ADAMS Accession no. ML22055A469

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HRMC
Huron Regional Medical Center

Huron Regional Medical Center
Huron, South Dakota
Reply to a Notice of Violation NRC Inspection Report 030-09603/2021-001

License # 40-15697-01

RECEIVED
FEB 17 2022

DNMS

To Whom it May Concern,

In direct response to NRC inspection on September 1st, 2021 3 Class IV violations were discovered. We have since determined the root cause of the violation and taken proper corrective steps and reached compliance.

A. 10 CFR 35.40(a) states in part that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material
B. 10 CFR 35.40(b)(2) states that the written directive must contain, for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration.

In response to violations A. and B. listed above upon procedural review we discovered there was no formal process of ensuring proper documentation of Radiotherapies. Lead Nuclear Medicine Technologist Callie Tebay CNMT has compiled a new procedure complete with pre-administration form will all required documentation. All other Nuclear staff have been educated on policy changes. New procedure and form included. Full compliance was achieved by November, 2021.

C. 10 CFR 35.60(a) states that for direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.
10 CFR 35.60(b) states that licensees must calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards of the manufacturer's instructions.

In response to Violation C. On October 4th 2021 a new Dose Calibrator and Well Counter was received and set up. This was calibrated on October 7th , 2021 and Linearity calibration was conducted at the same time. This was approved by Martha Moore, Physicist on same day. Going forward Linearities will be performed quarterly and sent to Physicist for approval as outline in our policy. All Nuclear Medicine staff have been educated on new procedures and compliance was meet on October 7th, 2021.

Debora Rycraft RT(R)(M)RVT,RDMS
Director of Medical Imaging
Huron Regional Medical Center

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All of Nuclear Medicine quality control is to be completed in house by nuclear medicine technologists. The physicist must be informed of the data, and approve of the results to insure accuracy and compliance with NRC guidelines. Quality control is to be performed upon the following schedule:

Daily: Dose Calibrator Constancy
Well Counter Constancy
Gamma Camera Co-57 Flood
Area Surveys
Area Wipe

Weekly: Gamma Camera Bars with Co-57
Gamma camera COR in L and H mode(s)
Well Counter Chi Square

Quarterly: Dose Calibrator Linearity

Bi-annually: Sealed Source Leak Test
Sealed Source Inventory

Annually: All Geiger Muller Survey Meters Calibrated and sources checked (Performed by Cardinal Health)
Dose Calibrator Accuracy

Performed at installation and after repair:
Dose Calibraror Constanstancy
Dose Calibrator Linearity
Dose Calibrator Accuracy
Dose Calibrator Geometry

HRMC
HURON REGIONAL MEDICAL CENTER
HERE FOR YOU

Radiotherapy Administration Form

Radiotherapy to be performed _____
Radiopharmaceutical _____ Dose _____
Calibration date and time _____ Date ordered _____
Ordering Dr._____ Who ordered the dose_____
Dose verified by _____ and Second verification by _____
Dose administered (Date, Time)_____ ☐ Oral ☐ IV

Patient Name (Last, First) _____ DOB_____ MRN_____
Pregnancy Test Required? ☐ Yes ☐ No If required, result _____
Indication for therapy _____ Referring physician _____

Did patient have opportunity to ask questions and receive appropriate answers?
☐ Yes ☐ No, Why _____
Were discharge instructions gone over with patient and did they receive a copy?
☐ Yes ☐ No, Why _____

Isotope disposed of _____ by _____ to_____
Background activity _____ mR/hr Activity _____ mR/hr
Survey Meter _____

I have read this document and in signing I agree that I have had the opportunity to ask questions, I understand my instructions after I leave, and I consent to having this radiotherapy performed.

_____Date_____Time_____
(Patient signature)

_____Date_____Time_____
(Technologist's signature)

_____Date_____Time_____
(Physician's signature)

FO54

October 7th, 2021 Linearity with Calicheck Tubes

Calicheck tube color(s)	Measured Activity
Black	32.1 mCi
Black/red	9.94 mCi
Black/orange	3.9 mCi
Black/yellow	1.74 mCi
Black/green	507 uCi
Black/blue	131.6 uCi
Black/ purple	288 uCk

Constancy

Auto Zero	0.01 mV
Background	0.42
Chamber Voltage	155.4
Data Check	Ok
Accuracy (Cs-137)	69.9 (Calculated: 71.0 -1.6% deviation)
Cs-137	69.9
Tc99m	132.1
I-123	60.2
Tl-201	75.2
Ga-67	117.8

Accuracy

-Measured with Source #3561178A-12, calibrated 11/14/1978 original activity 191 uCi

Cs-137: 69.7 uCi

Calculated: 71.0

Deviation: -1.8%

Geometry

volume	time	time diff	decay corr	meas act	corr act	volume	% dev	upper lim	lower lim
						0		5	-5
1	**1.0**	-1.0	1.0019	**7.49**	7.48	1	0.1	5	-5
2	**1.0**	-1.0	1.0019	**7.47**	7.46	2	-0.2	5	-5
4	**2.0**	0.0	1.0000	**7.47**	7.47	4	0.0	5	-5
8	**2.5**	0.5	0.9990	**7.49**	7.50	8	0.4	5	-5
10	**3.0**	1.0	0.9981	**7.49**	7.50	10	0.5	5	-5

						0		5	-5
0.5	**39.0**	-0.5	1.0010	**5.113**	5.11	0.5	0.0	5	-5
1	**39.0**	-0.5	1.0010	**5.111**	5.11	1	-0.1	5	-5
1.5	**39.5**	0.0	1.0000	**5.109**	5.11	1.5	0.0	5	-5
2	**40.5**	1.0	0.9981	**5.103**	5.11	2	0.1	5	-5
2.5	**41.0**	1.5	0.9971	**5.097**	5.11	2.5	0.1	5	-5
3	**41.5**	2.0	0.9962	**5.093**	5.11	3	0.1	5	-5

example time: 1:47 pm enter 47

Geometric Variation