SSM HEALTH CARE
St. Joseph Health Center
St. Joseph Hospital West

SSM St. Joseph Health Center
300 First Capitol Drive
St. Charles, MO 63301-2893
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030- 08664

July 6, 2006

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

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 patent'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,

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

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SSM HEALTH CARE St. Joseph Health Center

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
Galluim 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.

8/2/06

Dear Ms. Pistura,

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,

Sidney Hackbarth RT
RSO

SSM HEALTH CARE St. Joseph Health Center

NUCLEAR MEDICINE DEPARTMENT
I-131 Protocol

I. Greet the patient.

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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.

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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.