

State of California—Health and Human Services Agency
Department of Health ServicesCalifornia
Department of
Health ServicesSANDRA SHEWRY
DirectorARNOLD SCHWARZENEGGER
Governor

FACSIMILE TRANSMITTAL SHEET

Date: 4/28/05

To: DANTE
Company: INEEL
Fax Number: 208-526-2930From: Peggy Lee McKernan,
Staff Services Analyst

Total Number of Pages including Cover: 7

Notes/Comments

This is an initial report of this event from California (Agreement State). Additional information will be provided upon completion of the investigation of this event, which is expected within 60-90 days. If you require additional information before then, please let me know.

XCA 726 Eisenhower Medical Center
(additional correspondence)

Flex your
POWER

Food, Drug and Radiation Safety: Radiologic Health Branch
MS 7610, PO Box 997414, Sacramento, CA 95899-7414
(916) 440-7961 FAX (916) 341-7216
pmckerna@dhs.ca.gov
DHS Internet Address: www.dhs.ca.gov

4/28/05

MATTER REQUIRING INVESTIGATION/INSPECTION

HEALTH AND SAFETY ADMINISTRATIVE

XCA 726

LICENSEE / REGISTRANT / USER		ASSIGNMENT
LICENSEE/REGISTRANT/USER NAME Eisenhower Medical Center		5010 NUMBER (Date Notified) 041205
LICENSEE/REGISTRANT/USER CONTACT S. Becker	PHONE 626-616-5135	INSPECTION OFFICE (AGENCY) RHB - BREA / Region 5
TITLE RSO	OTHER PHONE/EMAIL	INSPECTOR
OFFICE ADDRESS 39000 Bob Hope Dr. / Rancho Mirage 92270		EVENT TYPE <input type="checkbox"/> MACHINE <input checked="" type="checkbox"/> MATERIALS (Check One) <input type="checkbox"/> Radiation Exposure (EXP) <input type="checkbox"/> X-ray Registration (XR) <input type="checkbox"/> Transportation (TRS) <input type="checkbox"/> Certification (CT) <input type="checkbox"/> Leaking Source (LKS) <input type="checkbox"/> Mammography (MM) <input checked="" type="checkbox"/> Misadministration (MD2) <input type="checkbox"/> Landfill/Scrap Yard (LY) <input type="checkbox"/> Release of Material (RLM) <input type="checkbox"/> Crematory (CR) <input type="checkbox"/> Theft or Loss (LAS) <input type="checkbox"/> Other (OTH) <input type="checkbox"/> Equipment Malfunction (EQP)
EVENT/SITE LOCATION		
OTHER CONTACT	PHONE	
LICENSE/REGISTRATION NUMBER 2425-33	OTHER PHONE/EMAIL	
INFORMATION SOURCE		Involve CA SS&D: <input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No Provided to RML: _____ (date)
NAME/POSITION Michael Prodanov		COMPLAINT (AL) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Forwarded by NRC <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Respond to Complainant <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Anonymity Requested <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
ADDRESS - Number Street		
TELEPHONE NUMBER	OTHER PHONE/EMAIL	
FIRST CONTACT BY (Check One Only) <input type="checkbox"/> Telephone <input checked="" type="checkbox"/> Letter/Form <input type="checkbox"/> Email <input type="checkbox"/> Other (Specify): _____		REPORTABLE EVENT (NMED) NRC reportable event? <input type="checkbox"/> ≤ 24-hr <input type="checkbox"/> 30-Day <input checked="" type="checkbox"/> Info <input type="checkbox"/> No Regulation Requiring Report: (NRC) _____ (CA) CCR, title 17, section 30322 If ≤ 24-hr, this form must be reported to NRC Ops. Ctr. within 24 hours. Report made to NRC Ops Center: Date: _____ Time: _____ (301) 951-0550 (telephone), (301) 816-5151 (fax), or hoo1@nrc.gov (email) If 30-day or Info report, RHB/HO (Peggy) submits 5010 to INEL, and inspector updates until "complete" in NMED database (http://nmed.inel.gov). CA NMED # (Sacto): XCA 726 NMED Item # (INEL): _____
Contact Date: <u>04/15/05</u> (month/day) Contact Time: _____		
Event Date: <u>04/12/05</u> (month/day) Discovery Date: _____ (month/day)		
OTHER NOTIFICATIONS (e.g., other agencies, patient, etc.) (*)		ABNORMAL OCCURRENCE? (See STP SA-300 Section 7) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
HP CONSULTANT USED: <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> UNK		
PRESS/MEDIA INVOLVEMENT: <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> UNK		

SUMMARY (Abstract of Event)

Any fact or complaint suggesting immediate threat to health and safety? YES NO

A patient, not scheduled to be administered any radioisotope, was administered 11 mCi Tc-99m MIBI for a myocardial perfusion scan, because the imaging technologists misunderstood the order in the chart.

Dx administration
 Intended: none
 Administered: 11 mCi Tc-99m MIBI
 Dosimetry: Whole body: 0.19 rads; upper large intestine wall: 2.05 rads

DIAGNOSTIC MISADMINISTRATION REPORT

Licensee name EISENHOWER Med CTR		License number 2425-33	
Address (number, street) 3900 BOB HOPE DRIVE		Event date Month Day Year	Report date Month Day Year
City RANCHO MIRAGE CA		ZIP code 92270	

Type of Misadministration	Did the misadministration involve an isotope of iodine?	Number of patients who received a misadministration under this report.
<input type="checkbox"/> Wrong radiopharmaceutical <input type="checkbox"/> Wrong patient <input checked="" type="checkbox"/> Dosage differing from prescribed by 50% <input type="checkbox"/> Wrong route	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	1

Intended	Intended	Given																
<input type="checkbox"/> No clinical procedure <input checked="" type="checkbox"/> Nuclear medicine study (complete "Intended" and "Given" sections) <input type="checkbox"/> X-ray study <input type="checkbox"/> Ultrasound <input type="checkbox"/> CT study <input type="checkbox"/> NMR study <input type="checkbox"/> Other	<table border="1"> <tr> <th>Millicuries</th> <th>Isotope</th> <th>Chemical Form</th> <th>Study</th> </tr> <tr> <td>0</td> <td>Tc</td> <td>MIBI</td> <td>HEART</td> </tr> </table>	Millicuries	Isotope	Chemical Form	Study	0	Tc	MIBI	HEART	<table border="1"> <tr> <th>Millicuries</th> <th>Isotope</th> <th>Chemical Form</th> <th>Study</th> </tr> <tr> <td>11.4</td> <td>Tc</td> <td>MIBI</td> <td>HEART</td> </tr> </table>	Millicuries	Isotope	Chemical Form	Study	11.4	Tc	MIBI	HEART
Millicuries	Isotope	Chemical Form	Study															
0	Tc	MIBI	HEART															
Millicuries	Isotope	Chemical Form	Study															
11.4	Tc	MIBI	HEART															

Precipitator	Authorized user	Hot lab technologist
<input type="checkbox"/> Referring physician <input type="checkbox"/> Ward nurse <input type="checkbox"/> Ward clerk <input type="checkbox"/> Nuclear pharmacy Name of nuclear pharmacy: _____	<input checked="" type="checkbox"/> Authorized user	<input checked="" type="checkbox"/> Imaging technologist <input type="checkbox"/> Clinical receptionist <input type="checkbox"/> Scheduling technologist <input type="checkbox"/> Patient <input type="checkbox"/> Other: _____

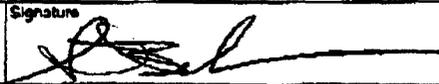
Error			
Hot Lab	Referral	Administration	Other
<input type="checkbox"/> Mislabeled a syringe <input type="checkbox"/> Mislabeled a vial or vial shield <input type="checkbox"/> Reconstituted wrong reagent kit <input type="checkbox"/> Placed reconstituted vial in wrong shield	<input type="checkbox"/> Selected wrong vial when drawing dosage <input type="checkbox"/> Set dose calibrator improperly <input type="checkbox"/> Misread dose calibrator <input type="checkbox"/> Misunderstood radiopharmaceutical or dosage order	<input checked="" type="checkbox"/> Misunderstood referring physician's request <input type="checkbox"/> Requested wrong study <input type="checkbox"/> Requested study for wrong patient	<input type="checkbox"/> Selected wrong patient <input type="checkbox"/> Answered waiting room page intended for other patient <input type="checkbox"/> Brought wrong patient to clinic <input type="checkbox"/> Selected wrong syringe from dosage cart

Contributing Factors		Action Taken to Prevent Recurrence	
<input type="checkbox"/> Student technologist <input type="checkbox"/> New employee <input type="checkbox"/> Foreign language <input type="checkbox"/> Patient incoherent or unconscious <input type="checkbox"/> ID bracelet not checked	<input type="checkbox"/> Requisition not checked <input checked="" type="checkbox"/> Patient chart not checked <input type="checkbox"/> New procedure <input checked="" type="checkbox"/> Heavy workload <input type="checkbox"/> Other	<input type="checkbox"/> Implement new procedures for: <input type="checkbox"/> Verification of request <input type="checkbox"/> Radiopharmaceutical labeling and handling <input checked="" type="checkbox"/> Verification of patient identification <input checked="" type="checkbox"/> Reinstruct personnel <input type="checkbox"/> Reprimand personnel	<input type="checkbox"/> Improve supervision of personnel <input type="checkbox"/> No action <input checked="" type="checkbox"/> Other: _____

Effect on Patients	<input checked="" type="checkbox"/> None apparent	<input type="checkbox"/> See abstract
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Attach abstract and mail completed form to:
 Compliance Unit
 California Department of Health Services
 Radiologic Health Branch, MS 7610
 P.O. Box 997414
 Sacramento, CA 95899-7414

For more information, go to www.dhs.ca.gov/rhb or phone (916) 327-6106.

Radiation Officer (printed name) S. Baker	Signature 	Telephone number 626-66-5135	Date 4/13/2005
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April 15, 2005

Mr. Mark Petes
Compliance Unit
California Department of Health Services
Radiologic health branch, MS 7610
P. O. Box 997414
Sacramento, Ca 95889-7414

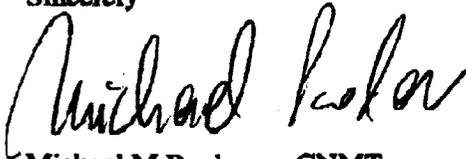
Mr. Petes,

As per our telephone conversation on 4/13, 2005 I am faxing you the data regarding Estimated absorbed dose due to mis-administration. *DONE 4/15/05*

This will be coming to you in the mail as well.

Thank you for your telephone consultation and your time.

Sincerely



Michael M Prodanov, CNMT
Nuclear Medicine Department
Eisenhower Medical Center
39000 Bob Hope Drive
Rancho Mirage, Ca 92270
Radioactive Material License Number 2425-33

Misadministration report on 4/12/2005

Patient was injected with 11.39 mci Tc Sestamibi iv for rest myocardial perfusion imaging by Mark Levin, CNMT

That was an in-patient.

Order was worded as "Exercise Stress Test".

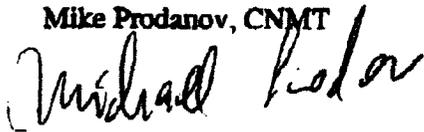
Nuclear medicine did receive a printed order stating that it was "Myocardial Perf Scan W / Treadmill".

Technologist injecting the patient did not clearly understand the order.

Further reports to EMC legal department as well as to the Department of Health will be filed, pending review by our RSO on 4/13/2005.

Mr Mark Petes at the State Department of Health was notified by phone on 4/13/2005 At about 1330 by me.

Mike Prodanov, CNMT

Handwritten signature of Michael Prodanov in cursive script.

April 13, 2005

Estimated Dosimeter following intravenous injection of 11.4 mCi Tc^{99m} Sestamibi

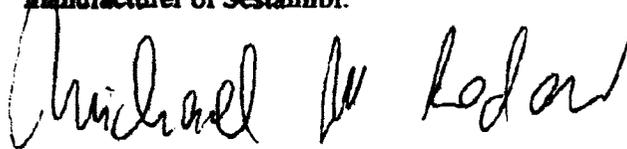
Our patient received 2.05 Rads to Upper Large Intestinal Wall

0.19 Rads to whole body

These figures are assumed that patient is a 70kg person, and receives 5.4 Rads to Upper Large Intestinal Wall and 0.5 Rads to whole body from a 30.0 mCi dose injected.

Since we injected 11.4 mCi, our estimated figures reflect that data.

**Absorbed dose data obtained from Package insert from Bristol-Myers Squibb,
manufacturer of Sestamibi.**

A handwritten signature in black ink, appearing to read "Michael M Prodanov". The signature is written in a cursive, flowing style.

Michael M Prodanov, CNMT

4/13/2005

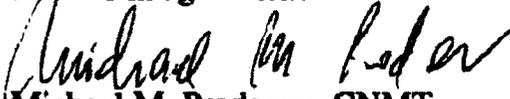
This is to certify that I have discussed the events preceding as well as resulting from the erroneous administration of Radioisotope to a patient on 4/12/2005 with Mark Levin, CNMT. He did indeed inject a patient with isotope while the order was not clearly defined in the patient's chart.

Our standard protocol is to verify order in the chart, confirm patient's identity by checking the name band as well as asking the patient to identify themselves.

All aspects of the protocol were followed, except there was no mention of "Nuclear or Isotope" stress test in the chart, rather just "Stress" test.

In the future, all aspects of the protocol for identifying proper patient as well as the appropriate procedure will be followed.

Mark is in agreement with me on this issue.


Michael M. Prodanov, CNMT


Mark Levin, CNMT