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www.DMSHealthTechnologies.com

August 13, 2009

United States Nuclear Regulatory Commission
Region IV
Attention: Jason M. Razo, Materials Inspector
612 East Lamar Blvd
Suite 400
Arlington, TX 76011-4125

RE: NRC License number 40-32477-01

Dear Mr. Razo:

This letter is sent in response to the inspection letter dated August 4, 2009 regarding the inspection conducted on June 22 and 26, 2009 of DMS Health Technologies operating under the NRC license number 40-32477-01.

Reply to Notice of Violation

1. During the inspection on June 26, 2009, DMS Health Technologies received a package labeled with a Radioactive Yellow II label during working hours, the package was not exempt from the monitoring requirement for radioactive contamination, and the licensee did not perform the required monitoring. Specifically, the package received by DMS Health Technologies contained unit doses of technetium-99m containing approximately 10-20 mCi each in unsealed form. This is a Severity Level IV violation under regulation 10 CFR 20.1906(b) and 10 CFR 20.1907(c).

DMS Health Technologies has contacted the technologist that was involved in this violation by Michelle White on Friday June 26, 2009 to reinforce to him/her the regulations for properly opening packages. DMS Health Technologies will and has conducted an annual Radiation Safety Competency Evaluation which is set to review with the technologist receiving packages according to 10 CFR 20.1906(b) and 10 CFR 20.1907(c). DMS Health Technologies will send out a reminder memorandum with the policy number EC-307 safely Opening Radioactive Material Packages to all Nuclear Medicine and PET technologist under the RAM license number 40-32477-01.

Full compliance of this violation will be achieved by Friday August 21, 2009.




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Thank you for your time in making our mobile Nuclear Medicine program in compliance with the United States Nuclear Regulatory Commission's regulations.

If you have any questions or concerns regarding this response, please feel free to contact me at 1-605-357-2610.

Sincerely,



Michelle White
Radiation Safety Officer

8-12-09
Date



Mary Hennings-Frank
Alternate Radiation Safety Officer

8/13/09
Date

Enclosed:
Radiation Safety Competency Evaluation
EC-307 Safely Opening Radioactive Material Packages Policy



Radiation Safety Competency Evaluation

Performance Review Score
Employee Identification

Overall Score: / 3.0

Name:

Job Title:

Evaluation Date:

Announced Visit:

Evaluated By:

Regional
Operations
Manager:

General Protection Procedures

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Technologist follows general rules for safe use and handling of RAM. (ALARA)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Gloves being used?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is aware of the emergency procedures instructions for spills and where this is posted in the mobile unit.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Spill kit is available in the work area and cab of vehicle.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is able to describe process to clean up a radioactive spill and notification process to supervising manager and RSO.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is wearing personal monitoring devices.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Syringes and vials containing radioactive material are properly labeled and shielded.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Facilities, Materials and Equipment

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Mobile unit is maintained in an orderly and clean condition.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Radioactive material is stored properly.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Adequate control to prevent unauthorized individuals from entering restricted areas.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Adequate controls to prevent access to sources of radiation that is stored in mobile unit.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Postings

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Radioactive material license posted.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Notice to employees posted.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is knowledgeable of the contents of the radioactive material license and notice to employees.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist permit to practice posted.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Clearance time and safety procedures for radioactive gas are posted.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
CLIA certificate of waiver posted.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Use and storage areas are posted "caution radioactive material" and/or "caution radiation area".	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Procedure for safety opening packages is posted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Film badge report is posted.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Receipt of radioactive material

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Incoming packages monitored for radioactive contamination and records maintained.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Incoming packages monitored for external radiation levels and records maintained.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Radioactive shipment receipt stickers used.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Radioactive material is received only in approved packages.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Packages containing radioactive material are labeled properly.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Waste Disposal

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Waste disposal policy is followed.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Records of transfer and disposal of radioactive material is being kept, is up to date and is available for review.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
No packages above 0.5 mR/hR are being shipped as a limited quantity.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Transportation

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Shipping papers in cab during transit. Pharmacy and sealed source shipping documents.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
All shipping papers contain emergency response information.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Survey meter in cab of vehicle during transit.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Ammo cans are blocked and braced properly during transit.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Area Surveys

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
End of day surveys are performed, documented and available for review on site.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Contamination surveys are conducted in areas where radiopharmaceuticals are routinely prepared for use, administered and where stored.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologists is familiar with action levels.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Dose rate survey records in millirems per hour.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Contamination survey records maintained in dpm.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Log Sheets/Dose accountability

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Patent log sheets are completed properly, up to date and maintained on site.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Patent log sheets are faxed/sent to appropriate destination.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Verification of all doses made prior to injection.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is familiar with the reporting requirements for misadministrations.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Camera quality control

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Camera quality control performed each day prior to injecting patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Camera quality control records being stored.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Camera quality control within acceptable limits.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Well counter

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Well counter quality control performed each day prior to use.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Well counter quality control records available to review on site.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Most recent chi-square and efficiency records stored on mobile unit.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Survey Meter

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Appropriate survey instrument is being used.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Survey meter constancy checked prior to use.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Survey meter battery checked and is good.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Survey meter daily check records available on site, are up to date and accurate.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Dose Calibrator

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Dose calibrator daily quality control performed each day prior to injecting patients.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Dose calibrator quarterly quality control records maintained on site and are up to date.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Instructions to workers/training

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Technologist radiation safety and hazardous materials training are up to date.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Technologist is aware of who the radiation safety officer is and knows how to contact them.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Radioactive shipment receipt stickers used.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Glucose Testing PET and PETCT

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
Able to perform monitor daily quality control.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Able to perform cleaning procedure on monitor.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Able to properly test patient glucose level.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

General Safety

Competent Y - Yes; N - No; N/A - Not Applicable.

Competency	Comments:	Competent			Score /3.0
		Y	N	N/A	
There is a process for comparing the patient's current medications with those ordered for the patient while under the care of DMS Imaging. This is documented on the patient verification form and completed prior to injection.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Initial pain assessments are performed as defined by the DMS Imaging policies. This is documented on patient verification form.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Written and verbal post procedure instructions are given to the patient. The information is consistent with DMS Imaging post procedure policy.		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
It is DMS Imaging policy to maintain a latex free environment of care. Is there compliance with this policy?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Is the Mobile Unit Life Safety (MULS) checklist posted and current?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Is the fire extinguisher inspection up to date?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Stairs and both railings are properly attached to the mobile coach?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Comments

Overall Comments

Employee

Evaluator



Policy:	Safely Opening Radioactive Material Packages
Policy Number:	EC-307
Employees Affected:	Nuclear Medicine and PET Technologists
Approved By:	Radiation Safety Officer, Radiation Safety Committee
Effective Date:	12/31/05
Reviewed Date:	10/29/08
Revised Date:	02/03/09

Purpose:

The purpose of this policy is to provide information and procedural instructions for safely opening packages containing radioactive material.

Policy and Procedure:

Appropriate safety precautions will be strictly followed at all times. All radioactive shipments will be assumed to be potentially contaminated until proven otherwise. Radioactive shipments will be monitored for external radiation levels and surface contamination within three hours after receipt if received during working hours or not later than three hours from the beginning of the next working day if received after hours. All packages will be opened using the following procedure:

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify the Radiation Safety Officer.
3. Measure exposure at one meter from the package surface and record. If the reading is greater than 10 mR/hr, stop the procedure and notify the Radiation Safety Officer.
4. Measure the surface exposure rate and record. If the measurement is greater than 200 mR/hr, stop the procedure and notify the Radiation Safety Officer.
5. Do a wipe test of the outer surface of the shipping container. Record the results on the sticker. If the outer surface wipe test shows contamination, or there is any damage to the package, a wipe of the external surface of the final source container should also be done. Acceptable limits are less than 2000 dpm/100 cm².
6. Open the package with the following precautionary steps:
 - a. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
 - b. Open the inner package and verify that the contents within agree with those on the packing slip, compare requisitions, packing slip and vial and/or syringe labels.
 - c. Check the integrity of the final source container (i.e., inspect for breakage of seals or vials, loss of liquid and/or discoloration of packaging materials).
7. Check that the shipment does not exceed possession limits and record all appropriate information log book or utilization form.
8. Monitor the packing materials and the package for contamination before discarding.

- a. If contaminated, obliterate radiation warning labels before discarding in the regular trash.
9. Records of the receipt of Radioactive Materials will be maintained and kept.

Communications:

Questions, concerns, and recommendations regarding this policy and procedure are welcome and should be directed to the Radiation Safety Committee and/or RSO of DMS Imaging.

Review Frequency:

Every three years or if new changes are needed.