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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 6, 1995

AD69-2

MEMORANDUM TO: Donald H. Lanham
Nuclear Document System (NUDOCS), Mail Stop P1-37
Office of Information Resource Management

FROM: Anthony N. Tse
Regulation Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

SUBJECT: INDEX AND DOCUMENTS FOR REGULATORY HISTORY FILE OF A FINAL RULE (10 CFR PARTS 30, 32, AND 35) ON MEDICAL USE OF BYPRODUCT MATERIAL

Attached are an index and the documents for regulatory history file of a final rule. This final rule, entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," was published on December 2, 1994 (59 FR 61767).

Each document that can be made available to the public document room is marked "PDR" in the upper right-hand corner of the front page. Documents that cannot be made available to the public are marked "CF" on the front page. As requested by M. Lesar of ADM in his memorandum dated December 7, 1994, documents marked "CF" are grouped after the documents marked "PDR."

If you have any questions, please call me at 415-6233.

Attachments:
1. Index
2. Documents

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

Attachment 1

Index

INDEX - REGULATORY HISTORY

Final Rule Entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use"

DATE	FROM	TO	SUBJECT
PDR			
07/09/93	ATse	DLanham	Letter to be placed in PDR
08/20/93	ATse	EJulian	A public comment letter to be docketed
01/07/94	PSmith	ATse	Forwarding documents on certification
03/21/94	JGlenn	PSmith	Requesting additional information
11/30/94	SBahadur	EJulian	Letters to be docketed
11/30/94	DRathbun	Congr Commtts	Forwarding final rule
11/30/94	(Associated with rule)		Public announcement
12/02/94	FR notice		Final rule (59 FR 61767)
12/02/94	(Associated with rule)		Regulatory analysis
12/02/94	(Associated with rule)		Environmental assessment
12/12/94	ATse	Petitioners	Forwarding final rule
CF			
03/21/94	CPaperiello	BMorris	Recognition of medical prof. boards
03/28/94	ATse	BShelton	Draft supporting statement
03/29/94	JGlenn	SBahadur	Recognition of ABOR in 10 CFR 35.900
04/14/94	CJHeltemes	Off Dirs	Off conc request-Commission paper
04/16/94	EJordan		Off conc (on conc sheet)
04/21/94	RBangart	CJHeltemes	Off conc
04/28/94	DMeyer	CJHeltemes	Off conc
04/29/94	JGray	CJHeltemes	Off conc
05/01/94	KStablein	SBahadur	Rule and guidance documents
05/02/94	GCranford	CJHeltemes	Off conc & comments on Paperwork Reduction Act statement
05/03/94	RBernero	CJHeltemes	Off conc
05/13/94	EHeumann	ATse	Comments on Comm paper on fees
05/20/94	GJackson	ATse	Additional comments on fees
09/07/94	CPaperiello	BMorris	Recognition of ABOR in 35.930
09/29/94	STreby		No legal objection (on conc sheet)
09/29/94	GCranford	OMB	Request for OMB review
09/30/94	EBackjord	JTaylor	Radiopharmacy final rule
10/20/94	MTaylor	Commissioners	SECY-94-261
10/26/94	Secretariat	Holders of SECY-94-261	Correction notice
11/03/94	PSantiago	ATse	Modification of 32.303 in SECY-94-261
11/15/94	SChilk	JTaylor	SRM on final rule
11/23/94	SBahadur	SWigginton	Forwarding final rule for publication
11/25/94	BStMary	MLesar	OMB approval
11/30/94	ATse	TStansbury	Printing and distribution of final rule
12/12/94	TStansbury	ATse	Mailing of final rule

Attachment 2

Documents

AD 69-2
PDR 002

JUL 9 1993

MEMORANDUM FOR: Donald H. Lanham
Document Control Desk
Nuclear Document System (NUDOCS)
Mail Stop P1-37
Office of Information Resources Management

FROM: Anthony N. Tse
Regu`ation Development Branch
Division of Regulatory Applications, RES

SUBJECT: LETTER TO BE PLACED IN PDR

Please transmit to the PDR the enclosed letter from Dr. Carol Marcus, dated March 8, 1993, pertaining to a proposed rule entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use." This proposed rule was published on June 17, 1993 (58 FR 33396). This letter should be place in the docket containing the proposed rule.

/S/

Anthony N. Tse
Regulation Development Branch
Division of Regulatory Applications, RES

Enclosure:
Letter

Distribution (w/o encl.):
Subj-chron-circ
RDB reading file
B. Morris
S. Bahadur
J. Telford
S. Jones
A. Tse (w/encl.)
L. Camper, NMSS

Concurrence:[rehhis tse] AT for Shah

Offc:	RDB:DRA AT	RDB:DRA	RDB:DRA
Name:	ATse	JTelford	SBahadur
Date:	7/9/93	7/9/93	7/9/93

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UCLA SCHOOL OF MEDICINE
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DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

March 8, 1993

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials, Safety, Safeguards
and Operation Support
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Thompson:

This letter is written as a member of the general public, and not as a member of NRC's Advisory Committee on Medical Uses of Isotopes.

I wish to comment on NRC's 2 Mar. 91 documents pertaining to Proposed Amendments on Preparation, Transfer, and Use of Byproduct Material for Medical Use, Secy-93-050. The documents are flawed and should not be published in their presently inaccurate state. Doing so would be dangerous to NRC, as it would appear from these documents that NRC is permitting hazardous behavior to go unchecked.

These documents refer to the ACNP/SNM Petition of June, 1989. However, the reason for the ACNP/SNM Petition was not, as stated by NRC, to "provide greater flexibility". The reason for the Petition was that NRC regulations and license conditions had become incompatible with State Medicine and Pharmacy Law, and were incompatible with the efficient and effective delivery of healthcare services by professional practitioners of nuclear medicine and nuclear pharmacy. These professionals were being forced by NRC to subject patients to unnecessary risks, unnecessary costs, and dangerous alternate procedures. In some cases, potentially life-saving therapy was being denied. Professionals were jeopardizing their ability to practice their profession in order to act in the best interests of their patients. NRC had loomed as a bigger danger to patients and professionals than the radioactive material being regulated. Clearly, this was a remarkable aberration of regulatory behavior that required immediate corrective action on NRC's part.

The rest of the Commission document is misleading in terms of what we "asked for", what the Immediately Effective Interim Final Rule "gives" us (actually, essentially nothing), and what this Proposed Rule "gives" us.

The most important failing in this document, and in the Federal Register notice as well, is that NRC completely missed the major point of the Petition. Once a physician is licensed to practice nuclear medicine, he must be free to use everything he knows or can learn to help his patient. The same is true for nuclear pharmacists. If NRC is licensing physicians who are really not capable of intelligently handling byproduct material and not intelligently directing and managing its uses, then NRC is guilty of criminal negligence, having not fulfilled its responsibility to the public. If NRC licenses a physician (or a pharmacist) and then restricts him from using his best judgment, he is essentially an "impaired physician", and his patients are at risk. Patients do not do well if their physician has had a "regulatory lobotomy".

If you do not understand this, let me try a military analogy. Let us assume that a group of Marines is undergoing basic training, and some of them miss a lot of target practice for some reason or other. Nevertheless, the platoon later lands on a hostile beach to fight an enemy. At the last minute, the platoon leader takes the guns away from the guys who missed target practice, but expects them to fight anyway. Now, the leader could presumably have required extra target practice and refused to let them join their platoon at that time. However, <u>once they hit the beach, they need a gun</u>. NRC is behaving like this foolish platoon leader.

The other, really malevolent thing about this document is that in deciding which nuclear physicians and which nuclear pharmacists will be permitted to practice their profession according to State Law, "NRC can consider an individual's character in addition to credentials in determining whether the individual should be approved as an authorized user or authorized nuclear pharmacist, such as verifying that the individual has not committed or caused others to commit any willful violations of the Commissions regulations". This is a "Catch-22". Every nuclear physician and nuclear pharmacist worth his salt has willfully violated NRC's regulations in order to provide appropriate services and patient care. <u>That is why we wrote the Petition</u>! Indeed, NRC is actually encouraging physicians to violate the Interim Final Rule by removing the recordkeeping requirement. I would argue that not a single legitimate package insert departure is permitted according to the dastardly definition in that Rule, which was never made available for public comment beforehand, and was not changed despite the requests of SNM and ACNP.

There are other problems with this Proposed Rule, such as the fact that a byproduct drug is presently going through FDA review

as a device, and the manufacturer will most likely be listed as a device manufacturer, not a drug manufacturer. Your Proposed Rule, which did not pay attention to the Petition, will cause a problem here. NRC also does not understand the Federal Policy for the Protection of Human Subjects, and I cannot concur with the concept of considering "human subjects" (for research purposes) as "patients". Separate laws and considerations apply to them. This is an inadvisable regulatory "convenience" that is a set-up for trouble with things like procedure manuals and the so-called "Quality Management" Program. There are problems with labeling, something NRC should avoid completely and leave in the competent hands of others such as FDA and Boards of Pharmacy. NRC is overly prescriptive with "time and date" of dose calibration. If NRC left it to professional judgment, it would be done right. Indeed, NRC has never shown that there was any need for a regulation here at all. When it comes to C-14, I do not care about the time, date, week, month, year, or decade. The nearest century will do just fine.

Some items in the Federal Register notice are not only wrong, but dangerous. The Petition never asked that we "compound radiopharmaceuticals whose manufacture and distribution are not regulated by the State or FDA". I can't think of anything not regulated by the State Board of Medicine, the State Board of Pharmacy, the State FDA, or the Federal FDA. The problem is that I believe this document is a "set up". I'll bet it is already in the hands of the Cleveland Plain Dealer, all ready for an "expose" as ugly as the last. However, you will have no defense, because your defense is that you made untrue statements in the Federal Register, and you can never admit to that.

Think about the following facts. Why did an NRC informer lie to the Plain Dealer about the writing of this Petition? Why is one of the reporters bragging that he has an uncensored version of the I-G report on McElroy and this Petition? (This is a security violation that calls for an FBI investigation). This Petition had nothing to do with the Plain Dealer articles. Yet. The reporter argues that he has nothing against medicine, but is presenting the views of an employee of NRC who feels that NRC is dangerously lax. Then, NRC publishes material suggesting that NRC is perfectly happy to let physicians and pharmacists do dangerous things. The connection is obvious. I'll bet the Plain Dealer even has old FDA letters relating to the Interim Final Rule and Syncor's lawsuit. This is going to be very unfortunate. Print this material in the Federal Register, and the Rule is going to become politically difficult to sustain.

Therefore, I urge you most strongly to cancel publication of this material. Please correct it, and think of it as a press release to the Plain Dealer as you do so.

Sincerely,

Carol Marcus

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

CSM:sfd