

TRI-STATE AREA NUCLEAR PHARMACY

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January 6, 1998

United States Nuclear Regulatory Commission, Region II  
101 Marietta Street, N.W. Suite 2900  
Atlanta, Georgia 30323-0199

SUBJECT: NRC INSPECTION REPORT NO. 47-25233-01MD/97-02

Dear Sirs:

This is in response to the above document received by Tri-States Area Nuclear Pharmacy on December 29, 1997. It is my intention to demonstrate that as manager and RSO of Tri-States Area Nuclear Pharmacy that I consider the matter at hand to hold the utmost importance and seriousness. I believe that we have rectified the areas of concern quickly and completely, while preparing to implement the long term solutions after this conference. My reasons for doing this are to get as much information about exactly what is required before finalizing anything as policy. In addition, although a Geodax Technology, Inc. representative is not attending this conference with me, they are equally dedicated to the swift and thorough resolution of this matter. It seemed appropriate to attend this conference before finalizing new policies.

In reading the report, I found there to be two major areas of concern, and I will address them separately for the most part, although there may be some overlap.

First: The licensee did not adequately control licensed material; front door unlocked.

Review: The background for this situation is as follows: The building as a whole was losing all of it's other tenants and as such there were a great deal of people working in a variety of areas. In the corner of our hot lab reside the main power panels and the telephone nerve center for the entire building (see diagram II). The building's owners also wanted to fix all of our facilities faults at this time as well. A repairman was in our office many times on the day in question attempting to repair an electrical fixture. The phone company also had repair people working on the phone system. Mr. Napier was not responsible for authorizing admittance to the restricted area, leading him to think people could enter at will. On interview of Chris Condren R Ph. he could not recall specifically training Mr. Napier on security issues.

In a review of our internal audit documentation, our NRC license, draft regulatory guide DG-0006, and our training manual, I found no reference to specific training on security of radioactive material.

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Enclosure 4

Causes: Door left unlocked purposefully. Inadequate training of Mr. Napier. Failure in understanding of severity of security issues. Failure to include specific training in training manual.

Action: Immediate training of Mr. Napier, refresher training of all other employees; with specific emphasis on overall importance of security of radioactive materials. Posting of a sign (attachment #1) indicating that the pharmacy must be either locked or attended at all times. Addition to training manual to include a section on security of radioactive material. Addition to competency test to include a question on security of radioactive material and pharmacy.

First: The licensee did not adequately control licensed material; unauthorized access to facility

Review: In interviewing other personnel, I found no similar instances of unauthorized personnel being found in a restricted area. I informed the new management that they could not enter the pharmacy without prior authorization.

Causes: Key to premises in possession of building management. Changes in building management with new tenants taking over other facilities in building. Inadequate control over access to premises by manager. Inadequate access prevention procedures.

Action: Locks on restricted access doors, with keys possessed only by Tri-States Area Nuclear Pharmacy personnel. Training on security of building and reasons for needing security. Signs on doors requiring locking when premises not monitored by Tri-States Area Nuclear Pharmacy personnel; including emergency numbers to obtain access (attachment #2). Additional training in training manual specific to security. Additional competency test question concerning security. Addition of security of premises to internal audit process. All staff are aware of this requirement, and the reasons for it. Safety issues (discussed regularly as necessary) through ALARA principles to include specifically general safety of the public through security of radioactive materials. Safety issues will be added as an area that is enforceable for non-compliance in our discipline procedures. Will add safety of radioactive materials to training manual and corresponding discipline procedures for non-compliance. I will suggest adding this to the corporate employees' handbook.

Second: The licensee transferred unit doses of byproduct material to a person not authorized to receive such materials

Review: It is the manager's responsibility to authorize and put initial information into the computer which will allow prescriptions to be generated. Internal audit procedure did not specifically check names of customers versus license.

Cause: This situation concerning Now Care Inc. was and still is confusing. Where I am quoted

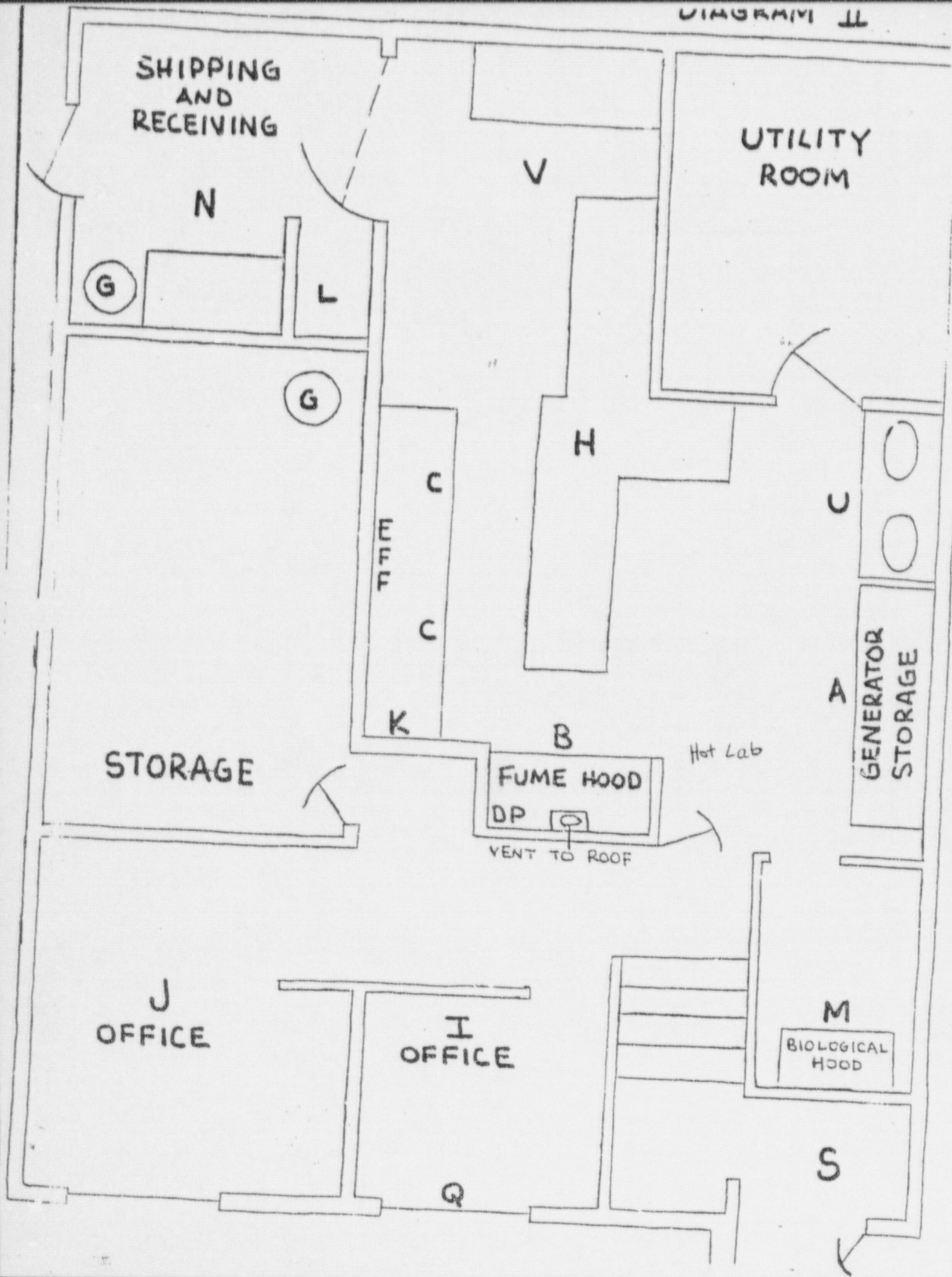


as being aware that Now Care Inc. filed for bankruptcy sometime after January, 1996 it should be added that to my knowledge they even today still have not finalized bankruptcy proceedings. I know my understanding of the bankruptcy laws is lacking, but I believe that they could have been doing business while under bankruptcy proceedings. I initially believed and called the account Health Center One; the name on the outside of the building. Now Care, Inc. was an immediate care facility within the building, and Advanced Diagnostic Imaging was the actual place we delivered the radiopharmaceuticals to. When the building changed to Tri-State Medical Center, Now Care, Inc. immediate care was still open and operating, with no apparent change in Advanced Diagnostic Imaging. Dr. Jain was the new person in charge of Tri-State Medical Center, and he was also part of the old group, Health Center One. But in review of the Now Care Inc. license it doesn't name Dr. Jain or any of the others on the license the only names I could see remained the same, Now Care, Inc and M. Douglas Allen as RSO. The nuclear technologist remained the same, and we were told that the equipment was being leased from Now Care, Inc. so I felt that no new license would be needed. It is my understanding that facilities may operate under a lease arrangement. It is my understanding that TSMC wanted to get their own license and that they were waiting for the Now Care Inc. to give up their license if they were to go through bankruptcy. It has come to my attention that it would have been possible for TSMC to also obtain a license for the same facility, though that would seem extremely confusing to have two licenses for the same site. Additional factors leading us to believe that a valid license was in place included that the RSO was the same, Mr. M. Douglas Allan, whom I know to be a very conscientious and knowledgeable person in his field. We also have a letter dated March 1, 1996 from the NRC extending the license for Now Care, Inc., as well as the knowledge that the facility was inspected in 1996 by an NRC inspector. I believe that I was acting appropriately and judiciously by transferring material to this facility; I can think of no reason that I would send byproduct material to someone whom I believed was not allowed by law to possess it.

Actions: Licensed materials were not shipped after it was discovered that there was a problem with the license. After the inspection I learned that the delivery name and address should be the same as the name on the license, which still confuses me in this instance if the leasing of equipment from Now Care, Inc. story is correct. In any case, we will in the future make sure that the responsible authorized party is indeed on the NRC license. I further acknowledge that when any question should arise in the future that I shall call the NRC for advice.

#### Suggested Additions to Training Programs for Couriers

Discussion of radioactive material safety and the reason this is necessary for protection of the public.  
 Procedures for securing Pharmacy when unoccupied.  
 No employee shall be responsible for security of the pharmacy until after 90 days.





# ATTENTION:

ALL TRI-STATE NUCLEAR  
PHARMACY EMPLOYEES

THIS DOOR TO BE CLOSED  
AND LOCKED WHEN  
PHARMACY IS  
UNATTENDED

YES, THIS MEANS EVEN IF JUST RUNNING TO THE BATHROOM !!

Attachment # 2

# RESTRICTED AREA

TRI-STATE NUCLEAR  
PHARMACY EMPLOYEES ONLY  
BEYOND THIS POINT !!!!

(All others must have permission and supervision)

For emergency access call pharmacist pager - 696-0286  
or Craig Lewandowski, RSO - 429-7232

THIS DOOR TO BE CLOSED  
AND LOCKED AFTER HOURS