREPARE RADIOPHARMACEUTICAL REAGENT KITS AND ELUTE  
RADIOPHARMACEUTICAL GENERATORS; USE OF RADIOPHARMACEUTICALS FOR THERAPY

DATE	FROM	TO	SUBJECT	PDR
03/09/90	BMorris	CPeck-CDER/FDA	Requesting Review and comment - Interim Final Rule (IFR) (Predecisional)	No
03/16/90	BMorris	Off. Dir.	Requesting Office concurrence	No
03/19/90	JLieberman	BMorris	Conc. and comment	No
03/19/90	PNorry	EBeckjord	Conc. and comment	No
03/19/90	HDenton	BMorris	Conc. and comment	No
03/19/90	RBernero	BMorris	Conc. (on conc. sheet)	No
03/19/90	STreby	BMorris	Conc. (on conc. sheet)	No
03/23/90	GMeyer-FDA	BMorris	Preliminary comments on IFR	No
05/18/90	CPeck-FDA	BMorris	Final comments on IFR	Yes
05/30/90	JTaylor	Commissioners	Interim Final Rule (SECY-90-193)	No
07/25/90	SChilk	JTaylor	SRM (Approved IFR with comments)	No
08/14/90	JTelford	MLesar	Transmitting revised FR notice	No
08/14/90	EBeckjord	JTaylor	Issuance of IFR	No
08/20/90	EBeckjord	Congr. Cmtees	Notification of Issuance of IFR	No
08/23/90	(FR notice published)		Interim Final Rule (55 FR 34513)	Yes
08/23/90	(Associated with IFR)		Regulatory analysis	Yes
08/23/90	(Associated with IFR)		Environmental assessment	Yes
08/23/90	(Associated with IFR)		Public announcement	Yes
09/05/90	ATse	LStevenson	Distribution of FR notice	No