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MAR 10 1994

University of Cincinnati
ATTN: Donald Harrison, M.D.
Senior Vice President and Provost
for Health Affairs
141 Health Professions Building
Mail Location 663
Cincinnati, OH 45267-0663

License No. 34-06903-05
License No. 34-06903-09
License No. 34-06903-11
License No. 34-06903-13
License No. SUD-265
License No. SNM-490
EA 94-039

Dear Dr. Harrison:

SUBJECT: NRC INSPECTION REPORTS NO. 030-02764/94001(DRSS);
NO. 030-11334/94001(DRSS); NO. 030-18949/94001(DRSS);
NO. 030-20526/94001(DRSS); NO. 040-02678/94001(DRSS);
NO. 070-00539/94001(DRSS)

This refers to a special, announced safety inspection conducted by Mr. Kevin Null and Ms. Teye Simmons of this office on January 16-17, 1994, in response to a reported misadministration involving a leaking iodine-125 source. This also refers to the routine, announced safety inspection conducted by Messrs. James L. Cameron, Robert G. Gattone, and Kevin Null of this office on February 7 through 11, 1994, of activities authorized by NRC Material Licenses No. 34-06903-05, No. 34-06903-09, No. 34-06903-11, No. 34-06903-13, No. SUD-265, and No. SNM-490. At the conclusion of the inspections, the preliminary findings were discussed with Ms. Victoria Morris, Mr. C. Kupferberg and other members of your organization, as described in the enclosed inspection report.

Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel. With regard to NRC Material License No. 34-06903-05, the inspection included reviews of your organization's notifications on October 6, 1993 of a lost strontium-90 eye applicator; on December 13, 1993 of a leaking nickel-63 sealed source; and on January 14, 1994 of a medical misadministration involving a ruptured iodine-125 implant seed. As you are aware, the NRC contracted a medical consultant, Melvin Griem, M.D., to evaluate the medical significance of the misadministration. The results of Dr. Griem's evaluation is described in an attachment to the enclosed report.

Based on the results of the inspections, several apparent violations and concerns with regard to NRC Material Licenses No. 34-06903-05 (Broad Scope) and No. 34-06903-13 (Teletherapy-type Irradiator) were identified. No apparent violations were identified for NRC Material Licenses No. 34-06903-09 (Pool Irradiator), No. 34-06903-11 (Self-contained Irradiator); No. SUD-265 (Subcritical Assembly); and No. SNM-490 (Sealed Neutron Sources). One of the apparent violations identified for your Broad Scope License is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement

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Policy), 10 CFR Part 2, Appendix C. The apparent violation consists of your failure to secure licensed material stored in an unrestricted area from unauthorized removal from the place of storage. Each of the identified apparent violations is described in the enclosed report. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of the apparent violations described in the enclosed report may change as a result of further NRC review.

An enforcement conference to discuss these apparent violations and concerns has been scheduled for March 16, 1994, at 10:00 a.m. (CST) via telephone. The purposes of this conference are to discuss the apparent violations and concerns, their root causes, and safety significance; to provide you the opportunity to point out any errors in our inspection report; to provide an opportunity for you to present your proposed corrective actions; and to discuss any other information that will help us determine the appropriate enforcement action in accordance with the Enforcement Policy.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed By Roy J. Caniano

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosure: Inspection Reports

- No. 030-02764/94001(DRSS);
- No. 030-11334/94001(DRSS);
- No. 030-18949/94001(DRSS);
- No. 030-20526/94001(DRSS);
- No. 040-02678/94001(DRSS);
- No. 070-00539/94001(DRSS)

See Attached Distribution

<u>Yes</u> RIII Cameron/dsc 03/11/94	<u>Yes</u> RIII Gattone 3/14/94	<u>Yes</u> RIII Null 3/10/94	<u>Yes</u> RIII Simmons 3/10/94	<u>Yes</u> RIII Holt 3/10/94	<u>Yes</u> RIII Caniano 3/10/94	<u>Yes</u> RIII DeFayette 3/10/94	<u>Yes</u> RIII Axelson 3/10/94
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MAR 10 1994

Distribution

cc w/enclosure:

1. University of Cincinnati
ATTN: Victoria Morris, RSO
Radiation Safety Office
234 Goodman Street, M. L. 591
Cincinnati, OH 45267-0591
2. The Barrett Cancer Center
ATTN: Robert E. Albright, M.D.
Referring Physician
234 Goodman St.
Cincinnati, OH 45267-0501

bcc w/enclosure:

Melvin L. Griem, M.D.
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS
D. Serig, Ph.D., NMSS
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