DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-HP

6 May 2010

MEMORANDUM FOR USNRC, Region I, Attn: Dr. Sandy Gabriel, 475 Allendale Road, King of Prussia, PA 19406-1415

SUBJECT: Incident report for loss of positive control of radioactive materials packages at Walter Reed Army Medical Center

1. Reportable items per 10CFR20.2201b.

a. Material involved- see item 2.a.1. and 2.a.2. below.

b. Circumstances under which the loss of control occurred- see item 2. below.

c. Statement of disposition of the material- all material is accounted for and secure.

2. The following is a timeline and brief narrative of temporary loss of positive control over radioactive materials (RAM) packages that occurred 1-3 May 2010 at Walter Reed Army Medical Center (USNRC License No. 08-01738-02).

a. Two orders were placed for radioactive materials to be used for the diagnosis and treatment of patients at Walter Reed Army Medical Center. The orders shipped from the manufacturer (Lantheus Medical Imaging) on 30 Apr 2010.

1. A 2 Ci Mo-99 (solid/salt) generator used to produce Tc-99m .

2. Three sources of Tl-201(thallous chloride; liquid) totaling 29.6 mCi.

b. The packages were scheduled for delivery by FedEx at around 1030 on Saturday, 1 May 2010, and was intended to be signed for and processed by SSG Ashcraft (the NCOIC of Nuclear Medicine), who was scheduled for duty that day as the Administrative Officer of the Day (AOD).

c. It should be noted that a courier service that is fully conversant with our RAM package receiving process normally delivers RAM packages to Walter Reed, but they were not available for a Saturday delivery. Further, the non-standard Saturday delivery was necessary due to the limited availability of Tc-99m generators world-wide. Nuclear Medicine must take these generators when they can get them, regardless of timing, or risk being unable to perform mission essential services.

d. In preparation for the arrival of the packages during the weekend, on Saturday morning around 0830, SSG Ashcraft posted signs on the doors to the Nuclear Medicine Department

directing that any packages should be delivered to the AOD/Concierge Desk in the Lobby of the first floor of the main hospital (Bldg 2).

e. The radioactive materials (RAM) packages were delivered by FedEx on Saturday, 1 May 2010 at 1249. They were signed for by Mr. who was the Concierge on duty at the time. Mr. placed the packages behind the Concierge Desk under the counter and behind the safe (see Encl 1). He did not inform the AOD that he signed for a packages or that he had placed them under the counter.

f. SSG Ashcraft began to become concerned, as the day wore on and the RAM packages had not been delivered, so he contacted FedEx and a Nuclear Medicine colleague, Yvette Marquez-Sayer. Unfortunately, they did not have access to the package tracking numbers which would have allowed them to confirm delivery date and time and identify who signed for the packages on behalf of WRAMC. FedEx was only able to confirm that the last package had been delivered at 1700 Saturday, and nothing else would be delivered until Monday. They concluded that the packages had not been delivered and would come in on Monday with the next delivery.

g. At 0740 on Monday, 3 May, Ms. Marquez-Sayer again contacted FedEx with the tracking numbers and was able to confirm that the packages had been delivered on Saturday at 1249 and was signed for by .

h. SSG Ashcraft immediately went down to the Concierge desk, and confirmed that Mr. Ramos worked for the Concierge Service. He searched the area extensively, and was able to locate the RAM packages. He secured and moved them up to Nuclear Medicine at 0815, where the packages were processed according to the RAM package receipt SOP. All RAM was secured and accounted for.

i. MAJ Andrew Scott of Health Physics was informed of the incident at about 0840, and after some preliminary investigation, contacted the NRC in accordance with 10CFR20.2201 and was given a notification time of 1127 by Mr. Dong Park.

j. SSG Ashcraft wrote and submitted and incident report to the WRAMC Command (see Encl 2).

k. Separate memoranda have been produced to cover the radiation dose of the personnel involved and a root cause analysis that includes recommended corrective actions to designed to prevent this type of incident from occurring again in the future (see Encl 3 and 4).

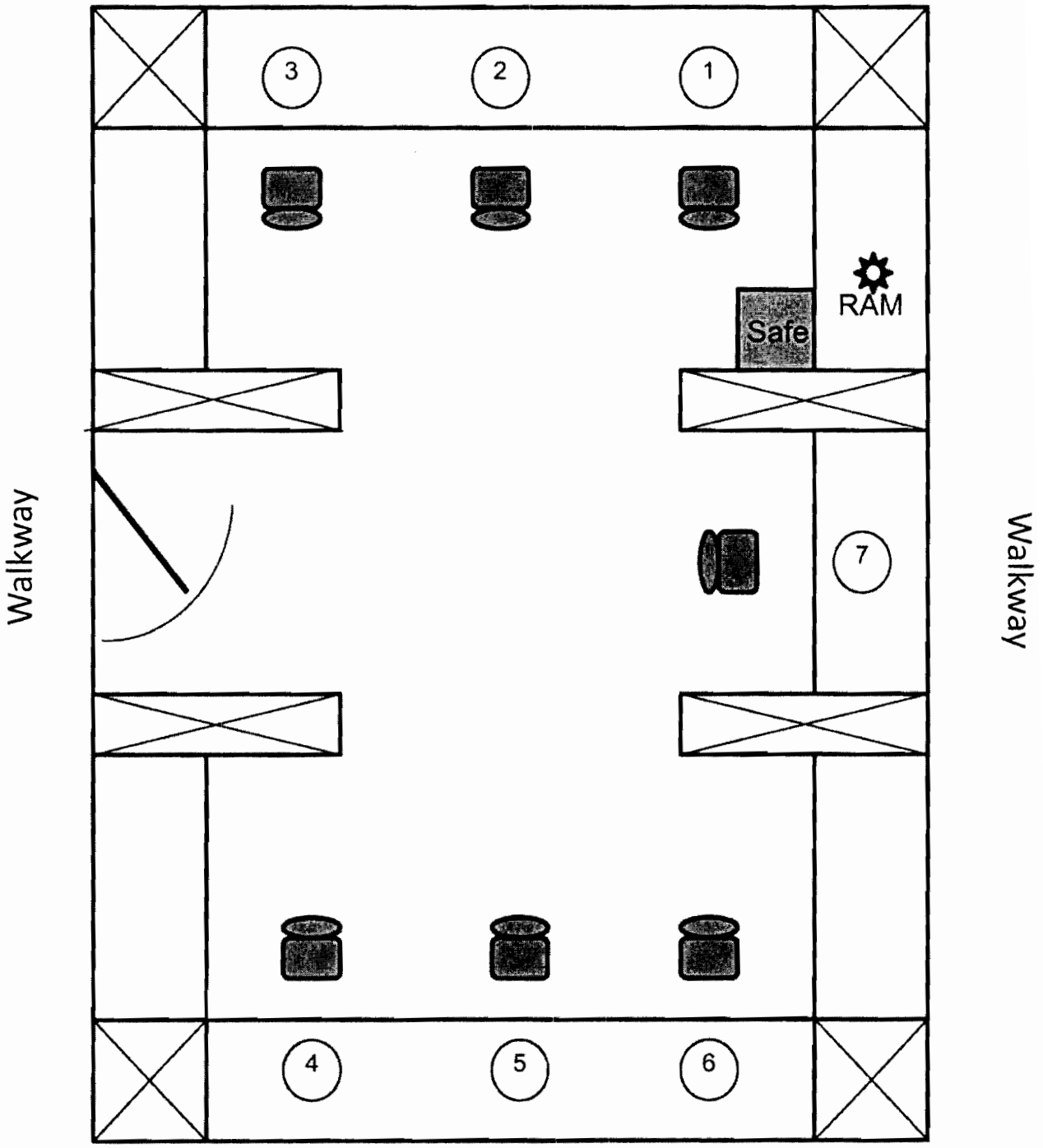
MCHL-HP
SUBJECT: Incident report for loss of positive control of radioactive materials packages at Walter Reed Army Medical Center

3. The point of contact for this memorandum is the undersigned at 202-356-0061 or andrew.scott1@us.army.mil .

Encls

ANDREW L. SCOTT
MAJ, MS
Chief, Health Physics Service

Patient Waiting Area



Dunkin' Donuts

Encl 1

INCIDENT REPORT

For use of this form, see AR 40-68; the proponent agency is OTSG.

Privacy Act of 1974, 5 USC 552a governs access to this document.

Quality Management Document under 10 USC 1102. Copies of this document, enclosures thereto, and information therefrom will not be further released under penalty of the law. Unauthorized disclosure carries a statutory penalty of up to $3,000 in the case of a first offense and up to $20,000 in the case of a subsequent offense. In addition to these statutory penalties, unauthorized disclosure may lead to adverse actions under the UCMJ and/or adverse administrative action, including separation from military or civilian service.

Instructions: See page 2 for instructions in completing this form and definitions of terms marked with an asterisk (*).

1. DATE OF EVENT *(YYYYMMDD)*	2. TIME OF EVENT *(Military time.)*	3. LOCATION OF EVENT
20100503	1250	First Floor Information Desk

4. This incident was a/an: *(Check one)* ☒ Actual Event/Incident* ☐ Near Miss/CloseCall*

5. This incident involved harm or the potential for harm to a patient. ☐ Yes ☐ No

6. This incident involved the following individuals: *(Check all that apply)*
☐ Patient ☐ Family Member (☐ Adult ☐ Child < 18 years old) ☒ Staff Member ☐ Visitor ☐ Volunteer ☐ Other

7. Type of Event. *(Check all that apply)* *NOTE: Items marked with ** require additional action; see reverse for further detail.*

☐	Adverse Drug Reaction**	☐	Fall	☐	Property Damaged/Destroyed
☐	AMA/Left Without Being Seen**	☐	Infant Abduction	☐	Property Lost/Stolen
☐	Assault *(e.g., physical, verbal, emotional)*	☐	Infant Discharge to Wrong Family	☒	Radiology Related
☐	Blood Products Related**	☐	Laboratory Related	☐	Rape
☐	Delay in: Diagnosis/Treatment/Transfer	☐	Medication Related	☐	Restrained Patient Injury
☐	Equipment/Supply Problem**	☐	Needle Stick/Sharp Injury	☐	Suicide in a 24-hour Facility
☐	Exposure to Blood/Body Fluids	☐	Obstetrics Related	☒	Other *(Specify)*
☐	Facility/Physical Plant Problem	☐	Operative/Invasive Procedure Related		Misplaced Radioactive Materials

8. Effect of this Incident on the Individual(s) Involved. *(Explain in Block 11.)*
☒ No harm*sustained ☐ Harm sustained

9. Witness(es) who may be able provide additional detail concerning this incident.

a. Name	b. Telephone Number
Jair Ramos	
SGT Robert Bennett	782-8641

10. Department(s) Involved in this Incident. *(Check all that apply)*

☐	Ambulatory Care	☐	Information Management	☐	Nursing	☒	Radiology
☐	Behavioral/Mental Health	☐	Laboratory	☐	OB/GYN	☐	Surgery
☐	Dental	☐	Logistics *(Maintenance, Grounds, Housekeeping)*	☐	Pediatrics	☒	Other *(Specify)*
☐	Emergency Care	☐	Medicine	☐	Pharmacy		

11. Description of Incident. *(Provide concise, factual, objective details.)*

I, SSG James Ashcraft, was assigned to AOD on Saturday, May 1. The Nuclear Medicine clinic on 7A was expecting a delivery of Radioactive materials (2 packages) from FedEx. At around 0830, I placed signs on the doors at Nuclear Medicine stating " Deliveries. Please go to Information Desk 1st Floor", beacuse the Standard Operating procedure for AOD stated that the AOD or his designate will sign for all after hours deliveries. I was manning the information desk along with SGT Bennett and PV2 Reese. SGT Bennett went to lunch at around 1130, so I had PV2 Reese assist me at the desk. At some point, FedEx came to the back side of the information desk and Mr. signed for it. FedEx tracking records show that the package was signed for at 1250.

(If more space is needed, use reverse or attach an additional page.)

12. What actions, if any, could have been taken to prevent this incident from occurring?

Concierge service could have informed the AOD that a package had been delivered.

13. Patient ID Plate or Printed Name and SSN, Address, and Daytime Telephone Number	14. Name, Grade, Title of Individual Completing Form	
	James O. Ashcraft E6,	
	15. Signature	16. Date of Report *(YYYYMMDD)*
	FOR ADMINISTRATIVE USE ONLY.	
	Incident Log Number _____ SAC score ____	
	Is additional event analysis required? ☐ YES ☐ NO	

Encl 2

1. PURPOSE. To provide an effective method of documenting events which may have quality assurance/risk management implications involving patients, visitors, or others. The reported data are used to monitor, evaluate, and improve functional processes, the environment of care, as well as the quality and safety of patient care and services. Based on the nature of the incident, other documentation (e.g., Patient Safety, Risk Management, etc.) may be required IAW local policy.

2. RESPONSIBILITY. The staff member who discovers the event or incident will initiate this document. All incidents should be recorded as soon after discovery as possible.

3. DIRECTIONS FOR COMPLETION OF FORM.

a. Block 1-16. Fill in all numbered blocks. If "Not Applicable" or "None", so state. If "Other" is marked for any response, please explain in the blank space provided, or in Block 11, Description of Incident.

b. Block 5. For those incidents involving harm, or the potential for harm, to a patient (inpatient or outpatient), refer to MTF Patient Safety guidance for additional documentation requirements.

c. Block 6. A patient may be involved in an incident that is ***not*** classified as a Patient Safety event, i.e., personal harm, or the risk of harm, was not present. Examples include: loss of valuables, a verbal altercation with another patient, etc.

d. Block 7. (1) For an adverse drug reaction, also complete FDA Form 1839, Adverse Reaction Report (Drugs and Biologics).
(2) For a blood products reaction, also complete the bottom portion of SF 518, Medical Record - Blood or Blood Component Transfusion and any other local documentation IAW MTF policy.
(3) For patients who depart AMA/Left without Being Seen, also complete DA Form 5009, Release Against Medical Advice.
(4) For medical equipment related incidents, contact Logistics Division for other required action IAW AR 40-61.

e. Block 8. Indicate the initial effect or injury (physical or psychological) sustained by those involved in the incident being reported. Individuals who are injured as a result of an incident or adverse event should be referred immediately for medical attention. The facility Risk Manager will be notified of any incident that results in harm to the individual(s) involved.

f. Block 9. List any witnesses to the event that may be asked to provide additional verbal or written information.

g. Block 10. Note the departments involved with this incident to ensure that corrective action, if appropriate, can be taken.

h. Block 11. Provide a brief but concise explanation of what occurred. Avoid speculation related to the cause of the incident.

4. ROUTING OF FORM. This document should be forwarded through appropriate local channels. At a minimum, it should be staffed within 24 hours of incident identification through the Departments/Services concerned. This form will be submitted to the MTF Patient Safety Manager, Risk Manager, or other responsible individual IAW local policy, NLT 48 hours after the event.

5. DEFINITION OF TERMS.

a. Actual Event/Incident - A situation that did occur either with or without harm or injury to the individual(s) involved.

b. Harm - Personal injury or damage of a physical or a psychological nature as a result of an incident.

c. Near Miss/Close Call - An event or situation that could have resulted in harm or injury to the individual(s) involved but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the individual(s) involved.

6. ADDITIONAL COMMENTS/DATA.

I made several phone calls to FedEx and was coordinating with Yvette Marquez-Sayer to try and track down the package. She and I were both unable to get delivery confirmation from FedEx. The local FedEx delivery office informed me at 1700 that the last package to Walter Reed had already been delivered and nothing would be sent again until Monday. On Monday, 3 May, at 0740, Yvette informed me that the package had been signed for at 1150 on Saturday by I walked downstairs to the information desk and verified that Mr. works for the concierge service. After searching around the information desk, I discovered both packages hidden under the counter. The packages had been in that spot since they were received on Saturday. I immediately retrieved the packages and delivered them to the Radiopharmacy. Packages were secured in Nuclear Medicine by 0830. Yvette and Robert Massey informed MAJ Scott at Health Physics.

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REPLY TO
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MCHL-HP

6 May 2010

MEMORANDUM FOR Deputy Commander for Clinical Services (MCHL-CDR)

SUBJECT: Radioactive materials (RAM) package incident (1-3 May 2010) dose assessment

1. REFERENCES

a. Various e-mail communications

b. Various telephonic communications

c. Attached diagram of Concierge Desk, 1st floor lobby, Bldg 2, WRAMC

2. Based on the information I was able to collect related to the RAM Package incident that occurred on 1-3 May 2010, I calculated the indicated maximum doses for the following personnel that were assigned to the Concierge Desk located on the first floor lobby of Bldg 2, WRAMC, during that time:

Name	Position	Estimated Max Dose (mrem)
		2.8
		2.8
		2.8
		3.4
		3.4
		9.3
		45.0
		62.2
		45.0
		22.5
		22.5
		22.5
		22.5
		22.5
		4.0
		4.0
		4.0
Nearest member of public	Waiting area	1.2

End 3

3. These doses were calculated by using the following conservative assumptions:

a. the concierge personnel were occupying the nearest station facing the patient waiting area for all of their assigned duty time;

b. the military personnel were occupying the nearest station facing the Dunkin' Donuts for all of their assigned duty time;

c. the exposure rate was assumed to be the decay corrected transport index at time of package receipt (2.1442 mR/hr at 1 m) for the entire time of the exposure (no decay correction while packages were stored under desk).

4. In order to put these doses in perspective, the annual limit established by the NRC for exposure to a member of the general public from licensed operations is 100 mrem/yr, the occupational exposure limit established is 5000 mrem/yr, the average background dose due to environmental sources of radiation is about 300 mrem/yr, a typical pelvis x-ray delivers a dose of about 70 mrem, and an abdominal CT delivers a dose of about 910 mrem.

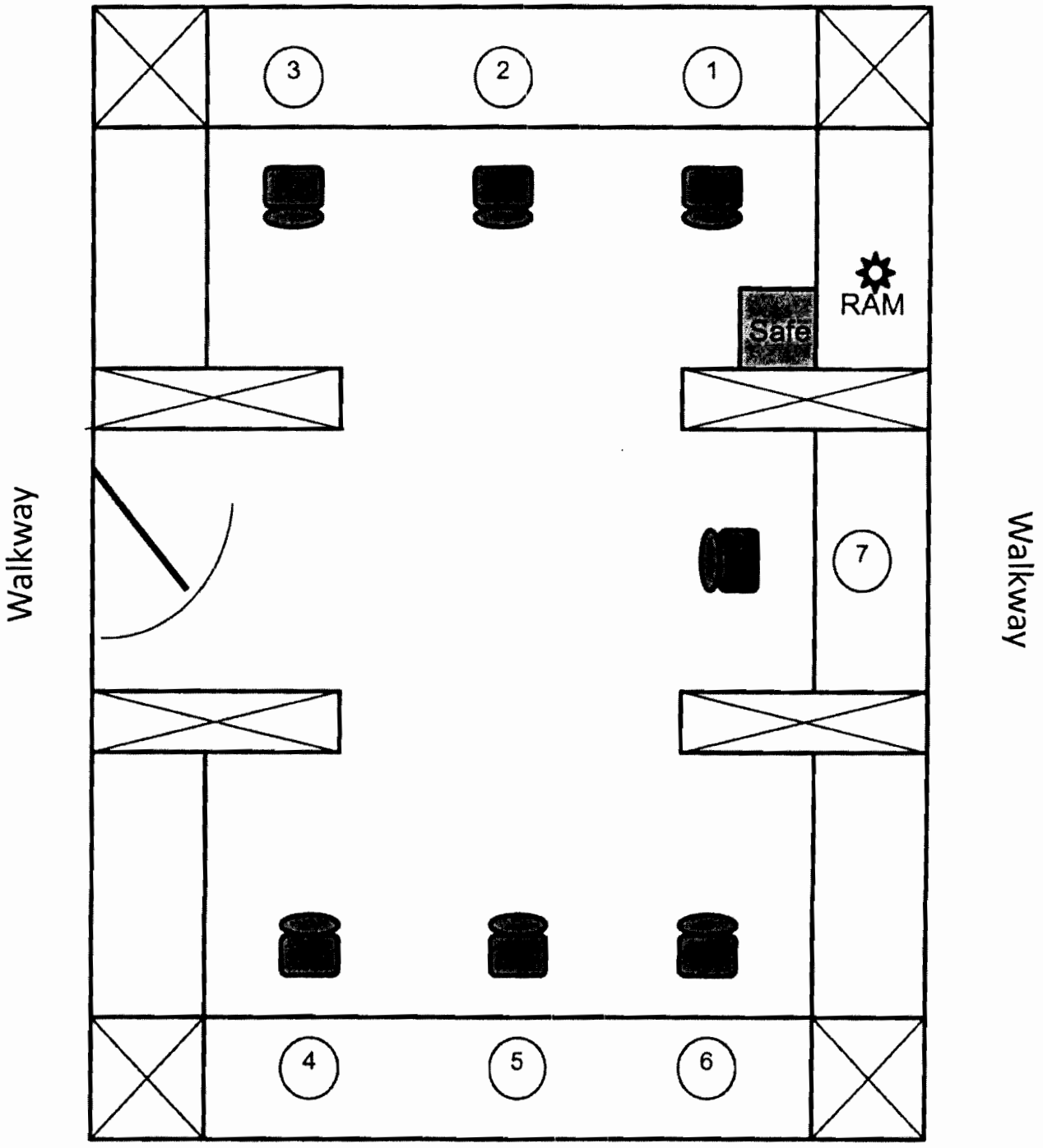
5. The Health Physics Society, in a Position Statement entitled Radiation Risk in Perspective, revised August 2004, indicated that for whole body exposures below 5000 mrem in one year, the "risks of health effects are either too small to be observed or are non-existent."

6. The point of contact for this memorandum is the undersigned at 202-356-0061 or andrew.scott1@us.army.mil .

Encl

ANDREW L. SCOTT
MAJ, MS
Chief, Health Physics Service

Patient Waiting Area



Walkway

Walkway

Dunkin' Donuts

End 1

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REPLY TO
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6 May 2010

MEMORANDUM FOR Deputy Commander for Clinical Services (MCHL-CDR)

SUBJECT: Radioactive materials (RAM) package incident (1-3 May 2010) root cause analysis and recommended corrective actions

1. REFERENCE. Memorandum (and enclosures) for USNRC, 6 May 2010, subject: Incident report for loss of positive control of radioactive materials packages at Walter Reed Army Medical Center.

2. Based on my investigation of the RAM package incident that occurred on 1-3 May 2010, the following findings contributed to the loss of positive control of the radioactive material.

a. The Concierge on duty signed for the packages against policy. The AOD is the only authorized person that can sign for packages after normal duty hours.

b. The RAM was delivered on a weekend, after normal duty hours. The limited availability of Tc-99m generators world-wide contributed to a situation where material was delivered outside of the normal duty day.

c. The carrier and delivery person were different from the normal weekday delivery service. The normal delivery person who delivers RAM packages during the week is fully conversant with the local delivery procedures, whereas the weekend FedEx delivery person was not familiar with these procedures.

d. The AOD on duty Saturday, 1 May 2010, when the packages were delivered was the NCOIC of Nuclear Medicine and was prepared to properly receive the RAM packages; however, he did not have the package tracking numbers which would have allowed him to confirm delivery date and time and identify who signed for the packages on behalf of WRAMC.

3. Additionally, I have identified the following potential weaknesses in our radioactive materials package receipt procedures.

a. There is a lack of specific guidance for the Administrative Officer of the Day (AOD) as to how to identify and handle a radioactive materials package delivery.

b. There is not a specific provision in the RAM Package Receipt SOP in the Nuclear Pharmacy outlining non-standard package delivery and receipt procedures.

4. Recommended corrective actions.

Encl 4

a. Reiterate the WRAMC policy outlining who is authorized to sign for packages with AOD and concierge personnel. This should be posted in the AOD binder and become a part of the duty in-brief for both groups.

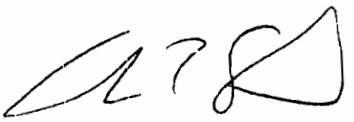
b. Make every effort to coordinate the delivery of radioactive materials packages during the normal duty day. If this is not possible, carefully coordinate the delivery with all personnel to be involved on the anticipated date and time of delivery. This should include the manufacturer, delivery company, Nuclear Medicine and Concierge Desk duty personnel.

c. Ensure that the package tracking number is provided to the personnel expected to receive packages to allow for identification of package status at any time throughout the process.

d. Write and post radioactive package identification and receipt instructions in the AOD binder.

e. Update the Nuclear Pharmacy's radioactive package receipt SOP, to include a discussion of procedures to be followed in the event of a non-standard RAM package delivery and receipt.

5. The point of contact for this memorandum is the undersigned at 202-356-0061 or andrew.scott1@us.army.mil .



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