



URO - Radiology Prostate Institute

*Northern Virginia Radiology and Nuclear Medicine, Inc.
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26 May 2000

**U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555**

RE: Reply to Notice of Violation

To Whom It May Concern:

- A. Our storage room for licensed material did not have a ceiling. However, the door of the suite is kept locked after hours. In addition, the doors of the building are kept locked after hours. It is barely conceivable in an extreme case, an unauthorized individual to gain entry to the building and to the suite and then climbing up from the adjourning dressing room to gain access to the storage. To eliminate this extreme possibility a ceiling was constructed over the storage room. The storage room is now completely enclosed and secured. Only authorized personnel have access to this room. The storage room is kept locked at all times. Compliance was achieved and reported to the NRC on 9/9/1999.**
- B. Our activities using radioactive materials were always safe. No radioactive materials were found outside the storage room. No radioactive materials were found in the operating room. The radiation exposure records of all personnel are below recommended levels (ALARA). Despite our good safety record some of our practices were not accordance with the NRC regulations particularly our practice regarding the inventory of Iodine 125 and Palladium 103 seeds. Although all the required information was in the patient's record, it was scattered on 10 different pages and not in a convenient form for inspection. In addition, physical inventory was not conducted. We were aware of the problems and we started correcting the situation prior to the inspection with the assignment of Ms. Marcie Templeton, C.N.M.T. to work 4 days a week at the Uro-Radiology lab. This was the first step. The NRC inspection revealed this problem and sited these violations. The route of these violations can be traced to personnel and management problems.**
- (1) Prior to corrective action, the order, the receipt and the storage of radioactive seeds was handled by the office manager in consultation with the RSO and consultant physicist. The RSO decided the calibration date, number of seeds and activity of seeds. After implantation the remaining seeds were placed in storage. Lack of qualified personnel contributed to the problem.**

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- (2) We had some standing orders of seeds, which were divided and used on multiple patients under the supervision of the RSO.**
- (3) The inventory was lost and a new log-book was initiated in May 1998.**
- (4) Practices in storage were relaxed without adequate attention until the problems were realized.**
- (5) Maintenance of patient records was handled by the office manager under the supervision of the authorized user and consultant physicist.**

CORRECTIVE ACTIONS:

- 1. Since 8/15/1999 we have a certified nuclear medicine technologist (Ms. Templeton) in charge of ordering, receiving, monitoring and storing radioactive seeds under the supervision of the RSO. She assists the RSO and consulting physicist in properly maintaining brachytherapy patient records.**
- 2. A certified medical physicist was appointed RSO for the handling and use of Palladium 103 and Iodine 125 seeds, Dr. Samir Darwish, PhD (ABR) and will start working as soon as the relevant amendment to our license is approved by the NRC (estimated time 7/31/2000).**
- 3. A complete inventory from the inception of brachytherapy implants was prepared and completed before 12/31/99 using the patient records (forms 1-6, certificates, order form and log book). In addition, all inventory records were placed on a computerized inventory, which is kept current by Ms. Templeton. All information is readily accessible and ready for inspection. A physical inventory was also completed. All seeds were accounted for. All seeds not used are in the storage room. The remaining seeds from each patient were traced and placed in a container and labeled "radioactive", number of seeds, isotope, date and activity. We reached compliance prior to 11/8/99. Presently at the end of each implant procedure any unused seeds are accounted for and placed in the same container that the seeds were received in which is appropriately labeled and traced to the patient. This procedure and accountability is compared with and logged into the log-book and computerized inventory. The inventory and the physical inventory are in agreement for each patient. Maintenance of patient records is handled with Ms. Templeton in co-operation with the authorized user and the physicist. The date of the implant, the time of the beginning and the time of completion is always noted on Form 2. The removal of seeds from the**



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storage is within one-hour prior to the implant. After the end of the survey and accountability all remaining seeds are immediately returned to the locked storage.

4. A list of individuals permitted to handle radioactive materials has been posted.

Compliance was achieved and reported to NRC on 11/8/99.

- C. Although the Quality Management Program is adequate to ensure safety, in practice, some written directives were not signed and some information was missing from some of them. This was due partly to the fact that the total number of seeds implanted may vary depending on medication or physical condition of the patient in which case correction was required. The radioactive materials order is based on the pre-plan (Form 2A). The day of the implant another pre-plan is made which in turn maybe changed during the procedure. The final plan is the written directive. The missing information or signature was written on one of the previous plans and was not actually missing but was not recorded on the written directive. Corrective action included inspection of all records, double-checked of all completed forms for completeness and particularly the written directive Form 2b (blue). Compliance was achieved on 10/25/99.

As a result of the inspection and the corrective actions taken, we believe that our practices have been improved and are in compliance with NRC regulations.

Sincerely,


Panos Koutrouvelis, M.D.

CC: (1) Thomas R. Decker, Chief
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Nuclear Regulatory Commission
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