10/23/2021

U.S. Nuclear Regulatory Commission
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U.S. Nuclear Regulatory Commission Region I
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West Virginia Radiological Health Program
350 Capitol Street, Room 313
Charleston, West Virginia 25301-3713

RE: Occupational Radiation Worker Overexposure Notification for U.S. Nuclear Regulatory Commission Radioactive Materials License No. 47-00404-02

In accordance with 10 CFR 20.2203 and WV 64 CSR 23 6.54, this report is to notify the Nuclear Regulatory Commission and West Virginia Radiological Health Program of an occupational radiation exposure in excess of the limits in 10 CFR 20.1201 and WV 64 CSR 23 6.5.

Description of Event

During the course of occupational exposure, an adult occupational radiation worker has exceeded the extremity exposure limit of 50 rem specified in 10 CFR 20.1201(a)(2)(ii) and WV 64 CSR 23 6.5.a.2.B.

Licensee

Associated medical facilities at which the reported high occupational exposure(s) occurred:

1. Cabell Huntington Hospital (referred to henceforth as CHH in this report), located at 1340 Hal Greer Blvd, Huntington, WV 25701
2. St. Mary's Medical Center (referred to henceforth as SMMC in this report), located at 2900 First Avenue, Huntington, WV 25702

Description of Occupational Radiation Worker

The occupational radiation worker is a physician who performs interventional radiology procedures using x-ray generating fluoroscopy and CT equipment and also performs radioembolization procedures using Y-90 microspheres at the above facilities. This individual shall be identified as MD in this report. The required additional personal identification information for this individual is stated in a separate and detachable part of this report and is labeled as "Privacy Act Information: Not For Public Disclosure".

Discovery and Initial Steps Timeline

CHH and SMMC utilize Landauer for occupational radiation dose monitoring. As part of this service, Landauer provides email notifications of unusually high exposure dosimeter readings to the Radiation Safety Officer and other on-site dosimetry account managers at CHH and SMMC.

On 9/21/2021, I received two emails from Landauer Dosimetry Records, one for CHH and one for SMMC, notifying me of elevated ring dosimeter readings for MD. The emails were received but, due to other commitments, were not able to be addressed at the time.

On the morning of 9/22/2021, I was able to initiate a review of the exposure notifications. In an effort to determine if the dosimeter readings are accurate, I contacted Landauer Customer Service and requested an additional review of these dosimeter readings to evaluate the dosimeter glow curve, reader QC, subtraction of background, static versus dynamic exposure, etc. I then called MD to inform him of his possible high extremity exposure, that I had begun the process of validating and investigating the exposure, that he should limit additional occupational exposure during this investigation and until further notice, and to discuss possible causes for high extremity exposure and ways to limit additional exposure. I then initiated a review of the current cumulative exposure readings for MD.

On 9/23/2021, the Landauer Technical Service Group responded to my additional review request by indicating that they believed the reported dosimeter readings were valid without any revision. I reviewed the cumulative exposure history year-to-date for MD. At that point, it appeared that the cumulative annual extremity exposure limit had been exceeded by MD. I then informed MD of the confirmed high extremity exposure and advised him to limit his extremity x-ray exposure to little or no additional occupation exposure for the remainder of the year, that he cannot perform any additional Y-90 treatments for the remainder of the year 2021, recommended that a dermatologist be consulted regarding any observed deterministic radiation-induced effects to the extremities, and to further investigate possible causes for the high exposure.

On 9/24/2021, I contacted our senior NRC inspector to informally advise her of the overexposure and discuss advised next steps from the NRC perspective. Next, I contacted the WV Radiological Health Program Chief to informally advise her of the overexposure and discuss advised next steps from the State perspective. I expressed strong concern that requiring MD to receive no additional occupational exposure for the remainder of the year would negatively affect our efforts to improve physician compliance with dose monitoring requirements. I described ways in which we proposed to limit additional extremity exposure for MD from x-rays to negligible levels for the remainder of the year and committed that MD would not performing any additional Y-90 treatments for the remainder of the year 2021. Based on these conversations and commitments, we planned to make implement numerous administrative measures and make changes to the radiation protection practices related to occupational exposure to MD. We believed that these measures would have an immediate effect on limiting additional extremity occupational exposure for MD. MD plays a critical role in providing essential and frequently emergent patient care. MD therefore continued to practice but committed to doing what is necessary to limit his extremity to little additional exposure for the remainder of 2021.

Investigation

Because MD receives occupational radiation exposure from x-rays and from Y-90 treatment deliveries, he is issued a whole body radiation dosimeter and also an extremity ring dosimeter. From my discussions with MD, he described how he has become quite vigilant in wearing both of these dosimeters for all occupational exposure activities and that he believes the high extremity exposures are from performing CT-guided interventional procedures. CT-guided interventional procedures can utilize both intermittent and continuous imaging with x-rays. Additionally, because of the higher x-ray energy, the scattered radiation from CT is typically more intense than that from interventional fluoroscopy systems. MD indicated that it has been his practice to be positioned adjacent to the patient near the CT beam and, at times, to position needles and ablation devices with his hands very near the CT beam.

Dosimetry records indicate that the wearing of dosimetry devices by MD has been inconsistent to absent in the past. This complicates the exposure source investigation and requires additional dose estimation considerations and assumptions.

1. Y-90 Treatment Extremity Exposure Estimation

Note that MD has not performed a SIR-Spheres Y-90 treatment administration since 1/12/2017. Also note that for each TheraSphere Y-90 dose administered, the dose rate from the Y-90 dose vial is measured before dose administration with a calibrated ion chamber survey meter. The TheraSphere manufacturer provides the Y-90 dose contained in a thick acrylic vial for beta shielding that is kept inside of a thick lead "Pig" during storage, transportation, and administration. In accordance with the manufacturer procedure, the dose delivered to the patient is determined using the preadministration dose vial exposure rate from a known source activity measured with the source vial outside of the lead "pig" at a distance of 30 cm (12") and comparing the result to the measured post administration exposure rate from the Nalgene jar containing the empty dose vial, administration tubing set, and any other radioactive waste or potentially contaminated items in order to infer a residual activity that is used to determine the net administered activity. During dose administration, the source vial is kept inside of the lead pig which is inside of the acrylic delivery box, and the delivery box is positioned between the patient and delivery tubing to shield the physician while the TheraSphere Y-90 microspheres are in the delivery tubing. The location of the physicians' hands during dose delivery is typically further than 30 cm from the source vial and behind the protective acrylic delivery box. This preadministration survey can be used to estimate the extremity exposure to MD from Y-90 treatments.

To estimate the potential extremity exposure year-to-date for MD from Y-90 TheraSphere treatment procedures, the preadministration dose vial measured exposure rate at 30 cm (12") was used to represent exposure rate near the location of the physicians' hands and an extremity exposure duration of 10 minutes per treatment was assumed. I believe these assumptions will result is an overestimation of actual extremity dose as treatment apparatus assembly with the Y-90 dose vial present usually takes only a few minutes with the physicians hands near the source, for most of this time the location of the hands is typically more than 30 cm away for the source, part of the exposure received during this time occurs at a much lower dose rate because the source is in the lead container, the part of the hand

exposure that occurs when the source is not in the lead container occurs at a lower dose rate because more acrylic shielding is provided by two sides of the administration box than the acrylic thickness of the dose vial, and that typically 90% or more of the treatment dose is delivered during the first 1 minute aliquot. Using this methodology, MDs extremity dose from Y-90 treatments in 2021 is estimated to be approximately 18 mrem.

Tx Date	Pt. Initials	GBq at Tx	A: Dose rate mR/hr @12" PreSurvey	B: 10 min / 60 min per hr	C: Dose mrem to hands @ 12" for 10 min*
3/10/21	RF	5.882	8.08	0.167	1.180
3/16/21	TD	5.508	8.00	0.167	1.168
3/16/21	VB	5.816	8.50	0.167	1.241
3/16/21	VB	5.846	8.30	0.167	1.212
3/17/21	SL	2.275	3.14	0.167	0.458
3/17/21	SL	2.204	3.04	0.167	0.444
3/18/21	DG	6.801	10.60	0.167	1.548
3/18/21	DG	4.090	6.30	0.167	0.920
5/19/21	MW	6.598	10.87	0.167	1.587
6/16/21	OC	6.923	10.59	0.167	1.546
6/16/21	EC	7.951	13.99	0.167	2.043
7/20/21	UC	4.072	5.72	0.167	0.835
7/20/21	AS	3.982	5.67	0.167	0.828
8/24/21	MT	8.444	11.76	0.167	1.717
9/9/21	LS	7.156	10.90	0.167	1.591
* C = A * B * 0.876 rad or rem / R				**Total**	**18.3**

From this analysis, it is my conclusion that relatively little extremity exposure can be attributed to MD performing TheraSphere Y-90 treatments. This conclusion agrees with the findings of the study titled **Comparison of Interventional Radiologist and the Nuclear Medicine Technologist radiation exposure when using TheraSphere and SIR-Spheres Y90 microspheres for liver cancer therapy** published in the Journal of Nuclear Medicine, found at https://jnm.snmjournals.org/content/58/supplement_1/802.

2. CT-Guided Interventional Procedures Extremity Exposure Estimation

CT-Guided interventional procedures are performed by MD on nearly a daily basis that includes ablations, aspirations, biopsies, drainages, and injections. These procedures can range from simple and fast to complex and prolonged. Both CHH and SMMC have GE CT scanners with the SmartStep interventional mode. I perform annual medical physics surveys on these CT scanners and verify that the systems are performing within manufacturer specifications, the measured versus report CTDIvol for CHH CT3 and SMMC CT1 and CT2 was found to agreed within 8%.

Most CT-guided interventional procedures are performed in the torso of adults using the standard SmartStep axial acquisition protocol. Complex CT-guided interventional procedures at CHH and SMMC typically report a total procedural dose metric in the range of approximately 500 to 2000 mGy CTDIvol with most procedures being closer to the low end of this range. For the typical patient approximated by the standard 32 cm diameter CTDI phantom, the peak skin dose from axial scanning is approximately 60% of the reported CTDIvol, see study titled **Validation of a method for estimating peak skin dose from CT-guided procedures** published in the Journal of Applied Clinical Medical Physics, found at

https://aapm.onlinelibrary.wiley.com/doi/pdf/10.1002/acm2.13261. This peak skin dose can be used as an estimate of the dose to the hand if it is within the radiation beam and in contact with the patients' skin.

Typical SmartStep Procedure CTDIvol mGy	Skin Dose Conversion Factor	Skin Dose per Procedure mGy	Hand/Skin Dose per procedure equivalent Sv	Extremity Exposure Limit Sv	Approx. Number of Procedures with hand in/near beam to reach limit
500	0.6	300	0.3	50	166.7
2000	0.6	1200	1.2	50	41.7

Due to scatter and the relatively high beam energy, exposure levels closely adjacent to the beam will remain high for the closest few centimeters and then begin to decrease rapidly with distance. From the above estimate, it very possible that if the and is near the beam for the normal busy procedure workload that the extremity exposure limit could be reached. By comparison, the potential for high extremity exposure from CT-Guided procedures is much greater than that expected from TheraSphere Y-90 treatment procedures. As theorized by MD, we therefore conclude that the source of the high extremity exposure for MD is very likely due to x-ray exposure from CT-guided interventional procedures.

Reported Occupational Dose

The cumulative 2021 Landauer dosimetry records for MD are shown below. Note that the reports for November dosimetry are not yet available. From the available records, the cumulative extremity exposure appears to have exceeded 50 mSv (50,000 mrem).

Facility	Begin wear date	End wear date	Total DDE mrem	Total LDE mrem	Total SDE mrem	Extremity mrem	Dose Assessment
SMMC	2021/08/01	2021/08/31	194	648	648		EDE2
	2021/07/01	2021/07/31	235	784	773		EDE2
	2021/06/01	2021/06/30	210	699	691	37029	EDE2
	2021/05/01	2021/05/31	93	309	306	3236	EDE2
	2021/04/01	2021/04/30	M	M	M	M	EDE2
	2021/03/01	2021/03/31	M	M	M		EDE2
	2021/02/01	2021/02/28	M	M	M	M	EDE2
	2021/01/01	2021/01/31	M	M	M	M	EDE2
CHH	2021/08/10	2021/09/09				11524	Standard
	2021/07/10	2021/08/09	50	166	163	690	EDE2
	2021/06/10	2021/07/09	225	750	728	2287	EDE2
	2021/05/10	2021/06/09	73	246	247	1853	EDE2
	2021/04/10	2021/05/09				M	Standard
	2021/03/10	2021/04/09				M	Standard
	2021/02/10	2021/03/09				M	Standard
	2021/01/10	2021/02/09				M	Standard
YTD	**2021/01/01**	**2021/09/09**	**1080**	**3602**	**3556**	**56619**	

Estimated Occupational Dose

It is clear from these records that the actual occupational exposure is higher is because the wearing of dosimeter devices has been inconsistent and lacking for many wear periods. In order to estimate the actual cumulative occupational exposure for MD in 2021, we can use data from actual dosimeter wear periods, assume it is typical, and apply it to the missing wear periods.

Facility	Begin wear date	End wear date	Total DDE mrem	Total LDE mrem	Total SDE mrem	Extremity mrem	Dose Assessment
SMMC	2021/08/01	2021/08/31	194	648	648	(Included in 37029)	EDE2
	2021/07/01	2021/07/31	235	784	773	(Included in 37029)	EDE2
	2021/06/01	2021/06/30	210	699	691	37029	EDE2
	2021/06/01	*2021/08/31*	*213*	*710*	*704*	*12343*	*AVG*
	2021/05/01	2021/05/31	93	309	306	3236	EDE2
	2021/05/01	2021/05/31	213	710	704	12343	Estimated
	2021/04/01	2021/04/30	213	710	704	12343	Estimated
	2021/03/01	2021/03/31	213	710	704	12343	Estimated
	2021/02/01	2021/02/28	213	710	704	12343	Estimated
	2021/01/01	2021/01/31	213	710	704	12343	Estimated
CHH	2021/08/10	2021/09/09	116	387	379	11524	Standard
	2021/07/10	2021/08/09	50	166	163	690	EDE2
	2021/06/10	2021/07/09	225	750	728	2287	EDE2
	2021/05/10	2021/06/09	73	246	247	1853	EDE2
	2021/05/10	*2021/08/09*	*116*	*387*	*379*	*1610*	*AVG*
	2021/04/10	2021/05/09	116	287	379	1610	Estimated
	2021/03/10	2021/04/09	116	287	379	1610	Estimated
	2021/02/10	2021/03/09	116	287	379	1610	Estimated
	2021/01/10	2021/02/09	116	287	379	1610	Estimated
YTD	**2021/01/01**	**2021/09/09**	**2632**	**8378**	**8665**	**121538**	**Estimated**

We therefore estimate the actual extremity exposure so far in 2021 for MD to be approximately 122000 mrem (122 rem, 1.2 Sv) which, for x-ray and gamma ray exposure, is equivalent to approximately 122000 mrad (122 rad, 1.2 Gy).

Expected Effects

The threshold for observed cutaneous radiation injury effects from an acute radiation exposure is considered to be approximately 200 rads (2 Gy). Possible effects at this dose include transient erythema

and epilation (reference https://www.cdc.gov/nceh/radiation/emergencies/criphysicianfactsheet.htm). Because the estimated extremity exposure is about half of this amount and the exposure was protracted over time, we do not expect there to be any negative effects for MD from his extremity overexposure.

MD reports no observed cutaneous radiation injury effects at this time. MD had a routine dermatologist consult about 2 months ago, no cutaneous injury was observed. MD now has a dermatologist consult scheduled for 11/4/2021. Any future dermatologic findings related to extremity radiation exposure will receive appropriate medical care.

Corrective Measures to Prevent a Reoccurrence

1. Education:
    a. MD has read and signed Memo from Radiation Safety Committee to Radiation Workers re Occupational Radiation Worker Dosimeter Agreement. This document describes the requirement to wear, how to wear, and how to manage radiation dosimeter(s).
    b. MD has read Best Practices Guidelines for CT-Guided Interventional Procedures, found at https://www.jvir.org/article/S1051-0443(17)30960-0/fulltext. This material aims to:
        i. Review relevant technical aspects of CT image acquisition, reconstruction, and dosimetry,
        ii. Review the use of CT to perform image-guided procedures,
        iii. Discuss strategies for managing radiation dose and image quality during CT-guided procedures,
        iv. Review radiation protection for the operator(s), staff, and patient during CT-guided procedures,
        v. Review essential CT-guided procedural quality-improvement activities.
    c. MD has read CHH/SMMC net learning Safe Fluoroscopy Practices. This material aims to:
        i. Review relevant technical aspects of fluoroscopy image acquisition and dosimetry,
        ii. Review the use of fluoroscopy to perform image-guided procedures,
        iii. Discuss strategies for managing radiation dose and image quality during fluoroscopy-guided procedures,
        iv. Review radiation protection for the operator(s), staff, and patient during fluoroscopy-guided procedures.
2. Radiation Protection: Shielding and Distance. Note that MD wears a lead apron, thyroid collar, and protective glasses during all occupational exposure.
    a. To further limit extremity exposure for MD during the remainder of 2021 from the use of CT-guidance, procedures will be modified to utilize CT biopsy mode. Additionally, MD will use shielding and or distance to reduce exposure by a variety of methods:
        i. Retreat to the CT control room area during CT guidance, or
        ii. Retreat to the sheltered sides of the CT gantry (green zone illustrated below) during x-ray production, or
        iii. If the procedure precludes the above, a mobile or ceiling mounted radiation shield (illustrated below) will be positioned to protect MD.

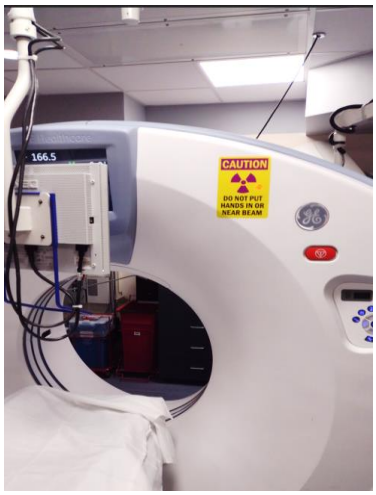
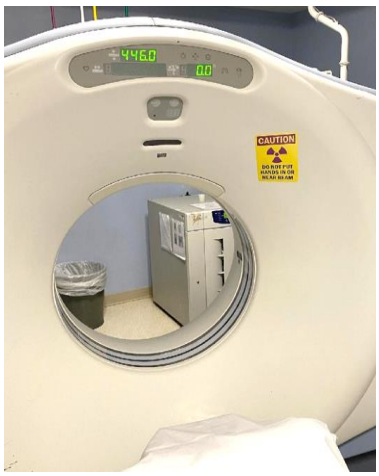
	1.5 m	1.0 m	0.5 m	0.0 m	0.5 m	1.0 m	1.5 m
1.5 m	0.015	0.038	0.047	0.051	0.045	0.038	0.014
1.0 m	0.004	0.029	0.094	0.115	0.090	0.032	0.004
0.5 m	0.002	0.004	0.207	0.423	0.194	0.004	0.002
0.0 m	0.002						0.002
0.5 m	0.005	0.031	0.253	0.513	0.176	0.037	0.006
1.0 m	0.036	0.064	0.102	0.125	0.100	0.067	0.033
1.5 m	0.031	0.039	0.050	0.053	0.048	0.041	0.029
2.0 m	0.022	0.025	0.029	0.030	0.028	0.027	0.022
2.5 m	0.016	0.018	0.019	0.019	0.018	0.018	0.016
3.0 m	0.012	0.012	0.014	0.013	0.013	0.013	0.012

µGy/mAs (140 kV, 24 x 1.2 mm)

b. To further limit extremity exposure for MD during the remainder of 2021 from the use of fluoroscopy-guidance, MD will use shielding and distance as much as practical to reduce exposure by positioning the ceiling mounted radiation shield (illustrated above and present in all interventional radiology procedures rooms) to protect MD.
c. MD will also wear the Proguard RR1 leaded protective surgical gloves whenever performing image-guided procedures and leaving the room during x-ray production is not possible. The manufacturer estimates that these gloves provide approximately 33% scatter reduction at the 120 kVp commonly used for CT-guided procedures and up to 50% scatter reduction at the kVp's commonly used for fluoroscopy-guided procedures.

3. Radiation dosimetry records will be reviewed on an ongoing basis for unusually high and unexpectedly low occupational exposure.
4. An administrative timeout/check step has been added to the TheraSphere Y-90 procedure callout sheet to verify that the interventional radiologist authorized user is wearing their whole body and extremity dosimeters. This checklist is followed step-by-step and read aloud be interventional radiology (IR) staff for procedure setup and during treatment devise assembly, dose delivery, and post-delivery disassembly.

5. Postings: The following Caution signs have been affixed to the interventional CT scanners and are viewable by the interventional radiologist during CT-guided procedures:

Caution Sign	CHH CT #3
	
SMMC CT #1	SMMC CT #2
	

Conclusion

We believe that the findings from the above investigation are accurate and that the corrective action measures will be effective to prevent a reoccurrence.

Sincerely

James Norweck, MS, DABR, Radiation Safety Officer