

BARNES
ST. PETERS HOSPITAL

10 Hospital Drive
St. Peters, Missouri 63376
Phone: 314/441-6500

5017414

September 15, 1994

John B. Martin
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: NRC License #24-18968-01
Demand for Information

Dear Mr. Martin:

This letter is in response to your *Demand for Information* request concerning activities and actions taken on the reported incident of December 1992 at Barnes St. Peters Hospital. We have included responses to all of the questions requested from your letter dated August 19, 1994. The following answers are being provided to you to the best of our ability.

- A. Identify when, notwithstanding being notified on December 7, 1992, the Radiation Safety Officer (RSO) and management team became aware of the activities and methods used to identify the apparent violations. Your response should also address:
1. If notification did not occur until December 7, 1992, an explanation why the Radiation Safety Officer (RSO) and management were not aware of the activities and methods used to identify the apparent violations prior to December 7, 1992.
 2. If management was aware of the activities and methods being used, identify who authorized the activities, specify what was authorized, and how long the authorization lasted.

The Charge Nuclear Medicine Technologist notified the Manager of Radiology on December 7, 1992 of improprieties occurring within the Nuclear Medicine Department. The manager immediately contacted the

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Radiation Safety Officer (RSO) and the Assistant Administrator. On December 8, 1992, a special Radiation Safety Committee meeting was convened to review the allegations. Upper management was not aware of any investigation until the data was presented to them on December 7, 1992. The Charge Nuclear Medicine Technologist began his investigation on November 8, 1992 without any upper management knowledge. The Charge Nuclear Medicine Technologist notified the Radiology Chief Technologist on November 25, 1992 and a Staff Radiologist who is an authorized user on December 1, 1992 who both assisted him with his observations. Upon further interview with the Charge Nuclear Medicine Technologist, it was discovered that he had notified the Radiology Chief Technologist of his suspicions a few weeks earlier at which time no communication was made to upper management. The Charge Nuclear Medicine Technologist chose not to reveal the final results of his suspicions to upper management until December 7, 1992 when he was able to confirm his impressions. His delay in notifying upper management was intentional. He was deliberate in his methodology due to the nature of the allegations so as not to falsely accuse a co-worker of such a serious offense. His activities and methods utilized were not authorized by Administration or the Radiation Safety Officer (RSO). Please keep in mind that the improprieties being taken by the Junior Nuclear Medicine Technologist were difficult to detect even after documented evidence was presented.

- B. An explanation of whether the potential health and safety impacts of the activities were considered in advance, who was involved in the considerations, and what conclusions were reached. Your response should also address:
1. A determination of how long batteries were actually removed from the survey instrument and how long the dead batteries were placed and remained inside the survey instrument.
 2. A determination of what precautions were taken to make sure an appropriate, operable survey meter was available and the required surveys were conducted.
 3. A determination of whether dose calibrator settings were altered, how much they were altered, and how long this status existed.

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4. An explanation of how patient doses were verified during the period when the dose calibrator settings were changed.

To the best of our knowledge, the Charge Nuclear Medicine Technologist has acted consistently with patient care and safety requirements. He did consider the potential health and safety impacts of his activities as evidenced in the following paragraphs. In review of the incident, we believe that no compromise was made to patient care, and that the safety of both the patients and the general public was not jeopardized during this observation period.

There was a total of three occurrences in which the batteries were removed or replaced with dead batteries. These occurred at the end of the working day after the completion of patient testing. The batteries were replaced in the survey instrument before the beginning of the next scheduled work day by the Charge Nuclear Medical Technologist. Area surveys were conducted by the Charge Nuclear Medicine Technologist at the beginning of each work day and no contamination was noted. Double records were kept by the Charge Nuclear Medicine Technologist that show the surveys were done and were within normal limits.

A total of three GM meters were available to the Junior Nuclear Medicine Technologist during the observation period. All three GM meters were kept in the Nuclear Medicine Department. Only one GM meter was impaired. However, it should be noted that two other GM meters were accessible and in good operating condition, and there was also an ample supply of replacement batteries available in the drawer of the Hot Lab located within the Nuclear Medicine Department.

The actual dose calibrator used at Barnes St. Peters Hospital has factory pre-set settings and cannot be altered. The setting to check the Cesium source was set on 225 by the Charge Nuclear Medicine Technologist and should have been changed to 220 for Cesium and 624 for Barium during the conduction of the test by the Junior Nuclear Medicine Technologist. If the Junior Nuclear

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Medicine Technologist had performed the required procedures, the settings should be changed. If the Junior Nuclear Medicine Technologist did not change the settings, the results of the test should still have been within a plus or minus 5% variation which is within the condition of our license. The dose calibrator setting was set on 225 for three days. One day of the three, the constancy of the dose calibrator was re-checked by the Charge Nuclear Medicine Technologist.

All radiopharmaceuticals are provided to Barnes St. Peters Hospital by the Syncor Corporation in unit dose form. Each patient dose is specific per physician order, is assayed by Syncor, and shipped to Barnes St. Peters Hospital with a prescription slip yielding an assay value. When compared to doses dispensed on the questioned days, the actual amount dispensed is concurrent with the values provided by Syncor. A dose review of all patients who received radiopharmaceuticals between November 23 - November 29, 1992 showed no deviation from the prescribed procedure and validated appropriate test results. Therefore, it is our conclusion that all patients received the correct radiopharmaceuticals and that no misadministrations occurred.

- C. If prior authorization was not provided, please identify who acted without authorization and what action the licensee has taken, if any, to assure that such contact does not recur.

The Charge Nuclear Medicine Technologist initiated the investigation without authorization from upper management as explained in question A. Since this incident, the chain of command has been changed so that all Nuclear Medicine technologists report directly to the Radiology Manager. The Charge Nuclear Medicine Technologist has been instructed on the revised chain of command, and the importance of immediate notification of any untoward activities, and has expressed an understanding of these requirements and willingness to fully comply. The Radiology Chief Technologist position has since been eliminated, and it should be noted that

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the Chief Radiology Technologist involved in this incident is no longer employed at Barnes St. Peters Hospital. The Junior Nuclear Medicine Technologist employed since the incident has been inserviced personally by the Radiology Manager on expectations of communication and proper protocol of Nuclear Regulatory Commission regulations, and has expressed an understanding of these requirements and willingness to fully comply.

- D. Provide those actions you have taken or plan to take to ensure that management and the RSO are consulted prior to taking actions that place the Licensee in potential noncompliance.

The chain of command reporting mechanism has been changed so that the Nuclear Medicine staff report directly to the department manager which promotes a continuous dialogue between them.

Both the Charge Nuclear Medicine Technologist and the Junior Nuclear Medicine Technologist have been personally counseled by the Radiology Manager on expectations of communication of any and all suspected Nuclear Regulatory Commission concerns or violations. This communication occurred with the Charge Nuclear Medicine Technologist after discovery of the initial incident, upon hire of the new Junior Nuclear Medicine Technologist, and was reiterated to both in August of 1994. This personal communication of expectations will be continued with all new employees of the Nuclear Medicine Department, and will be discussed at annual evaluation time.

Effective May 1994, biweekly charge technologist/management meetings were instituted to assure continuous flow of communication. The Radiation Safety Officer (RSO) also attends these meetings.

The Charge Nuclear Medicine Technologist has always been an active participant of the Radiation Safety Committee. The Junior Nuclear Medicine Technologist has become an active guest of the Radiation Safety Committee to ensure her understanding of the importance of radiation safety.

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The Hospital Administrator has sanctioned all of the above actions, and Administration continues to be informed of Nuclear Medicine activities by department management.

- E. Provide those actions you have taken or plan to take to ensure that Licensee management and the RSO are actively involved in the oversight of licensed activities, identification and correction of potential noncompliances. This response should indicate what training has been or is being given to your employees to assure that they understand the importance of properly performing surveys and using the dose calibrator to measure patient doses.

Both management and the Radiation Safety Officer (RSO) have taken a more pro-active involvement in the Nuclear Medicine Department activities, which includes:

- daily rounds by management;
- bi-weekly charge technologist meetings with both management and the Radiation Safety Officer (RSO);
- expanded orientation of new Junior Nuclear Medicine Technologist which entails extensive competency verification, including dose calibrator to measure patient doses;
- continuation of annual licensure status verification;
- random unannounced review of Nuclear Medicine records by the Radiology Manager;
- routine surveillance and consultation of Nuclear Medicine program by our medical physicist;
- bi-weekly Radiology management meetings (membership consists of Radiation Safety Officer (RSO), Hospital Assistant Administrator, and Radiology Manager);

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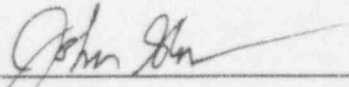
- revision of Nuclear Medicine job descriptions to include specific job duties which have been reviewed by both the Charge Nuclear Medicine Technologist and the Junior Nuclear Medicine Technologist in July of 1994;
- installation of the Syncor Unit Dose Management Computerized Tracking System on March 22, 1993. Both the Charge Nuclear Medicine Technologist and the Junior Nuclear Medicine Technologist were inserviced on this system upon installation;
- on July 1, 1994, the new Radiation Safety Officer (RSO) was briefed on this incident and responsive corrective actions. The new Radiation Safety Officer (RSO) has concurred with the corrective action approach and he will be updated on all subsequent related actions regarding it.

We wish to reiterate that we identified a violation, voluntarily reported it to the Nuclear Regulatory Commission, and have taken subsequent corrective actions to prevent future violations. A routine Nuclear Regulatory Commission inspection was conducted on February 26, 1993 by Michael Kurth and no violations of any Nuclear Regulatory Commission regulations were identified. Subsequent special safety inspections held on April 25-26, 1994 and May 23, 1994 have not resulted in any infractions. The reviewer implied in his summation to us from the most current inspection that he will recommend an expansion of our license from two to three years due to his favorable findings.

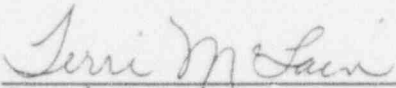
It has always been and will continue to be our goal to comply with all Nuclear Regulatory Commission regulations, and to ensure both patient and public safety at all times. Should you have any questions or require additional information or have suggestions for enhancing our corrective actions, please feel free to contact any of the undersigned.

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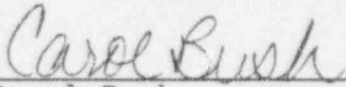
Respectfully,



John Gloss
President & Senior Executive Officer



Terri McLain
Assistant Administrator



Carol Bush
Radiology Manager

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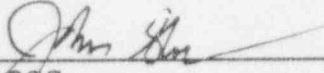
cc: Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Assistant General Counsel for Hearing & Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Robert Levitt, M.D.
Radiation Safety Officer (RSO)
Barnes St. Peters Hospital
10 Hospital Drive
St. Peters, Missouri 63376

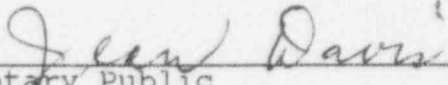
AFFIDAVIT

Comes now John Gloss, being of lawful age and first duly sworn, and states that the facts set forth in the attached September 15, 1994 response to U.S. Nuclear Regulatory Commission Demand for Information are true and correct to the best of my knowledge, information and belief.



John Gloss
President and Senior Executive Officer
Barnes St. Peters Hospital

Subscribed and sworn to before me this 16 day of September, 1994.



Notary Public

My commission expires: 8-30-98

AFFIDAVIT

Comes now Terri McLain, being of lawful age and first duly sworn, and states that the facts set forth in the attached September 15, 1994 response to U.S. Nuclear Regulatory Commission Demand for Information are true and correct to the best of my knowledge, information and belief.

Terri McLain

Terri McLain
Assistant Administrator
Barnes St. Peters Hospital

Subscribed and sworn to before me this 16 day of September, 1994.

Jean Davis

Notary Public

My commission expires: 8-30-98

AFFIDAVIT

Comes now Carol Bush, being of lawful age and first duly sworn, and states that the facts set forth in the attached September 15, 1994 response to U.S. Nuclear Regulatory Commission Demand for Information are true and correct to the best of my knowledge, information and belief.

Carol Bush

Carol Bush
Radiology Manager
Barnes St. Peters Hospital

Subscribed and sworn to before me this 16 day of September, 1994.

Jean Davis

Notary Public

My commission expires: 8-30-98