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Hospital Hill
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Lawrence Ricci, D.O.
2301 Holmes St
Kansas City, MO 64108

May 29, 2014

Andrew Bramnik
Health Physicist (Inspector)
U.S. Nuclear Regulatory Commission Region III

Dear Mr. Bramnik:

This letter and documents are in follow up to an NRC inspection of Truman Medical Center, Thursday May 22nd and Friday May 23rd.

Per NRC regulations Dr. John Steven Dykstra and Dr. Charles F Schwab should be removed within 30 days of termination: Our health physicist is in the process of creating a letter to generate an amendment to have both physicians removed from the RAM license. We have also updated our policy "Safety-Radiation Safety Officer (RSO) – Duties and Responsibilities" to reflect the removal of any separated Radiologist from the RAM license. *see attached policy*

We had two written directive/Quality Management Program forms signed by Dr. Jean Dykstra in January: Due to an oversight by nuclear technologists and physician this form was signed by Dr. Jean Dykstra when she was not on the license as an authorized signer. Upon review she has an AOBR certificate which will qualify her to sign written directives below 33 millicuries which both of these were below. Our health physicist is in the process of creating a letter to generate an amendment to have her added to the license to be able to sign written directives below 33 millicuries. Going forward she will not sign any directives until we have her on the license as a 300 user following preceptorship. We have also updated our policy "Safety-Radiation Safety Officer (RSO) – Duties and Responsibilities" to reflect the process of adding new Radiologist to the RAM license. *see attached policy*

Release of Patients Based on Measure Dose Rate calculations: Regarding the calculations of release criteria for patients dosed with I-131. Prior to April 2014 the Written Directive was based on a form developed by DTC (the previous health physics advisors). It referred to Patient-Specific factors per Regulatory Guide 8.39, Appendix B, E-0.25. These are the calculations that you were looking for. *see attached DTC form Patient Name: Standard Protocol*
This would be the standard based on a maximum dose of 220 mCi, it indicates that a patient dosed less than 220 mCi would measure below 0.5 rem required by regulations for the release of patients. Moving forward we will be utilizing the Cardinal Health Form 123C Record of Release Following Therapeutic Dose and attach to the QMP. *see attached Cardinal Form 123C*

I feel the above information should address all items as verbally discussed on Friday May 23rd. If you need any further information please don't hesitate to contact me.

Sincerely,

Lawrence R. Ricci, D.O.
Chairman, Department of Radiology
Radiation Safety Officer

McQueen, Andrea R

From: McQueen, Andrea R
Sent: Friday, May 23, 2014 2:25 PM
To: [redacted]
Subject: NRC License

Dr. Jean Dykstra,

We were audited by the NRC today and there were 2 written directive/Quality Management Program forms signed by you in January. Due to us only having you on the license as a 10 CFR 35.100 and 35.200 you are not licensed to sign these forms. Going forward please direct any request to one of the 300 users until we can get you on the license as a 300 user.

Thanks,

Andrea McQueen
Sr. Administrative Assistant / Medical Imaging -Radiology
Truman Medical Center Hospital Hill
2301 Holmes Street, Kansas City, MO 64108)
(816) 404-0751 | (816) 404-0701 fax) | [illegible]
Trumed.org |

* Email sent to Dr. Jean Dykstra, also followed up with phone call by Dr. Ricci.

MAXIMUM LIKELY DOSE TO AN INDIVIDUAL EXPOSED TO A PATIENT ADMINISTERED NaI-131 FOR THERAPY

Institution: Kansas Medical Center Date: _____

Patient Name: [illegible] Patient ID: _____

STEP 1

Has the patient had a thyroidectomy? ✓ Yes ___ No (If YES, go to Step 2. If NO, go to Step 4)

STEP 2 - Patient Information

i) Administered dose of NaI-131: 220 mCi (a)

ii) Time any individual will spend with patient during the first 8 hours after I-131 administration: 8 hrs ÷ 8 hrs = 1 (b)

iii) Patient's thyroid uptake: (If unknown, enter 0.05) 0.05 (c)

iv) Patient's body uptake: ? Do I do an uptake? How 1 - 0.05 = 0.95 (c) (d)

Audry

STEP 3 - Dose Calculation

$$D(\infty) = \frac{34.6\Gamma Q_0}{r^2}[E_1T_p(0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}E_2F_1T_{1eff} + e^{-0.693(0.33)/T_p}E_2F_2T_{2eff}]$$

Γ	= 2.2 R-cm²/mCi-hr	T_p	= 8 d	E_1	= (b)
F_1	= (d)	T_{1eff}	= 0.32 d	E_2	= 0.25
F_2	= (c)	T_{2eff}	= 7.3 d	r	= 100 cm

*Reference: NRC Regulatory Guide 8.39, April 1997

D(∞) = (220 (a) x 0.0076) [(1 (b) x 0.180) + (0.95 (d) x 0.078) + (0.05 (c) x 1.77)]

D(∞) = (1.67) [(0.180) + (0.0741) + (0.0885)]

D(∞) = (1.52) [0.3426]

D(∞) = 0.52 rem *Limit: 0.5 rem* Initials: [illegible]

END

Form provided by: DTC, Inc., 5930 Roe Ave., Mission, KS 66205 (913) 236-6000

STEP 4 - Patient Information (Non-Thyroidectomy Patient)

i) Administered dose of NaI-131: 100.5 mCi (a)

ii) Time any individual will spend with patient during the first 8 hours after I-131 administration: 8 hrs ÷ 8 hrs = 1 (b)

iii) Patient's thyroid uptake: (If unknown, enter 0.80) Do I do an uptake? 0.80 (c)

iv) Patient's body uptake: 1 - 0.80 (c) = 0.2 (d)

STEP 5 - Dose Calculation

$$D(\infty) = \frac{34.6\Gamma Q_0}{r^2}[E_1T_p(0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}E_2F_1T_{1eff} + e^{-0.693(0.33)/T_p}E_2F_2T_{2eff}]$$

Γ	= 2.2 R-cm²/mCi-hr	T_p	= 8 d	E_1	= (b)
F_1	= (d)	T_{1eff}	= 0.32 d	E_2	= 0.25
F_2	= (c)	T_{2eff}	= 5.2 d	r	= 100 cm

*Reference: NRC Regulatory Guide 8.39, April 1997

D(∞) = (100.5 (a) x 0.0076) [(1 (b) x 0.180) + (0.2 (d) x 0.078) + (0.8 (c) x 1.26)]

D(∞) = (0.460) [(0.180) + (0.02) + (1.01)]

D(∞) = (0.460) [1.21]

D(∞) = 0.55 rem *Limit: 0.5 rem* Initials: _____

END

Record Retention Advisory: Keep this record for 3 years.

RECORD OF RELEASE FOLLOWING THERAPEUTIC DOSE

Records of Release are required for every administration unless the release was based on administered activity and that activity is less than or equal to Column 1 of Table 1 (see Section 18(a)) values.

1. Date of Administration: _____

2. Radionuclide: _____ Activity: _____ mCi

3. Patient Name: _____ 4. Patient ID#: _____

5. Additional Information (Check One)

☐ Immediate Release Based on Measured Dose Rate

a. Instrument: _____ S/N: _____
b. mrem/hr at 1 meter - patient: _____
mrem/hr at 1 meter - limit :_____
(Table 4, Release - see Section 18b) _____
c. Name of Individual Performing Survey: _____

☐ Delayed Release Based on Measured Dose Rate

a. Instrument: _____ S/N: _____
b. mrem/hr at 1 meter - patient: _____
mrem/hr at 1 meter - limit (Table 4, Release): _____
c. Name of Individual Performing Survey: _____

☐ Immediate Release Based on Patient-specific or Case-Specific Calculations

a. Patient Information Form Completed.
b. Patient-specific or Case-specific calculations on file.

☐ Delayed Release Based on Radioactive Decay Calculations

a. Date and Time of Administration:_____ at _____ am/pm
b. Date and Time of Release: _____ at _____ am/pm
c. Results of Decay Calculations: _____ mCi
d. mCi Limit (Table 4, Release): _____ mCi

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Subject: **SAFETY – RADIATION SAFETY OFFICER (RSO) – DUTIES AND RESPONSIBILITIES**

Originator: Department of Medical Imaging

Approval Date: ~~**September 13, 2012**~~**May 28, 2014**

Approved By: Lawrence R. Ricci, D.O., Chairman, Department of Radiology

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Policy:
To establish typical duties and responsibilities of the Radiation Safety Officer (RSO). The RSO is a fulltime, part-time, or consulting radiologist who is a doctor of medicine or osteopathy qualified by education and experience in radiology, supervises ionizing radiology services.

Scope:
Radiation Safety Officer under recommendation of Medical Staff office.

Procedure:

I. The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. The credentialing process is based on recommendations by the organized medical staff. Typically, these duties and responsibilities include ensuring the following:
   A. Stopping unsafe activities involving licensed material.
   B. Radiation exposures are ALARA.
   C. Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented.
   D. Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions.
   E. Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.

F. Personnel training is conducted and is commensurate with the individual's duties regarding licensed material.
G. Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided.
H. When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained. These records are reviewed monthly by the Radiation Safety officer. If ALARA amount is exceeded on the monthly or quarterly report, the RSO will notify the employee in writing. Counseling as needed. Letter template attached.
I. Licensed material is properly secured.
J. Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.
K. Involvement with Patient Safety regarding any patient safety concerns.
L. Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
M. Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective actions(s) are identified, and timely corrective action(s) are taken.
N. Audits of the radiation protection program are performed at least annually and documented.
O. If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented.
P. Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
Q. Licensed material is disposed of properly.
R. Appropriate records are maintained.
S. An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.
   a. A request will be sent to the NRC to add any new Radiologist to our RAM license within 30 days of hire date.
   ~~S.~~b. A request will be sent to the NRC to remove any Radiologist that has been separated from Truman Medical Center from our RAM license within 30 days of separation.

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II. Truman Medical Center Department of Medical Imaging requires the Radiation Safety meetings be held bi-annually unless the Radiation Safety Officer (RSO) deems otherwise.

Original Approval Date: May 5, 2006
Revised Dates: (list dates in ascending order)
Revised Date: August 3, 2006
Revised Date: June 23, 2010
Revised Date: July 8, 2010
Revised Date: October 5, 2011
Revised Date: September 13, 2012
Revised Date: May 28, 2014

Reviewed Dates: (list dates in ascending order)
Reviewed Date: February 2008 Initials: _____
Reviewed Date: February 15, 2010 Initials: cjj
Reviewed Date: _____ Initials: _____

Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.

I accept the above responsibilities,

_____ _____
Signature of Management Representative Signature of Radiation Safety Officer

_____ _____
Date Date

cc: Affected department heads

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DATE:

TO:

FROM: Lawrence R. Ricci, D.O., Radiation Safety Officer

SUBJECT: Notification of Radiation Exposure

Each month, the Radiation Safety Officer reviews the radiation exposure monitor badge results. When an excessively high exposure is present, this creates a healthcare concern for that individual.

Name: _____ Dept: _____

Month of: _____ YTD: _____ Lifetime: _____

Deep _____ mrems	Deep _____ mrems	Deep _____ mrems
Eye _____ mrems	Eye _____ mrems	Eye _____ mrems
Shallow _____ mrems	Shallow _____ mrems	Shallow _____ mrems

Comments:

_____
Radiation Safety Officer