



Spectrum Health

Downtown Campus

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June 30, 1998

Robert G. Gattone, Jr.
Radiation Specialist
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Docket No. 030-01989
License No. 21-00243-06

SUBJECT: RESPONSE TO NRC VIOLATION OF FAILURE TO PERFORM
BIOASSAYS

1. The reason for the violation was stated as bioassays not being done on March 12, April 17, and May 22, 1998. The March 12 and April 17, 1998, bioassays were later found. They were filed in different places. I have enclosed the documentation for your review. The written directive date is different from the actual administration of the therapy. The May 22, 1998, bioassay was not performed due to a long holiday weekend.
2. Corrective steps taken include: a) in-service to staff stating that bioassays have to be done within a 72 hour period from time of dosing - no exceptions; and b) new filing system implemented to include written directive and hardcopy bioassay kept together in one place.

Results achieved: a) clear specific place for documentation; and b) technologist affirm that bioassays have to be done within a 72 hour period after dosing inpatient therapy over 33mCi.

3. Corrective steps taken to avoid further violations: a) one specific location for bioassay and written directive filed together; b) any new employee will be given in-service to ensure compliance; and c) log board will be put in hot lab and dosing tech will put initials and date of dosing to help remind that bioassay needs to be done.

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Robert G. Gattone, Jr.

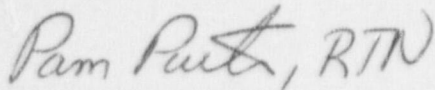
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4. Full compliance achieved: a) the filing system is in place as of June 24, 1998; b) the technologists have been in-serviced as of June 19, 1998; and c) we have not done an inpatient therapy since the visit on June 16-17, 1998, but we will be in compliance when the next therapy is done.

If I can be of any further assistance to clarify this violation, please do not hesitate to contact me at (616) 391-1637.

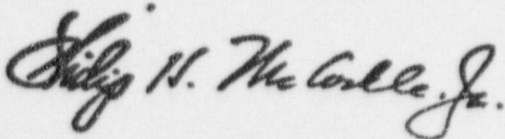
Sincerely,



Pam Puite, RTN

Manager Nuclear Medicine

Butterworth Hospital / Spectrum Health - Downtown Campus



Philip H. McCorkle, Jr.

Chief Executive Officer

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Tom Vitalis, RSO

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