

# Med – Share, Inc.

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**June 23, 2017**

ATTN: Region III Regional Administrator

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

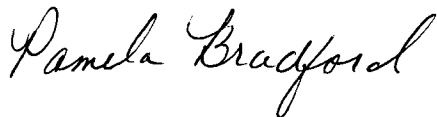
Reply To a Notice of Violation

RE: License 21-26098-01, Docket 030-31441

**ATTN: Region III Regional Administrator**

1. The Nuclear Technologist failed to secure from unauthorized removal or access licensed materials that were stored in the hotlab, by not closing and locking the door. Also, the key for the hotlab door was kept in plain sight.
2. The lock on the hotlab door has been changed to a keyless entry automatic – close locking door.
3. The Radiation Safety Officer has re-written the Safe Use rules to have more emphasis on the security needed for any radioactive materials on site. This has been distributed to all of the nuclear medicine technologists to make them more aware of the need for the required security and aware of the rules in Title 10 CFR 20.1801.
4. The change of the security of the hotlab controlled area was completed June 13, 2017 and the re-written Safe Use was distributed June 14, 2017.

Sincerely,



Pamela Bradford, BS, BSNMT, CNMT, NCT  
Radiation Safety Officer

enclosure

-- RECEIVED JUN 29 2017

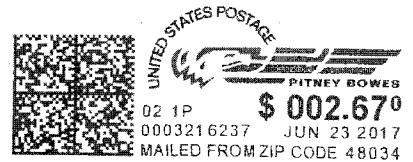
## **RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS**

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.
4. Use syringe shields for routine preparation of patient dosages and administration to patients.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.
6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.
7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices in a low-background area.
8. Wear a finger exposure monitor during the injection of radiopharmaceuticals, and when holding patients during procedures.
9. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
10. At fixed sites wipe test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for contamination.
11. At mobile sites wipe test the areas of use at the end of each site schedule. If a mobile unit performs testing at two sites, then there should be two wipe tests done, one for each site.
12. With a radiation detection survey meter, at a fixed or mobile site, survey stress and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive doses in shielded syringe containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation.
14. Mobile Sites: Each patient unit dose will be decay corrected, if needed, using the Technetium Chart for Unit Doses; a decay table, before administration. Do not use a dose if it differs from the prescribed dose by more than 10 percent, without AU approval. Check the patient's name and date of birth and the prescribed radionuclide, chemical form, and dosage before administering. As per 10 CFR Part 35.63.
15. Northland – Southfield Fixed Site: Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than 10 percent, without AU approval. Check the patient's name and medical record number, or date of birth and the prescribed radionuclide, chemical form, and dosage before administering. As per 10 CFR Part 35.63.
16. Always keep radioactive materials in shielded locations or containers.
17. When practical, use a cart or wheelchair to move flood sources, syringes, waste and other radioactive material.
18. It is prohibited to pipette by mouth.

Revised 5/26/2017

Med. Share, Inc  
26222 Telegraph  
Southfield, Mi 48033

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U. S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Rd., Ste 210  
Lisle, Il 60532-4352

Att: Regional Administrator