

JUN 15 1989

In Reply Refer To:  
License: 35-03176-04MD  
Docket: 30-12750/89-01 and 89-02  
EA: 89-128

The University of Oklahoma Health  
Sciences Center  
ATTN: Clayton Rich, M.D.  
Provost Marshall  
P.O. Box 26901  
Oklahoma City, Oklahoma 73190

Gentlemen:

This refers to the special, unannounced radiation safety inspection conducted by Ms. L. L. Kasner and Messrs. D. A. Powers, W. L. Holley, and S. W. Moore on May 2, 1989, of the activities authorized by NRC Byproduct Material License 35-03176-04MD and to the discussion of our findings held by the inspectors with you and other members of your staff on May 3, 1989. The enclosed NRC Inspection Report 30-12750/89-02 documents this inspection. This letter also concerns an unannounced, special NRC inspection conducted at Edmond Memorial Hospital on March 8, 1989, referred to as NRC Inspection 30-12750/89-01.

The inspections were an examination of the activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, and observations by the NRC inspectors.

The NRC inspection identified a significant weakness in the management of your radiation safety program, in that your organization, including the Nuclear Pharmacy Director, Radiation Safety Officer, and Radiation Safety Committee, did not recognize the noncompliance aspect of manufacturing iodine-131 capsules and dispensing/distributing iodine-131 not intended for human use. Also of significant concern is that three of your hot lab hoods were not functioning properly, were inadequately maintained, and did not exhaust through charcoal filters. This becomes a safety issue because one of these hoods was used for the compounding of the highly volatile radioiodine. We feel the results of this inspection are very important, inasmuch as you are training future nuclear pharmacists in conjunction with the College of Pharmacy and no doubt your actions will affect their work habits and philosophy.

We are releasing this report at this time for your information. You will be notified by separate correspondence of our decision regarding enforcement action based on the findings of this inspection. No written response to this report is required at this time; however, you may provide a response at this time, in particular if you wish to describe any corrective actions taken.

*RIV:NMIS	*NMIS	*NMSS	*C:NMIS	*C:NMLS	*C:NMSB
WHLolley:jt	LLKasner	SMoore	CLCain	DAPowers	WLFisher
/ /89	/ /89	/ /89	/ /89	/ /89	/ /89
*EO	<i>[Signature]</i>				
GFSanborn	D:DRSS				
/ /89	ABBeach				
	6/6/89				

\*Previously Concurred

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This letter also confirms the June 15, 1989, telephone conversation between C. L. Cain and Tom Godkin of your organization concerning NRC's request to conduct an enforcement conference concerning these issues. The date agreed upon was June 26, 1989, at 1 p.m. for this enforcement conference in our Arlington office. As discussed with Mr. Godkin, we have received your letters dated May 5, 11, 16, and 22, 1989, that were submitted in response to our Confirmation of Action Letter dated May 4, 1989. During the enforcement conference, you should be prepared to address those specific items referenced in the NRC inspection report as well as your plans to prevent further occurrence of similar incidents. Also during the enforcement conference, we will discuss the effectiveness of the radiation safety officer and committee functions.

The attached Notice of Violation lists violations of lesser significance that were identified by the NRC inspectors. These violations were identified during inspections and observations at Edmond Memorial Hospital and your nuclear pharmacy. NRC has categorized these violations at Severity Level IV. However, the violations indicate a need for improvements in the area of transportation of licensed material. Consequently, you are required to respond to this matter, in writing, in accordance with the provisions of Section 2.201 of the NRC "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter. Please note that the apparent violations discussed in the NRC Inspection Report 30-12750/89-02 are not included in the enclosed Notice of Violation.

The response directed by this letter and accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning these inspections, we will be pleased to discuss them with you.

Sincerely,  
*Original Signed By:*

R. E. HALL

*for*

A. B. Beach, Director  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection Report  
30-12750/89-02
3. Appendix C - Proposed Enforcement Conference Agenda

cc w/enclosures:

Oklahoma Radiation Control Program Director

bcc: (see next page)

bcc:

DMB - Original (IE-07)

RD Martin

AB Beach

RE Hall

WL Fisher

LShea, RM/ALF (AR-2015)

DA Powers

GF Sanborn

J Lieberman

DB Howe, NMSS

\*CL Cain

\*WL Holley

\*LL Kasner

\*NMSB

\*MIS System

\*RIV Files (2)

\*RSTS Operator

\*SMoore, NMSS

\*w/766