Missouri Baptist
MEDICAL CENTER

3015 N. Ballas Road
St. Louis, Missouri 63131

314-996-5000
www.missouribaptist.org

December 21, 2012
EA-12-242
EA-10-239
NMED 120643 (closed)

Anne T. Boland, Director
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: NRC routine inspection report #03008325/12001(DNMS); EA-12-242 and notice of violation-Missouri Baptist Medical Center

Ms. Boland,

In response to your letter dated December 10, 2012 addressed to Dr Ranney we at Missouri Baptist Medical Center are choosing to respond via a written response.

In regard to your concern with the level of oversight of the radiation oncology service by the radiation safety officer, we met with our Chief of Medical Staff and discussed how we could improve in this area. Our Radiation Safety Officer also had a discussion with Dr Fagundes who is our Medical Director of Radiation Oncology. It was collectively decided that our Radiation Safety Officer will observe procedures in the Radiation Oncology department to include: HDR Breast, HDR GYN, Zevalin, Samarium, Iodine 131 and Prostate Seed Implants when they are scheduled in order to further his knowledge of the procedures and the department operations. This is being done in order to ensure he has the same level of knowledge for the Radiation Oncology service as he does for the Nuclear Medicine program. He will observe a minimum of one procedure per quarter.

In regard to the process concern witnessed during the routine visit on October 18-19, 2012 (The Physicist transposed the numbers 32 to 23 while doing electronic form calculation. However, the correct dose was delivered to the patient). We have submitted via fax the new policies stating our procedures on December 3, 2012. In addition we have established an audit tool to audit all procedures for accuracy starting October 22, 2012. We have audited 100% of procedures performed to date and demonstrated 100% compliance with our revised policy. Going forward, an audit of all procedures will be completed by a person in the radiation oncology department, with results reported quarterly to the Radiation Safety Officer who will review it, sign it and keep it on file with other related documents. The audit will also be reported quarterly to the Radiation Safety Committee. The Radiation Oncology Staff were trained on the revised procedures. Training was completed prior to December 3, 2012. In addition the Radiopharmaceutical Therapy Record prescribed activity will be compared to the assayed

activity and any differences observed will be recorded. This change was made October 22, 2012 and on November 9, 2012 the verbiage to "% Difference from the Prescribed Activity" was added to the form.

We have attempted, unsuccessfully, to contact Mr. Geoffrey Warren to ascertain if the faxes that we sent on 12/3/12 were received. Included in that fax were:

1. Radiopharmaceutical Pre-treatment written directive verification
2. Radiopharmaceutical Therapy Record form
3. Radiopharmaceutical Pre-treatment checklist form
4. Radiopharmaceutical Pre-treatment checklist training Policy
5. Radiopharmaceutical QMP Review Policy (including the form)
6. Radiopharmaceutical QMP Review Training Policy

We will be sending the above 5 (five) documents attached to this written response.

Please let me know if there if I can be of any further assistance. We appreciate your consideration.

Respectfully submitted,

Thomas J Moenster

Thomas J Moenster, Radiation Safety Officer
Missouri Baptist Medical Center
3015 North Ballas Road
St Louis, MO 63131
Office: 314-996-5397
Cell: 314-574-7039

Core Policy Title	Radiopharmaceutical pre-treatment written directive verification
Hospital Name	*Missouri Baptist Medical Center*

I. Policy/Procedure Requirments:

A. Establish a standard of practice in the verification of the written directive for radiopharmaceutical administration.

II. Procedure:

A. Assessment/Re-assessment/Evaluation:

B. Materials and Equipment:

i. Impac EMR
ii. Written prescription
iii. Radiopharmaceutical Therapy Record
iv. Radiopharmaceutical pre-treatment checklist

C. Implementation:

i. If a radiopharmaceutical is ordered, the physician will provide the physicist with a written prescription detailing the patient's name, the radiopharmaceutical, and the prescribed dose.

ii. Based on the written prescription and the patient's electronic medical record the written directive (prescription) portion of the radiopharmaceutical therapy record is completed.

iii. Once the written directive has been filled out in the radiopharmaceutical therapy record, it must be verified by someone other than the individual who completed it. This individual will complete the radiopharmaceutical pre-treatment checklist.

iv. The diagnosis in the radiopharmaceutical therapy record will be verified with the diagnosis in the electronic medical record, and a check placed in the "Diagnosis agrees with EMR" field of the Radiopharamceutical pre-treatment checklist.

v. The radionuclide in the radiopharmaceutical therapy record will be verified with the radionuclide specified in the written prescription, and a check placed in the "Radionuclide" field of the radiopharmaceutical pre-treatment checklist.

vi. The form of the radionuclide will be verified with the written prescription, and a check placed in the "Form of Radionuclide" field of the radiopharmaceutical pre-treatment checklist.

vii. The route of administration in the radiopharmaceutical therapy record will be verified with the written prescription, and a check placed in the "Route of Administration" field of the radiopharmaceutical pre-treatment checklist.

viii. The activity in the radiopharmaceutical therapy record will be verified with the written prescription. If the prescription is written in mCi/kg, the activity can be calculated using the weight of the patient provided in the electronic medical record. If the weight is provided in lbs, the weight in lbs is divided by 2.2 to get the weight in kg. The activity is then the prescribed activity in mCi/kg multiplied by the patient's weight in kg. If the radiopharmaceutical is Zevalin (Y-90), the maximum activity is 32 mCi, therefore if the calculated activity is greater than 32mCi for Zevalin the prescribed activity is 32mCi. This calculation, if necessary, is placed in the "Activity calculations" field of the radiopharmaceutical pre-treatment checklist.

ix. Once the activity of the radiopharmaceutical has been verified place a check in the "Activity" field of the radiopharmaceutical pre-treatment checklist.

x. Once the radiopharmaceutical pre-treatment checklist has been completed, the reviewer will sign and date the radiopharmaceutical pre-treatment checklist.

xi. The radiopharmaceutical pre-treatment checklist will be kept in the patient's electronic medical record.

D. Patient Education: NA

III. Documentation: NA

IV. General Information: NA

V. Supportive Evidence: NA

Missouri Baptist MEDICAL CENTER
BJC HealthCare℠

Department of Radiation Oncology
RADIOPHARMACEUTICAL THERAPY RECORD

Patient Name: _____ Birth Date: _____ RadOnc#: _____

Primary Site: _____ Allergies: _____

Physician: _____ Ref. Physician(s): _____

PRESCRIPTION

Agent:	Form:	Route of Administration:
☑ Sodium Iodide (I-131)	☐ Solution	☑ Oral
☐ Quadramet (Sm-153)	☐ Colloid	☐ Instillation
☐ Zevalin (Y-90)	☑ Capsule	☐ Intravenous
Other	Other	Other

Prescribed Activity: _____ mCi Physician Signature: _____

Special Physics Requested? ☐ Yes ☑ No Physician Signature: _____

PACKAGE ACCEPTANCE

Package Condition is acceptable? ☐ Yes ☑ No Explain: _____

Wipe Test (100cm² or equivalent): _____ cpm - _____ bkgd = _____ netcpm Must be less than 2000 cpm/100cm² for I-131, Sm-153, Y-90.
(Lead Pig)

Exposure: Survey Instrument: _____ SN: _____ Calibrated: _____

At surface (< 200 mRem/h): _____ At 1m (< 10 mRem/h): _____ Transport Index: _____

ASSAY

Manufacturer	Lot#	Manufacturers Activity	Assayed Activity	% Difference from Prescribed Activity	Difference < 10%
				100.00%	NO

Physicist Signature: _____

ADMINISTRATION

Permit has been signed? ☐ Yes ☐ No

☐ Patient Identified by two methods
☐ Prescription agrees with container label
☐ Physicist has verified label accuracy
☐ Patient denies pregnancy/breast feeding
☐ Measured activity agrees with prescription within 10%

Dose Administered: Activity: _____ mCi Volume: NA

Date: _____ Time: _____

Patient given written safety instructions? ☐ Yes ☐ No

Physicist Signature: _____

PATIENT INSTRUCTIONS AND RELEASE CALCULATION

For I-131 patients, release instructions are required if the dosage is greater than 7 mCi or the measured dose rate is greater than 2 mRem/h at 1 meter from the patient. A release calculation is required if the dosage is greater than 33 mCi or the dose rate is greater than 7 mRem/h at 1 meter. Therefore, for therapeutic treatments, which always involve doses above 50 mCi, both patient instructions and release instructions are required.

We use the factor 2.27 mRem/mCi to determine maximum exposure to a member of the public, as discussed in "Rationale for Calculating Maximum Exposure to a Member of the Public for I-131 Treatments". Maximum exposure must be less than 500 mRem for release of the patient to take place.

Administered _____ mCi * 2.27 mRem/mCi = _____ mRem (exposure to public)

For Sm-153 patients, instructions are required if dosage is greater than 140 mCi and a release calculation is required of dosage is greater than 700 mCi. Doses are usually much less than 140 mCi and never as high as 700 mCi. Dose is typically 1 mCi for each kilogram of patient mass.

For Y-90 patients, "activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes."

Patient will be released: _____ (date)

Physicist Signature: _____

PATIENT AND AREA SURVEY

Exposure: Survey Instrument: _____ SN: _____ Calibrated: _____

Patient: At surface (1 foot)): _____ mR/h At 1m: _____ mR/h

Area: Including gloves, table, floor, sing, cup, medicine cup

Staff: Including hands, shoes, clothing

All area and staff measurements at background (< 0.02 mRem/h)? ☐ Yes ☐ No

Explain: _____

Physicist Signature: _____

EQUIPMENT DISPOSITION

(For Y-90 and Sm-153 Only)

All equipment contaminated during treatment stored in hot lab (e.g., tubing, syringes) ☐ Yes ☐ No ☑ NA

Physicist Signature: _____

PACKAGE RETURN

Wipe Test (100cm^2 or equivalent): (External Packaging) [ ] cpm - [ ] bkgd = [ ] netcpm Must be less than 2000 cpm/100cm^2 for I-131, Sm-153, Y-90.

Exposure: Survey Instrument: [ ] SN: [ ] Calibrated: [ ]

At surface (< 200 mRem/h): [ ] At 1m (< 10 mRem/h): [ ] Transport Index: [ ]

Packaging Disposition: [✓] Return [ ] Dispose [ ] Decay

Physicist Signature: [ ]

STAFF BIOASSAY

Staff Name:	Net Activity (uCi):	Results:	Date:	Time:
		Fail		
		Fail		
		Fail		

Physicist Signature: [ ]

COMMENTS

[ ]

CRC 15R Settings: I-131 (I-131); Sm-153 (259, Rdg. * 100); Y-90 (42 – 58, Rdg. * 10)

Missouri Baptist
MEDICAL CENTER
BJC HealthCare℠

Radiopharmaceutical
pre-treatment checklist

Written directive verification

Patient Name

	Correct	Comments
Diagnosis agrees with EMR	☐	
Radionuclide	☐	
Form of Radionuclide	☐	
Route of Administration	☐	
Activity	☐	
Activity calculations		

Reviewer:

Core Policy Title	Radiopharmaceutical Pre-treatment checklist training
Hospital Name	*Missouri Baptist Medical Center*

I. Policy/Procedure Requirements:

A. Establish a standard of practice for educating the staff to perform the radiopharmaceutical pre-treatment checklist.

II. Procedure:

A. Assessment/Re-assessment/Evaluation:

B. Materials and Equipment:

i. Radiopharmaceutical Therapy Record (RTR)
ii. Radiopharmaceutical pre-treatment checklist
iii. Radiopharmaceutical pre-treatment checklist policy

C. Implementation:

i. Annually or new staff completing the radiopharmaceutical pre-treatment checklist will be trained by a medical physicist.
ii. The physicist will review the radiopharmaceutical pre-treatment checklist policy with the staff.
iii. The physicist will review with the staff all aspects of the written prescription provided by the physician for each radiopharmaceutical.
iv. The physicist will review with the staff the written directive in the radiopharmaceutical therapy record.
v. The physicist will review with the staff the calculations for the prescribed activity for the applicable radiopharmaceuticals.
vi. The physicist will review the radiopharmaceutical pre-treatment checklist with the staff.
vii. Upon completion of the training the staff will sign stating that they have received the radiopharmaceutical pre-treatment checklist training.
viii. The physicist will keep a record of the staff training.

D. Patient Education: NA

III. Documentation: NA

IV. General Information: NA.

V. Supportive Evidence: NA

Core Policy Title	Radiopharmaceutical QMP Review
Hospital Name	*Missouri Baptist Medical Center*

I. Policy/Procedure Requirements:

A. Establish a standard of practice for performing the radiopharmaceutical QMP review.

II. Procedure:

A. Assessment/Re-assessment/Evaluation:

B. Materials and Equipment:

i. Radiopharmaceutical Therapy Record (RTR)
ii. Radiopharmaceutical QMP Review Form

C. Implementation:

i. Each quarter a review of the written directive and the treatment administration records will be performed for each patient receiving a radiopharmaceutical.
ii. The reviewer will place the procedure date in the QMP field marked implant date. The procedure date is found in the RTR field A, as seen in the example RTR.
iii. The reviewer will verify the written directive isotope in Field B of the RTR. Once verified, the reviewer will place a check in the "Written Directive Isotope" column of the Radiopharmaceutical QMP Review Form.
iv. The reviewer will verify the written directive radiopharmaceutical form in Field C of the RTR and place a check in the "Written Directive Form" field of the Radiopharmaceutical QMP Review Form.
v. The reviewer will verify the written directive route of administration in field D of the RTR and place a check in the "Written Directive Route" field of the Radiopharmaceutical QMP Review Form.
vi. The reviewer will verify the written directive activity, field E of the RTR, and place a check in the "Written Directive Activity" field of the Radiopharmaceutical QMP Review Form.
vii. The reviewer will verify that the written directive has been signed by the physician, field F of the RTR, and place a check in the "Written Directive Signed" field of the Radiopharmaceutical QMP Review Form.
viii. The reviewer will verify that the written directive has been dated by the physician, field G of the RTR, and place a check in the Radiopharmaceutical QMP Review Form.
ix. The reviewer will verify that the radiopharmaceutical has been assayed, field H of the RTR, and that this agrees with the prescribed activity, field E of the RTR. The reviewer will then place a check in the "Assay" field of the Radiopharmaceutical QMP Review Form.
x. The reviewer will verify that the patient was identified by two methods, field I of the RTR, and place a check in the "Patient Identified" field of

the Radiopharmaceutical QMP Review Form.

xi. The reviewer will verify that the measured activity of the radiopharmaceutical agrees with the prescribed activity, field J of the RTR, and place a check in the "Verify Script" field of the RTR.

xii. The reviewer will verify that a physicist has reviewed the activity of the radiopharmaceutical prior to administration, field K of the RTR, and place a check in the "Physics Review" field of the radiopharmaceutical QMP Review Form.

xiii. The reviewer will verify that the dose administered to the patient, field L of the RTR, agrees with the prescribed activity, field E of the RTR, and place a check in the "Administration agrees with Script" field of the Radiopharmaceutical QMP Review Form.

xiv. If any of the fields to be verified in the Radiopharmaceutical QMP Review Form are not satisfactory, indicate on the form and notify the physicist and/or the physician.

xv. Once all of the radiopharmaceutical patients for the quarter have been reviewed the reviewer will sign and date the Radiopharmaceutical QMP Review Form.

D. Patient Education: NA

III. Documentation: See attached RTR and Radiopharmaceutical QMP Review Form

IV. General Information: NA.

V. Supportive Evidence: NA

Missouri Baptist MEDICAL CENTER
BJC HealthCare

Department of Radiation Oncology
RADIOPHARMACEUTICAL THERAPY RECORD

Patient Name: _____ Birth Date: _____ RadOnc#: _____

Primary Site: _____ Allergies: _____

Physician: _____ Ref. Physician(s): _____

PRESCRIPTION

Agent: B
- [x] Sodium Iodide (I-131)
- [ ] Quadramet (Sm-153)
- [ ] Zevalin (Y-90)
- Other

Form: C
- [ ] Solution
- [ ] Colloid
- [x] Capsule
- Other

Route of Administration: D
- [x] Oral
- [ ] Instillation
- [ ] Intravenous
- Other

Prescribed Activity: E mCi Physician Signature: F Amy Sommer 2012.11.09 11:23:53 -06'00' G

Special Physics Requested? [ ] Yes [x] No Physician Signature: _____

PACKAGE ACCEPTANCE

Package Condition is acceptable? [ ] Yes [x] No Explain: _____

Wipe Test (100cm² or equivalent): _____ cpm - _____ bkgd = _____ netcpm Must be less than 2000 cpm/100cm² for I-131, Sm-153, Y-90.
(Lead Pig)

Exposure: Survey Instrument: _____ SN: _____ Calibrated: _____

At surface (< 200 mRem/h): _____ At 1m (< 10 mRem/h): _____ Transport Index: _____

ASSAY

Manufacturer	Lot#	Manufacturers Activity	Assayed Activity	% Difference from Prescribed Activity	Difference < 10%
			H	100.00%	NO

Physicist Signature: K Amy Sommer 2012.11.09 11:24:10 -06'00'

ADMINISTRATION

I *Permit has been signed?* [ ] Yes [ ] No

- [ ] Patient Identified by two methods
- [ ] Prescription agrees with container label
- [ ] Physicist has verified label accuracy

J
- [ ] Pa[illegible]enies pregnancy/breast feeding
- [x] Measured activity agrees with prescription within 10%

Dose Administered: Activity: L _____ mCi Volume: NA

Date: A _____ Time: _____

QMP Review
___Quarter ___

Radiopharmaceuticals (I-131, Sm-153, Y-90)

Implant Date A	Written Directive Isotope B	Written Directive Form C	Written Directive Route D	Written Directive Activity E	Written Directive Signed F	Written Directive Dated G	Assay H	Patient Identified I	Verify Script J	Physics Review K	Administration agrees with Script L

Reviewer _____ Date _____

Core Policy Title	**Radiopharmaceutical QMP review training**
Hospital Name	*Missouri Baptist Medical Center*

I. Policy/Procedure Requirements:

A. Establish a standard of practice for educating the staff to perform the radiopharmaceutical QMP review.

II. Procedure:

A. Assessment/Re-assessment/Evaluation:

B. Materials and Equipment:

i. Radiopharmaceutical Therapy Record (RTR)
ii. Radiopharmaceutical QMP Review form
iii. Radiopharmaceutical QMP Review policy

C. Implementation:

i. Annually or new staff completing the radiopharmaceutical QMP review will be trained by a medical physicist.
ii. The physicist will review the radiopharmaceutical QMP policy with the staff.
iii. The physicist will review with the staff all aspects of the written prescription provided by the physician for each radiopharmaceutical.
iv. The physicist will review with the staff the written directive, radiopharmaceutical assay, and the dose delivered in the radiopharmaceutical therapy record.
v. The physicist will review the radiopharmaceutical QMP review form and all of the associated fields in the Radiopharmaceutical Therapy Record with the staff.
vi. Upon completion of the training the staff will sign stating that they have received the radiopharmaceutical QMP review training.
vii. The physicist will keep a record of the staff training.

D. Patient Education: NA

III. Documentation: NA

IV. General Information: NA.

V. Supportive Evidence: NA