The University of Oklahoma
Oklahoma City Campus-Health Sciences Center

DEPARTMENT OF RADIOLOGICAL SCIENCES
College of Medicine

May 5, 1989

Dr. Dale A. Powers
U. S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, Texas 76011

Dear Dr. Powers:

With reference to our institutional NRC license No: 35-03176-04MD and your recent audit of the operations of our Nuclear Pharmacy and your recent directive, I write to state the following.

This directive was conveyed to me by Mr. Wesley L. Holley on May 3, 1989 at 2:45 p.m. and later reviewed by telephone conversation. This involves the O.U.H.S.C. operation of manufacturing/compounding of I-131 capsules for human use. I summarize below the action taken on all aspects specified by you.

1. O.U.H.S.C. Nuclear Pharmacy has stopped making these capsules.

2. I have taken possession of the capsules existing with the O.U.H.S.C. Nuclear Pharmacy. Attachment "A" provides the listing of each batch, number of capsules and the total activity (mCi) of the capsules in the batch. These capsules have been transferred to O.U.H.S.C. waste license and will be held for decay and disposed of according to our license.

3. The Nuclear Pharmacy personnel or I have informed all the hospitals who were provided these type of capsules since May 1, 1989, They have been directed to suspend the use of these capsules. They have returned unused capsules to me. This material was supplied to the following hospitals during May 1, 1989 to May 3, 1989.

   A. Grady Memorial Hospital, 2220 Iowa, Chickasha; Oklahoma.

      Six capsules were supplied on 5/3/89.
      Returned 4 capsules. These are listed in Item B, Attachment "B".

DmB IE-07

Post Office Box 26901 Oklahoma Memorial Hospital, Room 35X Oklahoma City, Oklahoma 73190 AC (405) 271-5125

89-953

B. Shawnee Medical Center, 1102 W. MacArther, Shawnee, Oklahoma.

Three capsules were supplied on 5/1/89.
Returned three capsules; 2 capsules from 5/1/89 supply and one from previous week.
These are listed in Items A and C in Attachment "B".

These capsules will be disposed of with other capsules as detailed above.

4. The computer of the O.U.H.S.C. Nuclear Pharmacy has been blocked, i.e. these capsules do not exist in the dispensing inventory. So that dispensing of these capsules can not be performed.

I shall report to you about the 2nd phase of directives by May 10, 1989.

Please feel free to contact me if any other information is required.

Sincerely yours,

B. Wally Ahluwalia

B. Wally Ahluwalia, Ph.D.
Director
Office of Radiation Safety
Diplomate ABR and ABSNM

BA/db
attachment
xc: Clayton Rich, M.D.
Provost

Victor Yanchick, Ph.D.
Dean, College of Pharmacy

Stanley L. Mills, Ph.D.
Director, Nuclear Pharmacy

William H. Knisely, Ph.D.
Associate Dean, Research Affairs

Tom Godkins
Assistant to the Provost

ATTACHMENT "A"

I-131 CAPS

QC	# Pills	Activity (mCi)
19NP42889	13	1.118 mCi
14NP41489	13	.320
14NP41489	5	.124
17NP33189	7	.054
5NP40889	6	.079
6NP32689	4	.016
19NP31789	12	.027
~~[illegible]~~ 21NP42189	12	.541
	Total 72 Capsules	Total = 2.279 mCi

Received inventory of I-131 Capsules from OU. Per NRC Directive. Nuclear ~~Shipment~~ dated May 3, ~~1988~~, ~~3:20~~ PM.

B. Ahluwalia

5-3-89

ATTACHMENT "B"

A

Received from Nuclear Pharmacy
I-131 Capsules

Lot # 21NP41989

Returned form Examinee Med Center Shawnee

Total Activity 0.038 mCi

Quantity 1

Date 5-5-89

by [signature] 5/5/89 3/30 PM.
Radiation Safety Office

B

Received from Nuclear Pharmacy
I-131 Capsules

Lot # 5NP4089

Returned form Grady Mem. Chickasha

Total Activity 0.045 mCi

Quantity 4

Date 5-5-89

by [signature] 5/5/89 3 30 PM.
Radiation Safety Office

C

Returned Form Shawnee Med Center Shawnee

Received from Nuclear Pharmacy
I-131 Capsules

Lot # 19NP42889

Total Activity 0.111 mCi

Quantity 2

Date 5-5-89

by [signature] 5/5/89 3 30 PM.
Radiation Safety Office

NMSB

MAY - 4 1989

In Reply Refer To:
Docket: 30-12750/CAL 89-15
License: 35-03176-04MD

The University of Oklahoma
Health Sciences Center
ATTN: Dr. B. Ahluwalia
Radiation Safety Officer
P O. Box 26901
1110 North Stonewall
Oklahoma City, Oklahoma 73190

Gentlemen:

SUBJECT: CONFIRMATION OF ACTION LETTER

In an inspection conducted by Ms. L. L. Kasner and Messrs. D. A. Powers, W. L. Holley, and S. Moore, on May 2, 1989, several apparent violations of NRC regulations were identified regarding the distribution of radiopharmaceuticals and the related radiation safety program for your nuclear pharmacy. These inspection findings will be documented and formally provided to you in an inspection report on a future date. However, one of the apparent violations pertains to the manufacture and distribution of iodine-131 capsules for medical use to hospitals and clinics. This is a significant safety concern to NRC inasmuch as your license does not authorize you to manufacture or otherwise prepare and dispense radiopharmaceuticals for human use that are not the subject of an FDA-approved "New Drug Application (NDA)" or "Notice of Claimed Investigational Exemption for New Drug (IND)."

The purpose of this letter is to confirm your commitments, as initially discussed with Mr. Holley and in subsequent conversation with Mr. A. Bill Beach, Dr. Dale Powers, and Ms. Linda Kasner on May 3, 1989, to address NRC's concern related to the manufacture and distribution of such capsules. Based on these conversations, it is my understanding that Oklahoma University Health Sciences Center is taking the following actions:

1. Immediately cease manufacturing and distribution of non-IND/NDA iodine-131 capsules.

2. By close of business (COB) May 3, 1989, secure or otherwise prevent further distribution of all non-IND/NDA radioiodine capsules in possession.

bcc: (see next page)

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

AI 89-126

*RIV:	*C:NMIS	*C:NMSB	*EO
LLKasner/ch	DAPowers	WLFisher	GFSanborn
/ /89	/ /89	/ /89	/ /89

*D:DRSS	RA
ABBeach	RDMartin
/ /89	/ /89

*Previously Concurred

IE07

9005170062
5pp.

3. By COB May 3, 1989, block, in the pharmacy computer system, the authorization for the dispensing of all non-IND/NDA radioiodine capsules.

4. As expeditiously as possible, but no later than COB May 4, 1989, contact all customers who have received non-IND/NDA radioiodine capsules and request that scheduled administrations of such material be cancelled and that unused capsules be made available for return to the pharmacy.

5. By COB May 8, 1989, collect all unused non-IND/NDA radioiodine capsules from customers and secure such material in the nuclear pharmacy.

6. Contact NRC Region IV by COB May 8, 1989, and report the status of the above-described actions.

7. Provide by COB May 12, 1989, the following information on the non-IND/NDA radioiodine to the Food and Drug Administration (NRC will provide you with a specific address by telephone) with a copy to NRC Region IV:

   A. The supplier.

   B. The manufacturer's product specifications; e.g., pH, specific activity, radionuclide purity.

   C. The quality control measures used by the Health Sciences Center in manufacturing the capsules.

   D. The procedures used by the Health Sciences Center for determining dosage in terms of activity.

   E. A statement as to whether the capsules were dispensed per written physician prescription and if so describe the prescriptions.

Issuance of this Confirmation of Action Letter does not preclude the issuance of an order formalizing the above commitments or requiring other actions on the part of Oklahoma University Health Sciences Center; nor does it preclude NRC from taking other enforcement action for the violations of NRC requirements that have prompted the issuance of this letter. If your understanding differs from that set forth above, please call Dr. Dale A. Powers at (817) 860-8195 immediately.

Sincerely,

Original Signed By

Robert D. Martin
Regional Administrator

cc:
Oklahoma Radiation Control Program Director

bcc: (see next page)

bcc:
DMB - IE-07
J. L. Lieberman, D/OE
H. L. Thompson, DEDS
J. H. Austin, AC/MACUS
R. D. Martin, RA
R. E. Hall
D. A. Powers
G. F. Sanborn
NMIS Inspectors (5)
RIV Files
J. M. Taylor, DEDR
L. J. Chandler, Asst. GC/OGC
R. M. Bernero, D/NMSS
B. Summers, OE
A. B. Beach, D/DRSS
W. L. Fisher
C. L. Cain
J. Carson, RA Sect'y
NMSB