

HUGH H. ALTICK  
ROBERT B. BRUMBAUGH  
ROBERT K. CORWIN  
FRANCIS S. McDANIEL  
RONALD H. McDONNELL, JR.  
JAMES R. GOULD  
ROBERT N. FAROUHAR  
MARSHALL D. RUCHMAN  
ARTHUR A. AMES  
STEPHEN M. PFARRER  
BRIAN D. WEAVER  
CHARLES A. LOWMAN, III  
R. PAUL PERKINS, JR.  
DAVID E. BEITZEL  
GAIL S. YOUNG

ALTICK & CORWIN  
ATTORNEYS AT LAW  
1300 TALBOTT TOWER  
DAYTON, OHIO 45402

Designated Original  
E. J. Hancock 12/18/81  
TELEPHONE 223-1201  
AREA CODE 513

EA-81-48  
Rec'd 7/31/81  
w/ \$1,000 check

July 30, 1981

LIC: 34-66904-01

United States Nuclear  
Regulatory Commission  
Office of Inspection and  
Enforcement  
Washington, D.C., 20555

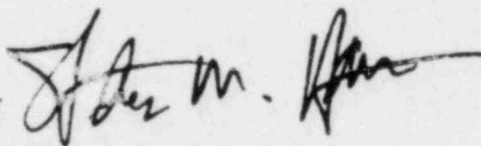
ATTENTION: Mr. Victor Stello, Jr., Director

Dear Gentlemen:

We are enclosing a copy of our Response to the  
Notice of Violation issued to Grandview Hospital on June  
1, 1981, and a copy of our Appeal of said Notice of  
Violation. We are sending copies of these documents to  
Region III as well.

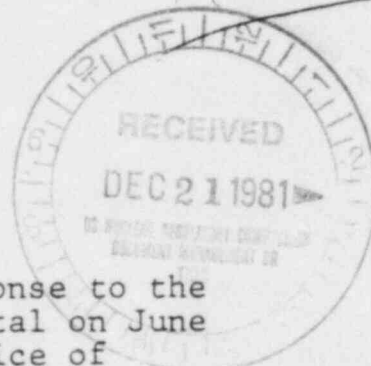
Please consider these documents confidential  
and not to be disclosed. If you have any questions con-  
cerning our Response or our Appeal, please do not hesitate  
to call.

Very truly yours,

By 

SMP:gcw  
Enclosures

8112220210 811730  
NMS LIC30  
34-06904-01 PDR



IE14  
1/1  
Delete: BC  
PM  
Add: nm62

BEFORE THE UNITED STATES NUCLEAR REGULATORY COMMISSION

IN RE: \* License Number: 34-06904-01  
\*  
THE NOTICE OF VIOLATION \*  
JUNE 1, 1981, \*  
DAYTON OSTEOPATHIC HOSPITAL \*  
DBA GRANDVIEW HOSPITAL \*  
405 West Grand Avenue \* RESPONSE TO NOTICE  
Dayton, Ohio 45405, \* OF VIOLATION  
\*  
Licensee \*

\* \* \* \* \*

Now comes Licensee, Dayton Osteopathic Hospital, DBA Grandview Hospital, and submits the following as its response to the Notice of Violation of June 1, 1981:

I. Appendix, I(A)(1): Performance 183 Procedures through an Unauthorized Route of Administration.

A. Admission: Licensee admits noncompliance with 10 CFR 35.14(b)(6) in failing to follow clinical procedures as specified in product labeling when administering radiopharmaceuticals.

B. Reason for Noncompliance: Licensee's contracted physicians failed to comply with the above regulation due to a misinterpretation of proposed NRC regulations (and comments to those proposals) which they believed granted them the discretion to alter the route of administration of the radiopharmaceutical.

C. Corrective Action Taken: The CAPP studies were immediately discontinued once Licensee determined that noncompliance had occurred. No further studies have been performed, and no studies will be performed until Licensee receives approval of an Investigational Exemption for a New Drug (IND) application from the United States Food and Drug Administration.

D. Corrective Action to be Taken: Licensee's medical staff has been instructed that any future requests to change procedures for studies involving radioactive materials must first be submitted to the Medical Isotopes Committee for approval.

ALTICK & CORWIN

E. Date of Full Compliance: September, 1980.

II. Appendix A, I(A)(2): Performance of Four Procedures by an Unauthorized Route of Administration.

A. Admission: See I(A) above.

B. Reason for Noncompliance: See I(A) above.

C. Corrective Action Taken: See I(A) above.

D. Corrective Action to be Taken: See I(A) above.

E. Date of Full Compliance: September, 1980.

III. Appendix A, II(B): Use of Licensed Material by an Individual Not Named on the License.

A. Denial: This "infraction" has been appealed.

IV. Appendix A, II(C): Failure of Attending Personnel to Wear Gloves When Caring for Patient Treated with Radiopharmaceuticals.

A. Denial: This "infraction" has been appealed.

V. Appendix A, II(C)(2): Failure of Licensee to Survey Incoming Packages of Radiopharmaceuticals.

A. Admission: Licensee admits noncompliance with License Condition #18 in failing to survey incoming packages of radiopharmaceuticals.

B. Reason for Noncompliance: Licensee changed its method of purchasing radiopharmaceuticals to a unit dose method of purchasing instead of purchases in bulk. At that time governing regulations were misinterpreted so as to cause the Licensee's employee to believe that surveys would no longer be necessary.

C. Corrective Action Taken: All packages of radiopharmaceuticals are now monitored and the results are properly recorded. (See License Item 14, Appendix F.)

D. Corrective Action to be Taken: Before any future changes are attempted in licensed procedures, all license

ALTICK & CORWIN

conditions and regulations will be thoroughly reviewed.

E. Date of Full Compliance: November, 1980.

VI. Appendix A, II(C)(3): Failure of Medical Isotopes Committee to Meet at Least Once Quarterly.

A. Admission: The Licensee admits noncompliance with License Condition 18 in failing to conduct quarterly meetings of the Medical Isotopes Committee.

B. Reason for Noncompliance: The significance and necessity of having regular quarterly meetings was not fully understood, thus making it difficult to obtain participants for these meetings.

C. Corrective Action Taken: Committee members have been informed that meetings will take place on a regularly scheduled basis. Their attendance will be required.

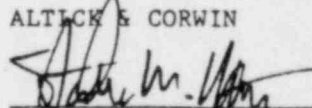
D. Corrective Action to be Taken: Licensee's administrative staff has assumed a significant role in the functions of the Committee, which includes shared responsibility with the Radiation Safety Officer for scheduling Committee meetings. Additionally, Licensee's administrative Director of Medical Affairs has been appointed Chairman of the Medical Isotopes Committee.

E. Date of Full Compliance: January, 1980.

Licensee hereby submits payment for the civil penalty of Five Hundred Dollars (\$500.00) assessed pursuant to Appendix A, I(A)(1) and Five Hundred Dollars (\$500.00) for the civil penalty assessed pursuant to Appendix A, I(A)(2). No civil penalties were assessed for other "infractions."

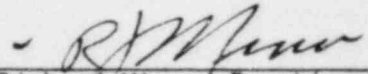
Respectfully Submitted,

ALTICK & CORWIN

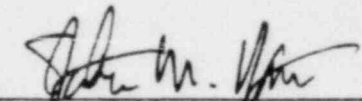
  
\_\_\_\_\_  
Stephen M. Pfarrer

ALTICK & CORWIN  
1300 Talbott Tower  
Dayton, Ohio 45402  
Telephone 513/223-1201

As a duly authorized representative of the Licensee, I hereby state and swear that, to the best of my knowledge, the information contained in this document is true and correct.

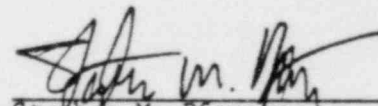
  
Richard Minor, President  
Grandview Hospital

Subscribed and sworn before me this 130 day of July, 1981.

  
Notary Public  
STEPHEN M. PFARRER, Attorney at Law  
NOTARY PUBLIC, STATE of OHIO  
My commission has no expiration  
Date 147.03 ORC

CERTIFICATE

I hereby certify that a copy of the above was mailed to the United States Nuclear Regulatory Commission, Washington, D. C. 20555, by certified U. S. mail this 30 day of July, 1981.

  
Stephen M. Pfarrer  
ALTICK & CORWIN  
1300 Talbott Tower  
Dayton, Ohio 45402  
Telephone 513/223-1201