Katanic, Janine

From:	Scott Fuller <fullersc@slhs.org></fullersc@slhs.org>
Sent:	Monday, August 3, 2020 9:04 PM
То:	Katanic, Janine; Jodi Vanderpool
Cc:	James Blacker; R4Enforcement
Subject:	[External_Sender] RE: St. Luke's response

Dr. Katanic,

We appreciate your attention to this matter. In particular, thank you for recognizing that various aspects of the document require redaction to ensure the privacy of individuals who are identified in our response.

In regards to the contents of Policy EC046, we do not intend for this attachment to be withheld from public posting in accordance with 10 CFR 2.390. We waive our right to mark this document as confidential. This response is made following consultation with Jodi Vanderpool.

Thank you for your timely review of our response.

Sincerely, Scott

From: Katanic, Janine <Janine.Katanic@nrc.gov>
Sent: Monday, August 3, 2020 4:54 PM
To: Jodi Vanderpool <vanderpj@slhs.org>; Scott Fuller <fullersc@slhs.org>
Cc: James Blacker <blackerj@slhs.org>; R4Enforcement <R4Enforcement.Resource@nrc.gov>
Subject: St. Luke's response

WARNING: This email originated outside of St. Luke's email system.

DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

Hi Jodi and Scott,

I've been going through your response to the apparent violations (dated July 7, 2020, and received on July 23, 2020) and redacting it where there are names associated with doses (personal privacy information), so that we can make your response publicly available. However, I noticed that "Attachment B – Policy EC046" says the following:

St. Luke's process for developing policies and the **content of policies is proprietary** business information St. Luke's **with permission** from a Sr. Director, Administrator, Vice President, or CEO, or as required to be provide duidance in the care ballow the information contained herein is used to provide duidance in the care

Please review 10 CFR 2.390 regarding requests for withholding. As noted in the regulation, the submitter shall request withholding at the time the document is submitted and shall comply with the document marking and affidavit requirements. If it is St. Luke's intent that "Attachment B – Policy EC046" is proprietary business information please follow the instructions in the requirement with respect to marking, affidavit, etc. so that it can be reviewed by our Regional Counsel.

Thanks Janine Janine F. Katanic, PhD, CHP Senior Health Physicist Division of Nuclear Materials Safety Materials Inspection Branch US Nuclear Regulatory Commission Region IV office: 817-200-1151 email: Janine.Katanic@nrc.gov

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Katanic, Janine

From:	Kramer, John
Sent:	Monday, July 27, 2020 4:14 PM
То:	Muessle, Mary; Howell, Linda; Silva, Patricia; Katanic, Janine
Cc:	Groom, Jeremy; Roberts, Austin
Subject:	St. Luke's NOV response
Attachments:	RSP_EA-20-065_St. Luke's.pdf
Follow Up Flag:	Follow up
Flag Status:	Flagged

Although the attached response letter is dated July 7, 2020, it was received in the R4Enforcement mailbox on the afternoon of Thursday, July 23, 2020.

John Kramer Senior Enforcement Specialist US NRC, Region IV 1600 East Lamar Blvd. Arlington, TX 76011-4511 Work: 817-200-1121

July 7, 2020

Ms. Mary Muessle Director, Division of Nuclear Materials Safety Region IV 1600 East Lamar Boulevard Arlington, TX 76011

RE: Response to Apparent Violations in NRC Inspection Report 030-32196/2020-001

Dear Ms. Muessle,

We appreciate the opportunity to present a written response to the apparent violations identified in NRC Inspection Report 030-32196/2020-001. According to the inspection report, these apparent violations are currently being considered for escalated enforcement actions.

St. Luke's takes radiation safety and compliance with NRC requirements seriously. Prompted by the gaps identified by the NRC inspection of our facilities in 2017, St. Luke's has devoted substantial human and financial resources to make significant changes and improvements to its radiation protection programs and procedures. Considering these significant efforts, we were proud to hear from the NRC inspector on site during this 2020 visit that the program in place is much improved and presently in need only of "fine-tuning."

Although St. Luke's is proud of the improvements we have made, especially since 2017, we recognize that there is room for improvement. In particular, we agree with the inspection report findings that our program had gaps related to the training and oversight of independent physicians working at St. Luke's under its contract with Boise Radiology Group. As explained in more detail below, we believe that the root cause of these apparent violations was our over-reliance on the professional training and contractual obligations of the independent BRG physicians to ensure compliance with requirements on use of personal dosimeters. We trusted the physicians to honor these obligations but, as the owner of the NRC license and responsible party, should have verified that they were.

Without disputing that St. Luke's should have done more to educate and verify compliance by BRG physicians, we note that St. Luke's had good reason to believe that the physicians' professional and contractual obligations would lead them to comply with the use of personal dosimeters. Indeed, each of the BRG physicians identified as not having received adequate training is listed as an Authorized User on our NRC-issued license. To be listed on the license and allowed to oversee the use of radioactive materials, an individual must demonstrate that he or she has had training and experience sufficient to meet NRC requirements in 10 CFR 35. The NRC also verifies this training prior to adding the physician to the license. Each of the individuals identified in the NRC report meets training requirements in 10 CFR 35.390, including

classroom and laboratory hours in Radiation Protection (See NRC Form 313A). Each individual is also board certified by the American Board of Radiology with active certification. Plainly, the BRG radiologists know or should know that use of personal dosimeters is required.

In addition to their training, the BRG physicians have agreed, through the contract between BRG and St. Luke's, to abide by St. Luke's rules, regulations, and policies. St. Luke's policy, EC046 – Radiation Exposure Monitoring Program (ALARA), is clear in its instruction on use of personal dosimeters to all employees and providers, including those who work at St. Luke's under independent contractor agreements. It reads in relevant part:

- D. Occupationally exposed personnel will:
 - 1. Wear monitoring badges or dosimeters when working with or in the vicinity of radiation sources.
 - 2. Return dosimeters at the end of the scheduled exchange period.
 - Refusal to wear radiation protection by any employee, contractor or physician will be reported to the Radiation Safety Officer.
 - 4. Attend training and perform online training modules related to good radiation safety practices.

In sum, St. Luke's had reason to believe that BRG and its physician partners would understand and adhere to the Radiation Safety Program, including the requirement to use personal dosimeters. Nonetheless, we acknowledge that such belief alone was not a sufficient basis for St. Luke's to ensure compliance. As explained below, we have taken corrective actions that will verify proper training is received and that monitoring is occurring in accordance with St. Luke's Policy and NRC regulations. In addition, we are using this opportunity to begin a review of other relationships with independent practitioners to determine whether additional provider education and verifications are necessary, including compliance with policies and processes outside of NRC direct oversight.

In the attachments to this letter, we address in detail each of the three apparent violations, including identification of root causes and completed and forthcoming corrective actions. In the final attachment, we explain why we believe the apparent violations should appropriately be categorized as a Level IV violation pursuant to the NRC Enforcement Policy.

If you have any questions related to the included response to NRC Inspection Report 030-32196/2020-001, please contact us at your convenience.

Sincerely

Jodi Vanderpool, Vice President Quality Operations and Patient Safety

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Scott Fuller, MS DABR Radiation Safety Officer

Response to Apparent Violation #1

Apparent Violation - 10 CFR 19.12(a)(3): All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be—

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material;

<u>Specifically, the inspection report states that St. Luke's has failed to provide adequate</u> <u>instructions regarding the proper use and storage of personal dosimeters to four IR physicians</u>.

ROOT-CAUSE OF APPARENT VIOLATION

Each of the individuals who were identified as not having been provided appropriate instruction are physicians of Boise Radiology Group (BRG). BRG physicians are highly trained independent contractors who support St. Luke's and are not employees of the hospital. Under its contract with St. Luke's, BRG is responsible for training its workforce and ensuring adherence with St. Luke's policies, including those related to radiation safety. Relying on the professionalism and contractual duties of the BRG physicians, St. Luke's did not require them to complete the hospital's annual training on radiation safety. All St. Luke's employees identified as likely receive in a year an occupational dose in excess of 100 mrem and others who work in departments that utilize sources of radiation." This training includes instruction on the required use of personal dosimeter devices. Because St. Luke's relied too heavily on BRG to ensure training and compliance – without independent verification by the hospital – the BRG physicians were not required to complete this training.

CORRECTIVE ACTIONS TAKEN TO DATE

The four identified physicians (and all other BRG physicians) were provided with instruction by the Radiation Safety Officer as soon as non-compliance was discovered. Three of the physicians received the training on February 26, 2020, during the NRC inspection. The fourth physician was on vacation and received the training on March 3, 2020. In addition, all four physicians have reviewed and signed attestation statements that they received the training materials and commit to wearing the assigned dosimeters as instructed. These attestations are enclosed with this submission.

All contracted radiology physicians have been enrolled in, and completed for 2020, the St. Luke's "Radiation Safety and Education" training module. They will be required to complete this annual training program going forward.

CORRECTIVE ACTIONS THAT WILL BE TAKEN

During the annual Radiation Protection Program review, the Radiation Safety Officer (RSO) will audit and ensure that all Authorized Users, Nuclear Medicine Technologists, and Medical Physicists, whether employed or independent contracts, have completed the annual training module. Results of this audit will be submitted to the Radiation Safety Committee (RSC) and St. Luke's management.

DATE WHEN FULL COMPLIANCE ACHIEVED

Full compliance was achieved when training was completed on 3/3/2020. All radiology providers received instruction from the RSO regarding the proper use and storage of personal dosimeters.

Response to Apparent Violation #2

Apparent Violation - 10 CFR 20.1101(a): Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

Specifically, the NRC inspection report indicates that policy EC046 failed to include provisions regarding actions to be taken when dosimeters were less than the licensee's ALARA I Investigational Level, such as those dosimeters that were returned unused or had unexpectedly low exposures.

ROOT-CAUSE OF FOR APPARENT VIOLATION

We acknowledge that St. Luke's did not have in place a protocol to detect lower-thananticipated dosimeter readings and report them to the RSC. To be sure, St. Luke's Policy EC046 (Occupational Radiation Exposure Program) includes requirements to conduct meaningful reviews of occupational exposure data and to report concerns to the Radiation Safety Committee. A copy of Policy EC046 is enclosed with this submission. However, those requirements did not include measures intended to detect "false negative" readings.

St. Luke's is not aware of any Regulatory Guidance or NUREG licensing guides that direct licensees to investigate when dosimeter readings are unexpectedly low. However, we acknowledge that doing so would have provided a means to detect non-compliance with personal dosimeter use requirements. As with Apparent Violation #1 above, the root cause of this failure was St. Luke's belief and expectation that providers would adhere to their training and to policy by consistently using personal dosimeter devices. It is now clear that such belief alone is insufficient and must be subject to testing and auditing.

CORRECTIVE ACTIONS TAKEN TO DATE

To our knowledge, neither Regulatory Guidance nor NUREG licensing guides describe how best to audit for lower-than-expected dosimeter readings that may indicate non-compliance with monitor use. In the absence of clear best practices, St. Luke's has implemented two steps, described below, aimed at addressing this concern. We recognize, however, that these corrective actions are new to St. Luke's. We anticipate that we may make changes to them over time or implement alternative, more effective audits as we gain experience in auditing for non-compliance. St. Luke's also welcomes any advice or feedback the NRC may have with respect to implementing an efficient, effective method for detecting non-compliance.

First, St. Luke's has begun, starting with the meeting in June 2020, to report to the RSC the dosimeter readings for all interventional radiologists subject to NRC's regulatory purview. Beginning with the September 2020 RSC meeting, dosimeter readings for all individuals subject to NRC's regulatory purview will be individually reported to the RSC. In addition, prior to reporting to the RSC, the Radiation Safety Officer will review and investigate the circumstances

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surrounding any such individual whose dosimeter reading for the quarter is labeled "M," meaning that the dosimeter device showed no measurable radiation exposure. Where the RSO identifies that the "M" reading was due to non-compliance with monitor use, the RSO will educate the individual on St. Luke's and NRC requirements and report the non-compliance to the RSC along with the full list of dosimeter readings for the quarter.

St. Luke's understands that this first corrective action may not identify individuals subject to NRC authority who are only partially compliant with monitor use, as these individuals' monitors may register some, but not all, workplace exposure. Therefore, with respect to the BRG practitioners, St. Luke's has implemented a second corrective action. Specifically, the RSO estimates the expected exposure for each BRG practitioner based on the number of procedures performed during the exposure review period multiplied by an estimate of the average physician exposure for a typical interventional procedure. The RSO compares this estimate to the practitioners' actual dosimeter readings for the period and investigates the circumstances surrounding any reading that falls well above or below the expected value to warrant inquiry.

This second corrective action is admittedly novel to St. Luke's and a work in progress. We will review the results of this periodic monitoring to assess the accuracy of our estimations and the appropriate thresholds for readings above and below normal to trigger further inquiry. This second corrective action is labor intensive, requiring collection of procedure data, estimation of exposures, manual comparison of expected and actual results, and in-person investigation when appropriate. Consequently, St. Luke's will be reviewing ways that it can more efficiently address and correct issues of non-compliance with the use of personal monitoring devices. Again, we welcome any recommendations or feedback the NRC may have with respect to this difficult auditing problem.

CORRECTIVE ACTIONS THAT WILL BE TAKEN

St. Luke's will continue to employ the two corrective actions identified above going forward unless and until St. Luke's identifies more efficient and effective means of detecting noncompliance. If necessary, an appropriate method will be used to assign an exposure to the badge if it is determined that wear and storage of the badge was not in accordance with policy and good practice. Assigned exposures will be based on maximum exposures to workers of similar roles, historical average exposure to recent badges, or other appropriate methods. Corrective actions will be taken if it is determined that the individual is not complying with badge-wearing requirements.

DATE WHEN FULL COMPLIANCE ACHIEVED

Full compliance with the regulations occurred on April 14, 2020, when analysis of physician exposures for the period in question were reported, in full, to the NRC inspector. The review process for badge readings was updated with the report submitted on June 6, 2020, the first RSC meeting following the NRC on-site inspection.

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Response to Apparent Violation #3

Apparent Violation - 10 CFR 20.1502: Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices

<u>Specifically, the NRC inspection report indicates that for four IR physicians, St. Luke's failed to</u> <u>monitor their occupational exposure to radiation from licensed and unlicensed radiation sources</u> <u>under our control and failed to require the use of individual monitoring devices by IR physicians.</u>

ROOT-CAUSE APPARENT VIOLATION

The root cause of Apparent Violation #3 is the same as for the other violations. St. Luke's believed it could rely on the professional and contractual commitments of the BRG physicians to ensure compliant use of dosimetry devices. That belief was unfounded. Indeed, four BRG physicians provided with monitoring devices failed to consistently wear them as required by policy. St. Luke's did not have sufficient verification systems in place to identify non-compliance with system policy.

CORRECTIVE ACTIONS TAKEN TO DATE

The corrective actions related to Apparent Violation #3 are the same as for Apparent Violation #2. The quarterly review of dose monitoring reports, as submitted to the RSC, now includes identification of authorized users who handle or administer radioactive materials and indicates the exposure information from the previous quarter. This provides an opportunity for the RSO and RSC to review exposures and identify BRG physicians, and others, whose badge readings are "M" and indicate no exposure during the period or non-compliance with proper badge wearing requirements. In addition, the RSO is monitoring BRG practitioners for dosimeter readings that fall outside of expected values, in order to detect partial non-compliance.

CORRECTIVE ACTIONS THAT WILL BE TAKEN

As indicated in our response to Apparent Violation #2, St. Luke's will continue to take both corrective action steps noted above until more effective or efficient methods are identified. An appropriate method will be used to assign an exposure to a badge if it is determined that wear and storage of the badge was not in accordance with policy and good practice. Assigned exposures will be based on maximum exposures to workers of similar roles, historical average exposure to recent badges, or other appropriate methods.

DATE WHEN FULL COMPLIANCE ACHIEVED

As indicated in our response to Apparent Violation #2, full compliance with the regulations occurred on April 14, 2020, when analysis of physician exposures for the period in question were reported, in full, to the NRC inspector. The review process for badge readings was updated with the report submitted on June 6, the first RSC meeting following the NRC on-site inspection.

Enforcement Position

St. Luke's believes that the apparent violations described above are appropriately categorized as a single NRC Severity Level IV violation. It is of more than minor concern to the NRC and to St. Luke's that the BRG physicians were not routinely educated on monitor use, that the BRG physicians failed to comply with their professional and contractual obligations to use personal dosimeters, and that St. Luke's did not have audit mechanisms in place to detect such non-compliance. However, considering other radiation safety measures implemented by St. Luke's, we do not believe that these gaps in the program caused appreciable potential safety or security concerns.

NRC Enforcement Policy 2.2.2 describes the distinction between escalated enforcement violations (Levels I, II, and III) and less severe violations (Level IV and minor). A Severity Level IV violation is described as "those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences."

We understand that the NRC Enforcement Policy states that several factors are reviewed when determining the assessment of the severity level of violations (*NRC Enforcement Policy 2.2.1*)

- 1. Whether the violation resulted in actual safety or security consequences
- 2. Whether the violation had potential safety or security consequences
- Whether the violation impacted the ability of the NRC to perform its regulatory oversight function
- 4. Whether the violation involved willfulness.

The description of the apparent violations in the inspection report does not indicate that there existed an actual safety or security consequence, that our facility impacted the ability of the NRC to perform its oversight function, or that there was willfulness in noncompliance. Thus, escalated enforcement would be appropriate only if the apparent violations posed a "potential safety or security consequence."

In this regard, the NRC inspection report asserts that there existed a "substantial potential" for individuals to exceed the NRC's regulatory limits for occupational radiation dose due to the identified gaps in St. Luke's dosimeter program. NRC Enforcement Policy defines substantial potential for overexposure as:

A situation where it was fortuitous that the resulting radiation exposure did not exceed the dose limits of 10 CFR part 20. The concern is not the significance of the resulting or potential exposure, but whether the licensee provided adequate controls over the situation, as required, to prevent exceedance of the 10 CFR Part 20 limits.

St. Luke's ensures the safety and protection of its patients and staff members and strives to ensure compliance with all regulatory standards using a multi-level approach. This work goes well beyond the use of personal radiation monitors, including providing adequate radiation protection and shielding devices, developing policies that promote safety, and continual review of available occupational exposure records. We acknowledge that, in the case of the four BRG physicians, St. Luke's failed to execute on one part of this multi-layered approach to radiation safety – ensuring compliance with personal dosimeter use. However, the robust nature of the other protection measures in place meant that, upon review, none of the four individuals exceeded or even approached regulatory dose limits. This review was previously submitted to the NRC (See previously submitted "Amended – Official Response to NRC 3 Mar 20).

Moreover, given the multi-faceted radiation safety program at St. Luke's, we believe that the BRG physicians did not face even a "potential" safety or security risk. Occupational exposures of individuals not identified in the NRC inspection report provide evidence of St. Luke's efforts to ensure that staff members' exposures do not approach regulatory limits (5000 mrem). This data includes individuals exposed to licensed and unlicensed sources of radiation, such as nuclear medicine and PET technologists, cardiologists, medical physicists, and other support staff. During the calendar years 2017 through 2019, the time period since the last NRC inspection, the <u>maximum</u> annual occupational exposures at our facility were:

Max Exposure 2017 – 1709 mrem Max Exposure 2018 – 1534 mrem Max Exposure 2019 – 1944 mrem

The individual with maximum exposure in 2017 and 2018 is identified in the NRC Inspection Report as "IR 2" and has demonstrated significant compliance with badge-wearing requirements. The individual with maximum exposure in 2019 is a separate interventional radiologist who does not administer byproduct material and is only exposed to unlicensed radiation sources.

Additional review of occupational exposure in 2018-2019 to individuals with other job descriptions, some of whom work alongside the identified interventional radiologists, demonstrates the level of occupational exposure that occurs within our healthcare system.

Job Description	2018 Max Exposure (mrem)	2019 Max Exposure (mrem)
Nuclear Medicine/PET Technologist	445	468
Interventional Radiologist	1534	1944
Interventional Radiology Technologist/Nurses	739	448
Cardiologist (Cardiac Catheterization Lab)	985	1394
Cardiac Cath Lab Technologist	657	663

Table 1 - Maximum occupational exposure to individuals for the 5 highest exposed job categories at St. Luke's in 2018-2019. Most staff members who receive occupational exposure to radiation have documented exposures significantly less than those in Table 1. Our interpretation of the data is that, based on safety control measures and operational procedures in place, there does not exist a substantial potential for interventional radiology providers, or other staff members at St. Luke's, to exceed NRC regulatory limits.

We agree that improvement of our practice and procedures is important to promoting a safe and compliant work environment. The NRC and its inspection process have provided us with additional opportunities to do so. However, we do not agree that St. Luke's has created an environment where there existed a substantial potential for overexposure. 影

St. Luke's Health System

Radiation Safety Committee

Provider TLD Badge Compliance Attestation

Deficiencies identified	Action plan to resolve	
 Not all providers are consistently wearing TLD badges when performing fluoroscopy procedures. 	 Annual radiation safety awareness training for badge wearers. Providers will be 100% compliant Notify RSO when emergent case arises and badge was not worn. Identify barriers to help with compliance Apron in IR suite with badge attached and not in CT suite Lanyards to attach badges and place outside of apron when needed Random audits for compliance Share quarterly results of radiation dose with BRG 	
 Policies referenced: 1. EC046 SLHS Radiation Exposure Monitoring Program (ALARA) 2. 19.12 Instructions to workers 	Occupationally exposed personnel will: 1. Wear monitoring badges or dosimeters when working with or in the vicinity of radiation sources. 2. Return dosimeters at the end of the scheduled exchange period. 3. Refusal to wear radiation protection by any employee, contractor or physician will be reported to the Radiation Safety Officer and hospital administration. 4. Attend training and perform online training modules related to good radiation safety practices.	
Signature	Print name: Sean Cav	
1/17/20		

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St. Luke's Health System

Radiation Safety Committee

Provider TLD Badge Compliance Attestation

Deficiencies identified	Action plan to resolve		
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Date:_ 2/28/2020

Attachment A - IR Physician Attestations

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St. Luke's Health System

Radiation Safety Committee

Provider TLD Badge Compliance Attestation

Deficiencies identified	Action plan to resolve
 Not all providers are consistently wearing TLD badges when performing fluoroscopy procedures. 	 Annual radiation safety awareness training for badge wearers. Providers will be 100% compliant Notify RSO when emergent case arises and badge was not worn. Identify barriers to help with compliance Apron in IR suite with badge attached and not in CT suite Lanyards to attach badges and place outside of apron when needed Random audits for compliance Share quarterly results of radiation dose with BRG
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3/20 Date:

Attachment A - IR Physician Attestations FEB-26-2020 04:00PM From:STLUKES 7065325

To:11791

Page: 1/1

TT St. Luke's Health System

Radiation Safety Committee

Provider TLD Badge Compliance Attestation

Deficiencies identified	Action plan to resolve
 Not all providers are consistently wearing TLD badges when performing fluoroscopy procedures. 	 Annual radiation safety awareness training for badge wearers. Providers will be 100% compliant Notify RSO when emergent case arises and badge was not worn. Identify barriers to help with compliance Apron in IR suite with badge attached and not in CT suite Lanyards to attach badges and place outside of apron when needed Random audits for compliance Share quarterly results of radiation dose with BRG
Policies referenced: 1. EC046 SLHS Radiation Exposure Monitoring Program (ALARA) 2. 19.12 Instructions to workers	Occupationally exposed personnel will: 1. Wear monitoring badges or dosimeters when working with or in the vicinity of radiation sources. 2. Return dosimeters at the end of the scheduled exchange period. 3. Refusal to wear radiation protection by any employee, contractor or physician will be reported to the Radiation Safety Officer and hospital administration. 4. Attend training and perform online training modules related to good radiation safety practices.
Signature 2176128	Print name: ?. David Sonntag

H II	Attachment B - Polic	y EC046
当는 St	Luke's	
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POLICY

TITLE	Radiation Exposure Monitoring Program (ALA	ARA)	
PURPOSE	The occupational radiation exposure program is intended to maintain radiation exposure As Low As Reasonably Achievable (ALARA). Personnel are monitored for radiation exposure to meet federal and state radiation exposure control guidelines with the intent to provide a safe environment for employees, patients, and visitors consistent with the ALARA philosophy.		
SCOPE	This policy applies to the specified St. Luke's Facilities, Post-Acute Services, Specialized Locations, Service Lines, Department, Units, Clinics, Personnel, and Patient Care Population selected below.		
Facilities	 St. Luke's Health System and all subsidiaries*, in Selected Facilities below: St. Luke's Elmore Medical Center St. Luke's Jerome St. Luke's Magic Valley Regional Medical Center St. Luke's McCall St. Luke's Nampa Medical Center St. Luke's Regional Medical Center St. Luke's Regional Medical Center St. Luke's Wood River Medical Center * Subsidiaries include, for example, Select Medical Network of Idaho, In Care, Ltd, dba St. Luke's Health Partners Accountable Care Organization 	 St. Luke's Health System and all subsidiaries*, including all Facilities listed below. Selected Facilities below: St. Luke's Elmore Medical Center St. Luke's Jerome St. Luke's Magic Valley Regional Medical Center St. Luke's McCall St. Luke's Nampa Medical Center St. Luke's Regional Medical Center St. Luke's Nampa Medical Center St. Luke's Nampa Medical Center St. Luke's Nampa Medical Center St. Luke's Regional Medical Center St. Luke's Regional Medical Center St. Luke's Regional Medical Center (Boise, Meridian, Eagle, Fruitland, MSTI) St. Luke's Wood River Medical Center 	
Post-Acute Services & Specialized Locations	 All Post-Acute Services and Specialized Location Selected Post-Acute Services and Specialized Location St. Luke's Hospice (MC, TV) St. Luke's Magic Valley Hospice St. Luke's Rehabilitation - Subacute Rehab U St. Luke's Rehabilitation Inpatient Acute Care St. Luke's Magic Valley Inpatient Rehab (Gwe St. Luke's Canyon View Behavioral Health Se St. Luke's Clinic - Eastern Oregon Medical As St. Luke's Jerome Family Medicine Not Applicable 	as listed below. Discretions below: St. Luke's Home Care (MC, TV, WR) St. Luke's Magic Valley Home Health Init (Boise) Unit (Boise) Unit (Boise) In Neilsen Anderson Rehabilitation Center) Ervices ssociates St. Luke's Elmore Long Term Care St. Luke's Salmon River Medical	
Service Lines/ Departments/ Units/Clinics	 All Service Lines/Departments/Units/Clinics Selected Service Lines/Department(s)/Unit(s)/Clinics Click here to list departments/units. Not Applicable 	nic(s) listed below	

St. Luke's process for developing policies and the content of policies is proprietary business information and may only be shared outside of St. Luke's with permission from a Sr. Director, Administrator, Vice President, or CEO, or as required by law.

If this is a patient care policy, the information contained herein is used to provide guidance in the care of patients, but should not, and does not replace or preclude the use of clinical judgment.

For Policy Admi	inistration use only. Please DO NOT add or remove dates.		
Originator:	Medical Imaging	Original Authorization Date	1989
Revised Date:	10/15/19		
Effective Date:	10/15/19		Page 1 of 7

Personnel	 All Personnel working, practicing, or performing services Selected Personnel (List competences if required) Click here to list personnel. 		
Patient Care Population	□ All Populations □ Neonatal (Nursery/NICU) □ Pediatric < ⊠ Not Applicable	: <18 yrs □ Adult ≥ 18 yrs	
DEFINITIONS	NA		
RELATED DOCUMENTS	Appendix A: Notification of Declared Pregnancy & Counseling		

I. MANAGEMENT COMMITMENT

- A. Management is committed to keeping individual and collective doses from radiation sources as low as is reasonably achievable (ALARA). The organization includes a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- B. An annual review of the radiation protection program is performed, including ALARA considerations. This includes reviews of dose records, audits and inspections.
- C. When feasible, modifications to operating procedures and to equipment and facilities will be made if they will reduce exposures without sacrificing image quality.
- D. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

II. RESPONSIBILITIES

- A. Review of ALARA Program:
 - 1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
 - 2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table 1 – Investigational Levels				
			ALARA I (mrem per calendar quarter)	ALARA II (mrem per calendar quarter)
	1.	Whole body; head and trunk; active blood-forming organs; or gonads.	125	375
	2.	Lens of eye	375	1125
	3.	Extremities; any individual organ or tissue other than lens of eye.	1250	3750

 The RSC will evaluate the organization's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of Management.

- B. Radiation Safety Officer (RSO):
 - 1. Annually, the RSO will perform a review of the radiation protection program for adherence to ALARA concepts.
 - 2. Quarterly, the RSO will review the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Table 1 of this program and will prepare a summary report for the RSC.
 - Annually, the RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.
 - 4. Ensure that a permanent file of all personnel monitoring reports is maintained.
 - 5. Provide upon request of former workers, a report of their exposure to radiation or radioactive material for each year the worker was monitored.
 - 6. The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
 - 7. The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that Management, the RSC, and the RSO are committed to implementing the ALARA concept.
 - 8. Ensure that occupationally exposed persons are properly trained to maintain their exposures as low as reasonably achievable.
- C. The Department Director or Clinical Supervisor will:
 - 1. Ensure radiation badges are ordered for all appropriate personnel.
 - 2. Ensure personnel wear their assigned dosimetry badges when in the vicinity of radiation sources.
 - Educate staff on the proper storage/maintenance of radiation badges:
 - a. Badges are to be stored in an area where radiation is near background levels.
 - b. If taken outside of the workplace, badges are not to be kept inside of a car for more than an hour or exposed to the sun while inside a car.
 - c. Avoid extreme heat.
 - d. Avoid exposure to water.
 - 4. Ensure that occupationally exposed persons are properly trained to maintain their exposures as low as reasonably achievable.
- D. Occupationally exposed personnel will:
 - 1. Wear monitoring badges or dosimeters when working with or in the vicinity of radiation sources.
 - 2. Return dosimeters at the end of the scheduled exchange period.
 - 3. Refusal to wear radiation protection by any employee, contractor or physician will be reported to the Radiation Safety Officer.
 - 4. Attend training and perform online training modules related to good radiation safety practices.
- E. Authorized Users New Methods of Use Involving Potential Radiation Doses:
 - 1. The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
 - 2. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

- F. Authorized User's Responsibility to Supervised Individuals
 - 1. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 - 2. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

III. PROCEDURES FOR PERSONNEL MONITORING

- A. The Radiation Safety Officer (RSO) reviews all occupational dosimetry exposure reports to ensure exposures are kept as low as reasonably achievable.
- B. Reports of occupational radiation exposures are available for employee review in the office of the RSO and at the individual departments of the radiation workers.
- C. All individuals who are occupationally exposed to ionizing radiation and are likely to receive 10% of the annual occupational limits will be issued a whole body dosimeter that will be processed on a monthly or quarterly basis. The exchange frequency is based on the department's typical radiation exposure levels.
- D. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a finger dosimeter that will be processed on a monthly or quarterly basis.
- E. All individuals who are occupationally exposed to radiation on an occasional basis will be issued a badge if their exposure is expected to exceed 10% of their allowable limit.
- F. Radiation workers who declare their pregnancy are issued a fetal dosimetry badge.
- G. Other individuals who are exposed to radiation on an occasional basis, such as environmental services personnel or clerical personnel who work in the nuclear medicine clinic but do not routinely work with patients, and nurses who occasionally care for patients who have received diagnostic nuclear medicine dosages, will not normally be issued dosimeters.
- H. Personnel doses less than the Investigational Level: Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level.
- I. Personnel doses equal to or greater than the Investigational Levels
 - 1. Personnel dose less than ALARA Level I: Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for ALARA Level I.
 - 2. Personnel dose equal to or greater than ALARA Level I but less than ALARA Level II: The RSO will review the dose of each individual whose quarterly dose equals or exceeds ALARA Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed ALARA Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee.
 - 3. Personnel dose equal to or greater than ALARA Level II. The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding ALARA Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation.
- J. Reestablishment of investigational levels to levels above those listed in Table 1: In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

IV. EXPOSURE MONITORING OF PREGNANT RADIATION WORKERS

- A. When a radiation worker declares her pregnancy, her occupational exposure limits decrease from 5000 millirem per year to no more than 500 millirem to the fetus for the total pregnancy with a monthly dose limit of 50 millirem to the fetus.
- B. Declaration of Pregnancy
 - 1. A radiation worker has the option to declare her pregnancy to her supervisor and to the Radiation Safety Officer using the attached form. Once declared, her occupational radiation dose is restricted to no more than 500 millirem to the fetus during the pregnancy and no greater than 50 millirem per month to the fetus for the duration of the pregnancy.
 - 2. Declaration is strictly voluntary. If the radiation worker does not choose to formally declare her pregnancy, her occupational radiation exposure limits remain at 5000 millirem per year.
 - 3. The radiation worker has the option to undeclare her pregnancy. At that time, the restrictions described in paragraph 1 above will end and she will return to the limits in paragraph 2.
- C. Assignment of the fetal radiation monitoring badge
 - 1. Two radiation monitoring badges will be issued to the declared pregnant worker. The whole body badge should be worn between the waist and neck, preferably on or near the collar and outside any lead apron. The second is to be worn at the abdomen level and beneath the lead apron if a lead apron is worn.
 - The RSO will discuss the fetal exposure monitoring with the employee. The pregnant worker will be asked to sign a statement to the effect that this interview has taken place and that she understands the radiation safety instructions (see appendices).
 - The declared pregnant worker is to wear her radiation detection badges as directed during all working hours.
- D. Job responsibilities of the pregnant radiation worker are not modified unless the RSO determines that the fetal badge may exceed regulatory limits.

AUTHORIZED BY:

Original signed by James Souza, MD James Souza, MD System Vice President, Chief Medical Officer 10/15/19 Date

Reference Section

The following list of supporting references is attached to the foregoing policy for the convenience of staff. This list is not part of the foregoing policy and may not include all resources that were used to research the subject of the policy or prepare the content of the policy.

Level all clinical references that use Johns Hopkins	Strength	Quality	

Evidence-based references are required on all clinical policies (e.g., Patient Care, Pharmacy, Clinical Nutrition, and Infection Prevention).

List all references used to determine content, accuracy, and decisions on final content (e.g., websites, journals, books, etc.). The Medical/Science Library will assist in the gathering of current references.

Level the strength and quality of each reference according to Johns Hopkins standards. The Center for Nursing Excellence will provide the tools and training to achieve this purpose. <u>http://inside.slrmc.org/nursing/SNRC.php</u>.

Attachment B - Policy EC046 APPROVAL APPLICATION

All sections	s must be completed. Ente	r "NA" if not applicable. Do not leave a	ny section b	ank!		
		Approval Application		and the last		
Re Scott Fulle	Responsible Party Department/Unit cott Fuller Radiation Safety					
James Blaci	Lead ker	Department/Unit Radiation Safety	Department/Unit Radiation Safety			
Document T	ype: Policy	Document is: Existing		6.		
Review Outc	come: No Changes to Conte	nt Document to be reviewed: Every	3 Years			
Date	Sum	nary of Change(s)	Auti	nor/Title		
09/18/18	Interim Change: Updates investigating exposures ex	to ALARA levels and procedures for ceeding ALARA level.	Scott Fuller	, Radiation Safety Director		
10/8/19	Review: Minor changes		Sc Director F	ott Fuller Radiation Safety		
Education pla NA Retired or re Keywords:	an needed to implement policy eplaced documents: NA Add keywords, abbreviat	P □ Yes ⊠ No. If yes, describe the commu	inication and ec	lucation plan:		
radiation m	posure, radiation exposure m	radiation protection program, radiation sa	tety, monitorir	ig badges,		
Leads - Sub	ject Matter Experts – Stakeh	olders – Committees (list chair name)				
Facilities\ Locations*	Name	Role/Titl	6	Date Approved		
SLHS	Radiation Safety Committee	Committee (Chair: Chris Jenni	ngs, MD)	10/8/19		
SLHS	Radiation Oncology	Department Stakeholders & Le	Department Stakeholders & Leads Department Stakeholders & Leads			
			0-0			

* EL=Elmore, JR=Jerome, MC=McCall, MV=Magic Valley, NP=Nampa, SLHS=System, TV=Treasure Valley (SLRMC), WR=Wood River

т т 1 Attachment C - Quarterly ALARA Program Review Completed In February 2020 Prior to NRC Inspection

Radiation Safety Quarterly Dosimetry Review

This report is furnished by the Radiation Safety Officer to the St. Luke's Health System Radiation Safety Committee in accordance with the Radiation Exposure Monitoring Program (ALARA), as documented in Policy EC046. This is documentation that all available badge reports for the given period have been reviewed by the Radiation Safety Officer.

Completed By:	Scott Fuller, RSO	Period of Review:	4th Quarter - 2019
Signature:	Suffitz		
Date of Review:	2/7, 2/14, 2/19		

1. Review all Landauer sub-accounts and document individuals who have exceeded Quarterly ALARA Level I or ALARA Level 2 exposure levels.

Subaccount Name	Review Completed	Individuals Exceeding ALARA Levels (mrem)	
Americana Imaging Center	Yes	and the second	1
Boise Cath Lab	Yes		3
Boise Endoscopy/Surgery	Yes		5
Boise Imaging	Yes	(164), (126), (132), (132), (189), (157), (149), (381), (381), (533)	14
Boise Nuc Med	Yes		3
Capital City Fam	Yes		
Cardiovascular Surgery	Yes	(155), (203)	
Elmore	Yes		
Eagle Medical Plaza	Yes		
Fruitland Imaging	Yes		
Idaho Cardiology	Yes		
Idaho Family Physicians / Internal Medicine / Intermountain Orthopedic	Yes		
Jerome	Yes		
Meridian Cath Lab	Yes		
Meridian Endoscopy	Yes	(162)	
Meridian Imaging	Yes	(148), (218), (280)	55
Meridian Surgery Center	Yes		4
Meridian Nuclear Medicine	Yes		
Nampa Southside	Yes		
Nampa Cath Lab	Yes		
Nampa Imaging	Yes		4

Radiation Safety Quarterly Dosimetry Review

	Review		Absent
Subaccount Name	Completed	Individuals Exceeding ALARA Levels	Badges
Nampa IR / Nurse	Yes		3
Nampa MD / PA / ST	Yes		2
Nampa Nuclear Medicine	Yes		
Oncology - Boise	Yes		
Oncology - Fruitland	Yes		
Oncology - Meridian	Yes		1
Oncology - Nampa	Yes		
Portico Imaging	Yes		
Park Center Clinic	Yes		1
South Meridian YMCA	Yes		
SL Clinic East Oregon	Yes		
SLFH 10 Mile	Yes		
SLFH East Boise	Yes		
SLFH Meridian	Yes		
SLFH West Boise	Yes		
SL - McCall	Yes	1 (w. 1945)	4
Surgery Center - N 1st	Yes		3
Surgery Center - Robbins	Yes		1
Wood River	Yes		
Magic Valley CT Scan	Yes		
Magic Valley Cath Lab	Yes	(507), (204), (364)
Magic Valley Medical Plaza 2	Yes	(304)	
Magic Valley MSTI	Yes		
Magic Valley Nuc Med	Yes	(127)	
Magic Valley Nurses	Yes		1
Magic Valley Outpatient GI	Yes		3
Magic Valley OP Surgery Center	Yes		
Magic Valley Radiologists	Yes	(148), (131), 230), (129	
Magic Valley Outpatient Imaging	Yes		1
Magic Valley Surgery	Yes	(213)	
Magic Valley X-Ray	Yes	142)	3

Attachment C - Quarterly ALARA Program Review Completed In February 2020 Prior to NRC Inspection

Radiation Safety Quarterly Dosimetry Review

2. Review all fetal dosimetry monitors.

Have all employees who have decla consultation from Radiation Safety on record?	red pregnancies received Officer and documentation	Yes
Did any fetal monitoring badge exce	eed 50 mrem during any month?	No
If yes, describe the actions taken:	One badge in October reported 10 mr	em. All other badges in
	the quarter reported less than 3 mren	n.

3. Notify all individuals who have exceeded ALARA Level 1 exposure levels and provide with report of quarterly exposure and instructions to reduce exposure.

27

Yes

Total number of individuals exceeding ALARA Level 1:

Have all individuals exceeding ALARA Level 1 been notified?

4. List all individuals who have exceeded ALARA Level 2 exposure levels. These individuals must be contacted and an explanation of their high exposure levels must be documented.

Name	Subaccount	Explanation/Actions Taken
MD (507 mrem)	Magic Valley Cath Lab	Magic Valley Cath Lab providers frequently exceed ALARA II levels. We have issued waist badges for the group, beginning in January, which will provide a more accurate estimate of exposure to personnel and place greater weighting on the use of lead aprons.
381 mrem)	Magic Valley Surgical Services	Valley. There were no reported issues with the badge reading and it is expected that this exposure is within the normal range for the type of practice completed.
(533 mrem)	Boise Imaging	who primarily works in the EP Lab. We have requested that Landauer begin using EDE1 calculations, as a second wears a lead apron. Would have resulted in 160 mrem during quarter. RSO will continue to monitor.
(446 mrem)	Multiple	BRG interventional radiologists routinely exceed ALARA II levels during busy periods. This level of exposure is consistent with past exposure readings for

Attachment C - Quarterly ALARA Program Review Completed In February 2020 Prior to NRC Inspection

Radiation Safety Quarterly Dosimetry Review

Have all individuals exceeding ALARA Level 2 been contacted?	Yes
Additional Comments:	
5. Additional information	
METER (Multiple Employer Total Exposure Report) reviewed?	YES
Total number of badges "Unreturned" during quarter at time of RSO review (using myldr tool "Unreturned Dosimeter"):	112
Total number of badges "Unreturned" from <i>previous</i> quarter at time of RSO review (3-6 months past due):	24
*These badges have been reported as lost and assigned an exposure by RSO Total number of fetal monitoring badges in the system:	35

Investigational Levels					
	ALARA II (mrem per calendar quarter)				
 Whole body; head and trunk; active blood-forming organs; or gonads. 	125	375			
2. Lens of eye	375	1125			
3. Extremities; any individual organ or tissue other than lens of eye.	1250	3750			

Additional Comments:

Attachment D - Copy of Official Response to NRC Inspector Prior to Completion of Review



March 6, 2020 (Original) April 14, 2020 (Updated)

Janine F. Katanic, PhD, CHP Senior Health Physicist US Nuclear Regulatory Commission Region IV 1600 East Lamar Boulevard Arlington, Texas 76011-4511

RE: Follow-Up from NRC Inspection (License 11-27312-01)

Dear Dr. Katanic:

During your recent inspection of our operations there was a discussion regarding the exposure monitoring program for several physicians who are authorized for handling Y-90 Theraspheres and SIR-Spheres. This letter is to inform you of the corrective actions that have been taken and to provide you with the estimated exposure details for these physicians.

Description of Discovery

Our license currently includes 6 physicians who are authorized for use of Y-90. They are listed here:



Of the six individuals listed, four are active in our Y-90 program. Dr. and Dr. have not participated in this procedure for years and we attest that they have not handled yttrium-90 since the last NRC inspection.

The remaining 4 physicians are the active authorized users for Y-90 on our license. Each of these individuals also participates in interventional fluoroscopy procedures. 10 CFR 20.1201 requires that we monitor these individuals for their exposure to all licensed and unlicensed sources of radiation. During the course of your inspection, there were questions as to whether the badge readings for these individuals are accurate representations of their exposure to unlicensed sources of radiation (x-ray producing equipment).

Reason for Incomplete Monitoring Data of Personnel

Each of the identified individuals receives monthly dosimeters to be used for monitoring exposure to ionizing radiation. The dosimeters are readily available for use at each facility in our system. Following a thorough review of the program, it was decided that the education materials previously provided to this group were not enough to ensure that wearing the dosimeters was a priority. We have worked with the provider group to ensure that immediate training has been provided and we commit to additional training, as documented in this letter.

Actions Taken To Resolve The Issue

- On 2/26/20, the Radiation Safety Officer provided a video-recorded in-service to the physician group to ensure that all individuals are aware of current policies and regulations regarding our monitoring program. 3 out of 4 of the identified physicians received the training this same week, prior to you completing your inspection. The 4th physician, Dr. **Sector** was out of town and received the training on 3/3/2020. All 4 physicians have reviewed and signed an attestation statement that they received the training materials and commit to wearing the assigned badges when working with or in the vicinity of radiation sources.
- We commit to ensuring that the provider group is enrolled in the annual Radiation Safety and Education training module, which describes the requirements surrounding radiation monitoring and employee responsibilities.
- We have reviewed all available dosimetry data for the periods during which the identified physicians participated in Y-90 use. We have included this data for your review but have not referenced this information when completing our dose analysis based on scattered radiation survey measurements.
- Although there is available data from Landauer for each of these physicians, we have determined it appropriate to make independent assessments of the exposure to these four individuals for relevant time periods. We have made the assessments for the following years, based on dates when individuals began handling of Y-90 at our facility:

2014-19-	MD
2018-19-	. MD
2012-19-	MD
2013-19-	MD

Assigned Deep Dose Equivalent (mrem)								
Physician	2019	2018	2017	2016	2015	2014	2013	2012
	1652	2115	2015	2115	2115	2115		
	1005	1186	-	1.74		37.5	÷	-
	1019	1498	1406	1498	1498	1498	1498	1498
	944	1142	1029	1142	1142	1142	386) .

No individuals exceeded annual regulatory limits during these years, based on either the independent assessment or the badge data that was available.

- Estimates between 2017-2019 are made based on the attached document, "*Physician Exposure Estimates*, 2017-2019". DDE Estimates from 2012-2016 for the referenced physicians are made based on the maximum estimated exposure for these individuals between 2017-2019. We assert this to be a conservative approach to estimating the annual exposure for all years discussed in this letter. The 2013 estimate for the reported exposure for Dr. The provided by University of Wisconsin for January August of that year (5 mrem). The total is expressed in the table above.
- Over the course of the next 12 months we will be reporting to the Radiation Safety Committee the exposure of all individuals who routinely handle Yttrium-90 and assess whether these exposures are appropriate for the workload during the previous period. Any badge readings that fall outside of expectations for that period will be corrected, based on procedure volume.
- Based on the data available from Landauer, in conjunction with our independent assessment
 of physician exposure, we report to the NRC that there were no individuals who exceeded
 regulatory limits during the period in question.

I look forward to your response regarding the actions and reviews that have taken place. If you require additional information, please feel free to contact me at your convenience. We sincerely appreciate your attention to this response and the constructive feedback that was provided during your recent visit.

Sincerely,

24Fills

Scott Fuller, MS DABR Radiation Safety Director

The Filter

James Blacker, MS Assistant Radiation Safety Director

Attachment D - Copy of Official Response to NRC Inspector Prior to Completion of Review

Attachment A Physician Exposure Estimates, 2017-2019

Materials and Methods:

- All Interventional Radiology (IR) procedures for each physician for 2019 has been pulled for review with fluoroscopy time for each case being summated to produce a total fluoroscopy time. There was no fluoroscopy time captured for the year of 2017 and 2018 however the total number of IR procedures were available to use as a data point.
- The patient report list does not separate fluoroscopy modes (Normal or Cine) so a conservative ratio of 9:1 for Normal and Cine use respectively is applied to each unit of time. By reviewing Multiple IR patient cases we were able to determine a reasonable representation of Cine use.
- Using the Boise Philips IR room, we replicated a patient procedural case using 30 cm of water in a plastic bucket as a patient phantom and measured the exposure at 2 distances (50 cm and 100 cm) and using 2 fluoroscopy modes (Normal and Cine).
- The exposure reading was measured with a Fluke 451p ion chamber (SN: 4798) that is currently calibrated with a calibration date of 9/11/2019.

To accurately assign an exposure to a physician, we determined to make the estimate as conservative as practical by incorporating numerous assumptions that will provide a reasonable exposure that would be on the upper range. The following assumptions are asserted to provide an over-estimate while maintaining a reasonable output. It was necessary to account for Cine mode since it produces a much higher exposure rate than the Normal mode.

Assumptions:

- We will not rely on physician badge readings during this independent assessment of DDE. Although we have badge data, this assessment is based on scattered survey measurements, total fluoroscopy time, and overall procedure volume.
- Physician is in IR room during every Cine run. This is not routine in the clinic as physicians normally leave the room during the Cine run
- Every IR case contains a Cine mode component which accounts for 10% of the total exam exposure.

There were over 3008 medical procedures in 2019 that have been evaluated. Due to the voluminous amounts of data and the challenging task of reviewing each case we determined that the most expeditious and reasonable approach would be to attach a predefined calculated value to each unit of fluoroscopy time that was delivered by the physician to the patient. We obtained every IR procedure in question for the 2019 year and summated the total fluoroscopy time for each of the physicians listed below in Table 3. Not every case used Cine mode, but in order to account for the cases that did we attached an additional dose exposure contribution. We accounted for this by reviewing multiple complex IR cases to determine the Cine exposure contribution to the total procedural fluoroscopy time. Shown below in Table 1.

Procedural total time (seconds)	Cine time (seconds)	Fluoroscopy time (seconds)	Cine use of total fluoroscopy time
1608	132	1476	8.2%
2562	106	2456	4.1%
1182	52	1130	4.4%

Table 1. Percentage of Cine use vs. normal Fluoroscopy time

We interviewed the IR staff to learn more about the standard setup of procedures, their use of fluoroscopy modes as well as the positional location of the physician. We measured the distance from the fluoroscopy image receptor to the point where the physician is generally positioned during procedures and was determined to be 50 cm. To determine the actual exposure experienced by the physician we set up a water phantom and measured the exposure rate at a distance of 50 cm from the water phantom behind a floating shield that provided 0.5 mm of lead attenuation. All measurements used a tightly collimated 15 cm x 15 cm field size which represents an average field size used in IR. We made multiple measurements at multiple distances using the Standard mode as well as the Cine mode. The data is shown below in Table 2. The distance of 100 cm was used as a point of reference, only.

adult abdome	n (30 cm water) behind the floa	ting shield.
Operating Mode	50 cm	100 cm
Normal	13.20 mR/hr	6.50 mR/hr
DSA / Cine	114.00 mR/hr	50.00 mR/hr

Table 2. Fluoroscopy Survey Information

The total 2019 fluoroscopy time and number of procedures are summarized below in Table 3 while years 2017-2018 procedural numbers are shown below in Table 4.

Physician Name	2019 Fluoroscopy Minutes	2019 Fluoroscopy Hours	2019 # Procedures	2019 # Y-90 Procedures
	1750	29.2	520	13
	2838	47.3	576	3
	1726	28.8	631	21
	1622	27.0	680	7

Table 3. The total fluoroscopy time and procedures for each physician

Unlike 2019, the 2017 and 2018 fluoroscopy time was not captured in the medical procedure reports. To overcome this absence of data we compare the total number of procedures performed in previous years to those performed in 2019, shown in Table 4. Once the percentage differences were known they were used to assign an annual approx. DDE by multiplying the percentage difference by the physician's 2019 assigned DDE. There

was a significant reduction in procedures completed by the listed physicians for the year of 2019. This reduction was due to the reassignment of many of these procedures to the IR's physician assistants (PAs) who now handle a portion of medical fluoroscopy procedures.

Physician Name	2019 # Procedures	2017 # Procedures	2017 % Increase over 2019	2018 # Procedures	2018 % Increase over 2019
	520	715	38%	762	47%
	576	704	22%	735	28%
	631	760	20%	744	18%
	680	741	9%	820	21%

 Table 4. The total 2017 and 2018 procedures and the % increase from 2019

Formula (1) below is how we arrived at the total DDE for any given year. The 0.9 and 0.1 below make up the contributing amount of exposure representing Normal mode and Cine mode respectively.

Total EDE = (Fluoro Time hr x $0.9 \times 13.20 \text{ mR/hr}$) + (Cine time hr x $0.1 \times 114 \text{ mR/hr}$) (1)

Since our approach was to assign the most reasonable and conservative DDE we chose not to provide the DDE for a distance of 100 cm since it was an unrealistic distance for a physician to work at. As shown below in Table 5, 6, and 7 the annual DDE for 2017-2019 is well below the 5000 mrem limit for occupational workers. Since there is an innumerable amount of variance with each medical procedure that cannot be captured or quantified, we feel an additional factor of 1.5 is prudent to be applied to once again provide a reasonable DDE.

Physician	Normal Fluoro Exposure mR	Cine Fluoro Exposure mR	Approx. DDE 2019	Approx. DDE 2019 with the Additional Variability of 1.5
	346.5	332.5	679 mrem	1019 mrem
	561.9	539.2	1101 mrem	1652 mrem
	341.8	327.9	670 mrem	1005 mrem
	321.2	308.2	629 mrem	944 mrem

Table 5. DDE for the year 2019 with the Additional Variability

Physician	Approx. DDE 2019 with the Additional Variability of 1.5	rox. DDE 20192018 % increase of procedures overthe Additional riability of 1.52019	
	1019 mrem	47%	1498 mrem
	1652 mrem	28%	2115 mrem
	1005 mrem	18%	1186 mrem
	944 mrem	21%	1142 mrem

Table 6. DDE for the year 2018 with the Additional Variability

Attachment D - Copy of Official Response to NRC Inspector Prior to Completion of Review

Physician	Approx. DDE 2019 with the Additional Variability of 1.5	2017 % increase of procedures over 2019	Approx. DDE 2017	
	1019 mrem	38%	1406 mrem	
	1652 mrem	22%	2015 mrem	
	1005 mrem	20%	1206 mrem	
	944 mrem	9%	1029 mrem	

Table 7. DDE for the year 2017 with the Additional Variability

We feel that we have taken a reasonably conservative approach in determining the annual DDE for the above-mentioned physicians. We also hold a high level of confidence that the DDE that we will assign will be on the upper range thereby maintaining an overly conservative yet reasonable DDE for the years 2017-2019.

	Jan 19	Feb 19	Mar 19	Apr. 19	May 19	Jun. 19	Jul. 19	Aug. 19	Sep. 19	Oct. 19	Nov. 19	Dec. 19	Annual 19
-	71	91	58	253	145	192	65	128	85	295	95	56	1534
-	20	07	128	95	24	100	128	18	58	54	55	89	896
-	33	57	17	95	13	10	4	10	50		7	-	60
						10	2						2
	Jan. 18	Feb. 18	Mar. 18	Apr. 18	May. 18	Jun. 18	Jul. 18	Aug. 18	Sep. 18	Oct. 18	Nov. 18	Dec. 18	Annual 18
	-	*	41	5	311	80	75	226	266	238	74	87	1403
	22	21	31	38	22	35	53	18	36	121	126	6	529
	-	-	323	6	-		1		5	4		-	339
		•		6			1		1	2		•	10
	Jan. 17	Feb. 17	Mar. 17	Apr. 17	May. 17	Jun. 17	Jul. 17	Aug. 17	Sep. 17	Oct. 17	Nov. 17	Dec. 17	Annual 17
	5	63	162	116	152	277	99	246	2	213	206	168	1709
	41	113	105	34	60	127	183	60	154	105	96		1078
	134	-	2	1	264	20	36	39	76	83		273	928
	5	2	•	-		-		.+:	2	1			10
	Jan. 16	Feb. 16	Mar. 16	Apr. 16	May. 16	Jun. 16	Jul. 16	Aug. 16	Sep. 16	Oct. 16	Nov. 16	Dec. 16	Annual 16
	53	58	4	143	132	28	53	14		-	76	28	589
				-	-			2	.*		-		2
	•			3	•	•		3	•	•	•		6
	Jan. 15	Feb. 15	Mar. 15	Apr. 15	May. 15	Jun. 15	Jul. 15	Aug. 15	Sep. 15	Oct. 15	Nov. 15	Dec. 15	Annual 15
1	73	74		68	60	131	100	32	35	43	18	-	634
ſ			•	-		3	2	2	5	-	2	2	16
-		14.5	•			5	2	•	3		2		12
-	Jan. 14	Feb. 14	Mar. 14	Apr. 14	May. 14	Jun. 14	Jul. 14	Aug. 14	Sep. 14	Oct. 14	Nov. 14	Dec. 14	Annual 14
	27	294	80	105	109	136	65	133	93	161	125	87	1415
1	6	3	2	12	59	32	33		-	-	1	-	147
	14	4		27	-	-	-		1	-	-	-	42
	Jan. 13	Feb. 13	Mar. 13	Apr. 13	May. 13	Jun. 13	Jul. 13	Aug. 13	Sep. 13	Oct. 13	Nov. 13	Dec. 13	Annual 1
			Employed b	y University	of Wiscons	in (5 mrem,)			-	156	30	191
	-	-	-	-	5	-	3		14°	-		-	8
_	Jan. 12	Feb. 12	Mar. 12	Apr. 12	May. 12	Jun. 12	Jul. 12	Aug. 12	Sep. 12	Oct. 12	Nov. 12	Dec. 12	Annual 12
-	1.042	-	-	116		-	5	1.00	-	-			121

Available Physician Badge Data (Landauer, 2012-2019) Attachment B

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Attachment D - Copy of Official Response to NRC Inspector Prior to Completion of Review

Attachment E - Copy of Addendum to Response to NRC Inspector Prior to Completion of Review



April 15, 2020

Janine F. Katanic, PhD, CHP Senior Health Physicist US Nuclear Regulatory Commission Region IV 1600 East Lamar Boulevard Arlington, Texas 76011-4511

RE: Addendum to "Follow-Up from NRC Inspection (License 11-27312-01)"

Dear Dr. Katanic:

I appreciate the opportunity that you have given us to respond to additional questions that you provided following your review of our letter "Follow-Up from NRC Inspection (License 11-27312-01)". We have taken steps to respond to these questions to the best of our ability and submit this document as an addendum to our original response.

In addition, we have made updates to the original document and have provided the updated response, with edits, for submission and review. Please consider replacing the original response with this updated document.

The following bullet-point responses correspond to each of the questions that you presented in your e-mail on April 9th, 2020. We have made every effort to address each of your questions and make appropriate updates to the original document.

• Based on the feedback that you provided, we have reviewed the dates when individuals first proctored cases to train and participate in Y-90 handling. We have updated the date range of exposure data review based on this information. The dates have been updated in our report and are included here.

- April, 2012 (1st proctored case) - January, 2014 (1st proctored case) - December, 2016 (1st proctored case) - Hired in 2013, (added as AU in 8/2013)

• The dosimetry information that was reviewed from Landauer and provided in our report includes all exposure data from all St. Luke's facilities for these physicians and from licensed and unlicensed activities. All available dosimeters were reviewed and summed for the time period reported.

- The original submission to you indicated that we were more confident in the Landauer exposure data for Dr. The and that this data might be used as a 2nd verification. This statement has been removed from the updated submission. While we feel more confident that Dr. The was wearing his badge at greater compliance, we also became aware that his monitoring badge was occasionally left on his lead apron in the procedure room. This activity, while ensuring greater compliance with wearing the badge during procedures, may account for badge exposure readings above the assigned exposure based on scatter survey measurements and annual procedure volume.
- Prior to being employed by St. Luke's in 2013, Dr. was employed by the University of Wisconsin. The recorded DDE on the available Form 5 during 2013, as provided by UW, is 5 mrem. I have updated Attachment B to include this reported exposure. I have also added the 5 mrem reported exposure to the table in the cover letter, which would be the total assigned exposure (381 mrem + 5 mrem).
- None of the individuals involved in this report are engaged in licensed or unlicensed activities at any other facility besides St. Luke's, except for Dr. during 2013 (while employed at University of Wisconsin). Annually, we inform authorized users of our requirement to monitor exposure of employees who work at other facilities and request that facility information be provided. We have again consulted with the radiology staff, following your request, and they have confirmed that Drs.
- Due to a lack of high confidence in machine records prior to 2017 (due to the adoption of the new health information technology system, EPIC), we determined that the most appropriate manner for estimating physician exposures from 2012-2016 was to use the maximum exposure assigned to these physicians from 2017-2019. For all physicians, the maximum assigned exposure was in 2018. This year was a high volume year for interventional radiology and resulted in the assigning of additional cases to physician assistants and hiring of new radiology staff, which reduced volumes in 2019 for the physicians in question.
- During the time period in question, all interventional radiology equipment at St. Luke's hospitals in Boise, Nampa, and Meridian were similar Philips Allura systems. While each unit may operate with slight differences in output based on calibration settings, the equipment is designed by the same manufacturer with similar dose options/settings. We have considered that each unit may provide slightly different scattered dose profiles when utilizing our "Variability Factor" of 1.5.

• The parameters (kVp, mA) were not documented at the time of our survey of the Boise IR room and the unit has since been decommissioned due to its age. However, a similar setup in another Philips lab at our Meridian hospital provided the following techniques and survey results:

All measurements we used to represent an a the	re made with a scatt dult abdomen (30 ci e floating shield.	tering phantom m water) behind		
Operating Mode	50 cm	100 cm		
Normal (kVp: 78; mA: 9)	11.7 mR/hr	5.90 mR/hr		
DSA / Cine (kVp: 125; mA: 27)	92.00 mR/hr	52.00 mR/hr		

- Scatter data for this room was not previously available based on recent annual physics evaluations. We determined it to be most appropriate that we make these survey measurements for use in our report provided to you, with the survey data included in that report.
- We have removed the wording that indicates "dosimeter readings may not provide a
 reasonable representation of physician DDE" and "physicians may not have worn their
 dosimeter in a manner that would provide a reasonable representation of actual
 exposure". We have updated the assumptions section of this document to indicate that we
 are not relying on badge data for this assessment of exposures during the time period in
 question. Although we do have some badge data during this period, we prefer to make an
 independent assessment of physician exposure based on scatter survey measurements, total
 fluoroscopy time, and procedure volumes.
- We confirm that the number of procedures provided in our report includes procedures at all St. Luke's facilities for the physicians in question.

Your attention and support of our program is greatly appreciated. Please contact me at your convenience if we can provide an y additional information.

Sincerely,

Scott Fuller, MS DABR Radiation Safety Director

James Blacker, MS Assistant Radiation Safety Director