



St. Joseph Health Center
St. Joseph Hospital West

SSM St. Joseph Health Center
300 First Capitol Drive
St. Charles, MO 63301-2893
(636) 947 5000 phone

SSM St. Joseph Hospital West
100 Medical Plaza
Lake Saint Louis, MO 63367-1395
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www.ssmstjoseph.com

July 6, 2006

US Nuclear Regulatory Commission
Regional Licensing Section
2443 Warrenville Road
Lisle, IL 60532-4352

030-08664

RE: Misadministration (medical event) License 24-15159-01

Gentlemen:

I would like to report a medical event (misadministration) at St. Joseph Health Center on 6/28/2006 license number 24-15159-01. The patient who had been prescribed 15 uci I 131 for an uptake study was actually given 5.4 mci I 131. The event was discovered the same day. The authorized user does not anticipate any adverse medical effects to the patient since she was confirmed to be hyperthyroid by her blood work and by an elevated thyroid uptake. She had a history of a tubal ligation.

The patient and the patient's physician were informed about the actual dose given. Both the patient and the patient's physician were satisfied with the explanation and the outcome.

The licensee has implemented a corrective action to prevent a recurrence of the circumstances that resulted in this misadministration. A senior technologist will always be present from start to finish when I 131 is to be administered to a patient. This includes uptake, treatment and whole body scans related to I 131.

Sincerely,

A handwritten signature in black ink, appearing to read "Sidney M. Machefsky".

Sidney Machefsky, M.D.
Radiation Safety Officer

SM/bmg



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July 12, 2006

US Nuclear Regulatory Commission
Regional Licensing Section
2443 Warrenville Road
Lisle, IL 60532-4352

RE: Addended report as per request of Deborah A. Piskura

US Nuclear Regulatory Commission representative:

This letter is to report that a medical event that occurred at St. Joseph Health Center, St. Charles, MO, license number 24-15159-01 on 6/28/2006 at approximately 1:30 p.m. A patient was given 5.4 mCi of I-131 instead of 15 uCi of I-131. The patient was scheduled for a Thyroid uptake and scan.

The patient presented to the Nuclear Medicine Department and stated that she has hyperthyroidism. The physician's order was for an I-131 Thyroid uptake and Pertechnetate Thyroid scan for hyperthyroidism. The technologist mistakenly assumed that the patient had been previously diagnosed and came for a treatment dose of I-131. The technologist calibrated the 5.4 mCi capsule and prepared the dose for administration while another technologist entered the patient's information into the hospital information system to generate a requisition. The technologist confirmed the patient's name and birth date with the patient and then gave the patient the iodine dose and allowed the patient to leave. The technologist then proceeded to crosscheck the dose the patient received in the Pinestar dosing computer. She then realized that the patient was given the wrong I-131 dose.

She immediately reported the mistake to another technologist who informed the Nuclear Medicine supervisor and the radiologist on duty. The patient was paged over the hospital intercom, but did not respond. The radiologist contacted the patient's physician and reported the incident to him. The patient's physician indicated that he was going to order an I-131 hyperthyroidism treatment based on the patient's laboratory results anyway. It was determined that the patient was not harmed based on the patient's diagnosis of hyperthyroidism. The physicist was consulted and he agreed that the patient was not harmed. A written directive was generated and signed by Dr. Machefsky after the dose was given.

The patient was contacted and was informed of the medical event on June 29, 2006. Dr. Machefsky explained to the patient that he contacted the patient's physician and it was determined that the patient was to receive an I-131 treatment dose based on her hyperthyroid condition.



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St. Joseph Health Center strives to insure that all patients are handled in a safe matter. We have never experienced an event of this nature and we have taken corrective action to prevent any future occurrences.

Action plan:

1. The I-131 protocol has been revised and implemented.
2. The Nuclear Medicine Technologist orientation and competency checklist has been revised and implemented.

Sincerely,

Sidney Machefsky, M.D.
Radiation Safety Officer

Lewis Halverson, M.D.
Radiology Medical Director

enclosures



NUCLEAR MEDICINE DEPARTMENT

I-131 Protocol

- I. Greet the patient.
1. Take the patient's paperwork. Make sure the paperwork includes a face sheet from registration and a copy of the physician's orders.
 2. Establish who the patient is and what Nuc Med procedure they are going to have.
 3. Check the out-patient schedule to ensure that the patient is on the schedule and that the orders match the schedule.
 4. Ask the patient?
 - Do you have any drug allergies?
 - Are you taking thyroid meds?
 - If it is a woman of child bearing age she must have a negative pregnancy test, a tubal ligation or a hysterectomy.
- II If the patient is having I131 Therapy the patient will first need to talk to a radiologist who is an Authorized User for I131 Therapy. Wait for instructions from the radiologist about ordering a dose and scheduling the patient for the actual therapy.
- III If the patient is an Uptake go to the Hot Lab with the physician's order in hand. Find the patient's dose and put it in the dose calibrator. How much does it measure? Is this the correct dose and is there another capsule from the same lot number available for a standard. If yes have another tech check the dose and the physician's order. Go to the Pinestar computer make a dose sticker for the patient. Does the measured dose match the prescribed dose in the computer? If yes you may give the I-131 capsule to the patient.
- IV If the patient is having an I-131 Whole Body Scan or is receiving more than 30 uCi I131, additional paperwork for the NRC has to be filled out before administering the dose. This paperwork will include a permit form, a written directive, a patient identification form, a dose identification form and a form for the tech to fill out stating that all of the above was done and that the patient was given written information about patient safety. A radiologist who is an Authorized User must sign the paperwork. Go to the Hot Lab with the physician's order in hand. Find the patient's I-131 dose. The label will have the patient's name along with all the other needed information. Put the dose in the dose calibrator. How much does it measure? Is this the correct dose for the exam ordered? If yes have another tech check the dose and the physician's order. Go to the Pinestar computer and make a dose sticker for the patient. Does the measured dose match the prescribed dose in the computer? If yes you may give the I-131 capsule to the patient after you recheck the NRC paperwork and make sure that it is filled out correctly and the radiologist has signed the written directive.

St. Joseph Health Center
Nuclear Medicine Technologist Orientation and Competency Checklist

Employee _____	Hire Date _____	Instructor Initials	Employee Initials	Date
Radiopharmaceuticals				
How to order		_____	_____	_____
How to monitor upon arrival		_____	_____	_____
Proper technique for handling		_____	_____	_____
How to use dose calibrator		_____	_____	_____
Quality control-dose calibrator		_____	_____	_____
How to dispose of		_____	_____	_____
How to use the Pinestar computer for dose tracking		_____	_____	_____
Radiation Safety				
Badges		_____	_____	_____
Wipe testing		_____	_____	_____
Monitoring		_____	_____	_____
Clean up of spills		_____	_____	_____
Hand survey		_____	_____	_____
Daily department survey		_____	_____	_____
Introduction & use of				
DPX – Alpha Bone Density		_____	_____	_____
Forte		_____	_____	_____
Siemens camera & computer		_____	_____	_____
Uptake probe & counter		_____	_____	_____
Quality control for all of the above (floods-bars etc.)		_____	_____	_____
How to perform specific procedures				
ER chest pain Mibi Spect		_____	_____	_____
TI 201 Mibi Spect		_____	_____	_____
Myoview Stress-Rest		_____	_____	_____
MI scan – Muga		_____	_____	_____
TI 201 stress and rest – T12 planar		_____	_____	_____
TI 201 Spec T – persantine adenosine		_____	_____	_____
Renal studies – Capoten & Lasix		_____	_____	_____
Thyroid uptake & scan		_____	_____	_____
SR 89 therapy (tech's responsibilities)		_____	_____	_____
I – 131 thyroid therapy (tech's responsibilities)		_____	_____	_____
Whole body I – 131 scan		_____	_____	_____
Patient permit		_____	_____	_____
Written directive		_____	_____	_____
Patient identifier		_____	_____	_____
Dose identifier		_____	_____	_____
Completion document		_____	_____	_____
Bone scan whole body		_____	_____	_____
Bone with spect		_____	_____	_____
Liver spleen		_____	_____	_____
VQ lung		_____	_____	_____

	Instructor Initials	Employee Initials	Date
Gallium study	_____	_____	_____
Testicular study	_____	_____	_____
Parathyroid imaging	_____	_____	_____
GI bleed	_____	_____	_____
Octreo scan	_____	_____	_____
Hemangioma with spect	_____	_____	_____
Diff VQ lung	_____	_____	_____
Indium study	_____	_____	_____
Meckel's	_____	_____	_____
Hepato-biliary	_____	_____	_____
Cisternogram - shunt studies	_____	_____	_____
Dexa hip and spine	_____	_____	_____
Patient Injections			
Copy of physician's orders	_____	_____	_____
How to make patient dose stickers	_____	_____	_____
Prior to exam patient education	_____	_____	_____
Proper technique for injection	_____	_____	_____
Disposal of sharps - blood products	_____	_____	_____
Disposal of radioactive materials	_____	_____	_____
Record keeping in house	_____	_____	_____
Supplies - location of/restocking	_____	_____	_____
Pregnant patient policy	_____	_____	_____
Age specific (geriatric special needs)	_____	_____	_____
Starting IVs	_____	_____	_____
Patient Transportation			
Walk - w/c - str - bed	_____	_____	_____
O ₂ use and location of	_____	_____	_____
Isolation precautions	_____	_____	_____
IV poles - I meds - pumps	_____	_____	_____
"Smooth" mover use and location of	_____	_____	_____
Age specific special requirements	_____	_____	_____
Call			
Use of beeper	_____	_____	_____
Location of call board in radiology office	_____	_____	_____
Call tech's responsibilities	_____	_____	_____
How to use Rad Works	_____	_____	_____
How to report patient results	_____	_____	_____
How to use VRC	_____	_____	_____
Office			
How to use in house computer	_____	_____	_____
How to use phone system	_____	_____	_____
Generation of patient's requisition	_____	_____	_____
Coding patient's requisitions	_____	_____	_____
Patient record keeping in house - NRC	_____	_____	_____
Set up of patient films	_____	_____	_____
Reporting patient results	_____	_____	_____

	Instructor Initials	Employee Initials	Date
Film Processing			
Drystar printer & supplies	_____	_____	_____
Codonics printer & supplies	_____	_____	_____
Computer			
HBOC	_____	_____	_____
ABN	_____	_____	_____
Pegasys	_____	_____	_____
Pinestar	_____	_____	_____

PLEASE READ AND SIGN BELOW:

I have completed orientation to the job I am expected to perform and have had my questions answered to my satisfaction. I can perform the job in a manner safe for myself and others.

Employee
Date

Instructor
Date

St Joseph Health Center
St Charles, MO

Thyroid Uptake

→ Radiopharmaceutical: I-131 as Sodium Iodide capsule

Dose: Adult-15 uci - 18 uci

Pediatric - see physician

Route of Administration: Oral

Ensure that there is an I-131 capsule with the same lot number for a standard.

Procedure: Use the well-counter with the probe calibrated for I-131 with a 100% window. Count the standard capsule in the Lucite phantom for two minutes. Count room background for two minutes. Count the thyroid gland for two minutes. Count the patients thigh for two minutes. Do all sets of counts twice.

Formula: $\frac{\text{CPM thyroid} - \text{CPM patient bkg}}{\text{CPM standard} - \text{CPM room bkg}} \times 100 = \% \text{ uptake}$

24 hour normal = 10% - 25%

6 hour normal = 2% - 14%

St Joseph Health Center
St Charles, Mo

I-131 Whole Body Scan

Radiopharmaceutical: I-131 as Sodium Iodide capsule

Dose: Adult 5 mCi

Pediatric- as directed by physician

Route of administration: Oral

Check the I-131 capsule for correct patient name.

Make sure the written directive is filled out.

Procedure: Image at 48 hours unless otherwise directed. Use standard or large field-of-view camera with high energy diverging or parallel collimator calibrated for 360 keV with a 20% window. Routine views include:

- Anterior head and neck
- Anterior chest
- Anterior abdomen
- Anterior pelvis
- Posterior chest
- Posterior lumbar spine
- Posterior pelvis

Collect for 50K or 10 minutes whichever occurs first. Check film with physician before moving patient as an occasional pinhole view of the neck may be required.

St Joseph Health Center
St Charles, MO

Out Patient Protocol

- 1) Greet the patient.
- 2) Take the patient's paperwork. Insure that the patient has registered and has orders for the exam on the out patient schedule.
- 3) Ask the patient if they have any drug allergies. Women of child bearing age if they are pregnant.
- 4) With the patient's orders in your hand, go to the Hot Lab and prepare their dose and enter it into the Pine star dose computer.
- 5) Make sure you have the correct patient and dose by using two patient identifiers and that the drawn dose is within acceptable limits and that it is the proper radionuclide for the patient's exam.
- 6) Administer the dose only after all of these safeguards have been done.
- 7) If you have any doubts about anything do not administer the dose. Take a time out.
- 8) After completing the patient's exam make sure the patient is directed out of the department and is told that a report will be sent to their referring physician.

8/12/06

Dear Ms. Piskura,

I want to personally thank you for all the advice and expertise you have given our nuclear medicine department. Your recommendations have resulted in a safer department at St. Joseph's Health Center. We appreciate all the time and advice rendered.

Sincerely yours
Sandy Hechler
R50



**NUCLEAR MEDICINE DEPARTMENT
I-131 Protocol**

- I. **Greet the patient.**
 1. Take the patient's paperwork. Make sure the paperwork includes a face sheet from registration and a copy of the physician's orders.
 2. Establish who the patient is and what Nuclear Medicine procedure they are going to have.
 3. Check the out-patient schedule to ensure that the patient is on the schedule and that the orders match the schedule.
 4. Ask the patient?
 - Do you have any drug allergies?
 - Are you taking thyroid meds?
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- II. If the patient is having I131 Therapy the patient will first need to talk to a radiologist who is an Authorized User for I131 Therapy. Wait for instructions from the radiologist about ordering a dose and scheduling the patient for the actual therapy.

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make sure that it is filled out correctly and the radiologist has signed the written directive.

I have observed two I-131 administration and performed two I-131 administrations following the above protocol.

_____ Tech _____ Chief Tech _____ RSO

Didactic training on administration and safety principles including completion of the written directive when appropriate for all I-131 doses greater than 30 uci has been implemented. The education will include:

- 1) Use of the dose calibrator
- 2) Use of the pine star dosing computer
- 3) Correct identification of the patient
- 4) Matching the patient to the exam being performed
- 5) Matching the radiopharmaceutical to the exam being performed and to the patient
- 6) Reading the labels on the unit doses

Any new Nuclear Medicine Technologist will observe two I-131 administration from start to finish, including completion of the written directive when indicated. This will include I-131 uptakes, I-131 whole body scans and I-131 therapy cases. The new Nuclear Medical Technologist will perform two administrations of I-131 under the supervision of a senior technologist who is a CNMT. After completing the above in house training the RSO and the chief technologist will confirm the competency of the newly hired technologist and each one will sign off on the I-131 Protocol form.

These new procedures and corrective actions have been implemented. They will be discussed along with the misadministration at the next Radiation Safety Committee meeting.