Licensee: Avera St. Luke's dba Avera St. Luke's Hospital

Facility: Aberdeen, South Dakota

License No.: 40-18000-01

Docket No.: 030-13778

EA-19-126

PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY

On February 13, 2020, representatives of Avera St. Luke's met with U.S. Nuclear Regulatory Commission (NRC) personnel in Aberdeen, South Dakota to discuss the apparent violations identified in NRC Inspection Report Number 030-13778/2019-001. The conference was held at the request of the licensee. The list of attendees is provided as an enclosure to this summary (Enclosure 1).

The NRC representatives discussed the apparent violations that were described in the subject inspection report and provided an overview of NRC's Enforcement Program (Enclosure 2).

The licensee's Director of Radiology Services presented Avera St. Luke's response to the apparent violations (Enclosure 3). The Director and the executive leadership representatives stated that they accepted all the apparent violations, as well as the supporting facts and circumstances, as detailed in the NRC inspection report. The corrective actions described by licensee representatives included:

(1) Revising and updating the radiation protection program policies;

(2) Implementing a management software to create routine reviews and revisions as necessary to the radiation protection program policies;

(3) Revising the occupational exposure investigation process and trigger levels;

(4) Moving the responsibility of radiation dosimetry reports to the Radiology Director rather than the Radiation Safety Officer;

(5) Clarifying and formalizing logistics and expectations for dosimetry collection, distribution, and wearing in a new badge policy;

(6) Recalculating the subject authorized user's occupational radiation exposure for calendar years 2018 and 2019 (see IR 030-13778/2019-001);

(7) Conducting interviews and review of ALARA practices with catheterization laboratory ("cath lab") staff;

(8) Implementation of a dosimetry check in the existing "Time Out" procedure prior to interventional radiology procedures;

(9) Revising standing calculations with the dosimetry vendor for catheterization laboratory staff; and

(10) Conducting spot checks of dosimetry compliance and ALARA practices.

(11) Initiating an Avera-wide (across NRC and Agreement State boundaries) initiative to standardize and implement greater oversight for radiology in general, and interventional radiology specifically.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this summary and its enclosures will be made available electronically for public inspection in the NRC Public Document room or in the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Enclosures:
1. Attendance List
2. NRC Presentation
3. Licensee Presentation

ATTENDANCE LIST

PREDECISIONAL ENFORCEMENT CONFERENCE

Avera St. Luke's

February 13, 2020

Name	Title & Organization (if applicable)
Jason VonEhr	HP, MIB, DNMS, NRC
Patricia Silva	Chief, MIB1, DNMS, NRC
Linda Howell	Deputy Director, RIV, NRC
David Cylkowski	Regional Counsel, RIV, NRC
Casey Alldredge	Enforcement Specialist, RIV, NRC
Jess Winter	Radiology CNO (CNO)
Nicholas Stevens	VP Operations Avera St Lukes
TODD FORKEL	CEO, AVERA ST LUKES
Jess Mueller	Quality Officer, Avera St. Luke's
David Martin	Lead Nuc Med Tech / Avera St. Lukes
Tony Kallas	Radiology Director / Avera St Lukes
Remotely From NRC Region IV:	
Mary Muessle	Director, DNMS, Region IV, NRC
Jeremy Groom	Team Leader, Allegations Coordination and Enforcement Staff
Remotely From NRC Headquarters:	
Robert Sun	Project Manager, NMSS
Leelavathi Sreenivas	Enforcement Specialist, OE

ATTENDANCE LIST

PREDECISIONAL ENFORCEMENT CONFERENCE

Avera St. Luke's

February 13, 2020

Name	Title & Organization (if applicable)
Remotely as a Member of the Public	
Brian Miller	State of Nebraska
	Department of Health & Human Services
	Office of Radiological Health
Remotely for Avera Corporate	
Victoria Lusk	Communications Coordinator
	Marketing and Public Relations
Jay Gravholt	Director of Media Relations
	Public Relations

NRC Enforcement Program

Predecisional Enforcement Conference

Avera St. Luke's
February 13, 2020
Aberdeen, SD

PEC Summary: Enclosure 2

FOR TODAY'S MEETING

1. No Final Decision Yet
2. We Want **Your Perspective**
   - Whether violations occurred
   - Significance of the violations
   - Enforcement actions (if any)

SIGNIFICANCE = "Severity Level"

SEVERITY LEVEL – I
(most significant regulatory concern)

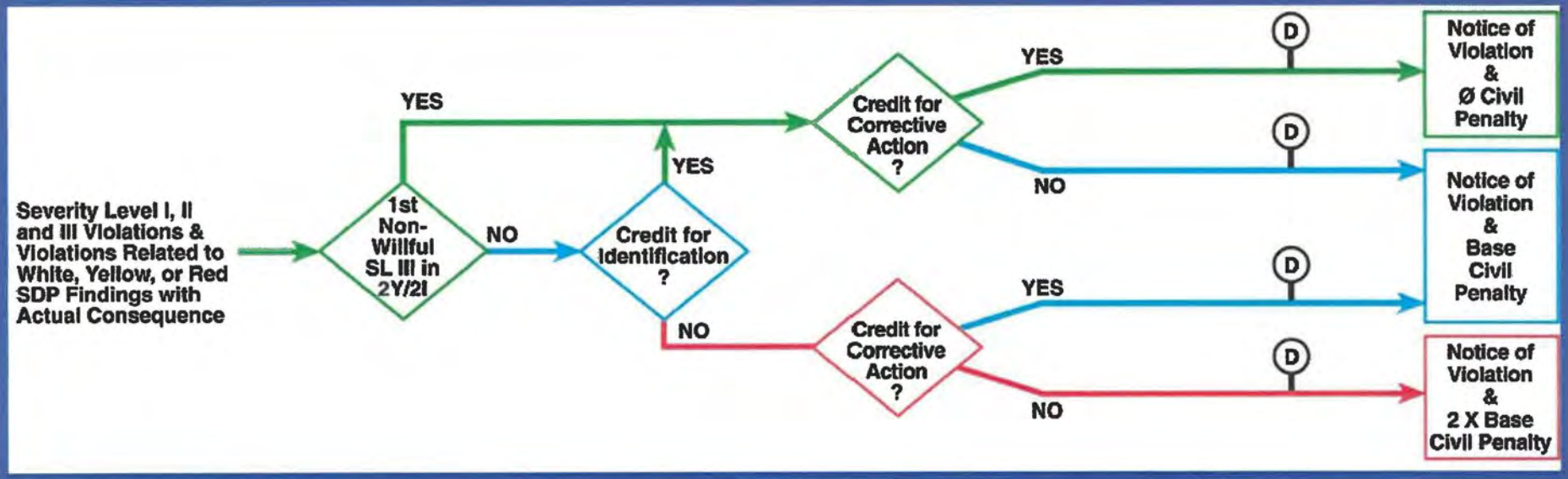
SEVERITY LEVEL – II
(very significant regulatory concern)

SEVERITY LEVEL – III
(significant regulatory concern)

(Non-Escalated Enforcement)

SEVERITY LEVEL – IV
(less significant concern, but more than minor)

CP: WHEN & HOW MUCH?



Primary Considerations:

1. How the violation was identified
2. The promptness and completeness of any corrective actions

WHAT IS A BASE CP?

d.	Test reactors, contractors, waste disposal licensees, industrial radiographers, and other large material users	$30,000
e.	Research reactors, academic, medical, or other small material users[21]	$15,000

TABLE B

Severity Level	Base Civil Penalty Amount (Percent of amount listed in Table A)
I	100%
II	80%
III	50%

POSSIBLE OUTCOMES

1. No Action
2. Notice of Violation (NOV)
3. NOV with Civil Penalty ($)
4. Order

PUBLIC INFORMATION

1. If NRC takes enforcement action, it is generally **Publicly Available** on NRC's website. Security-related information will not be publicly available.

2. In the event a civil penalty or an Order is issued, normally, a Press Release will be issued.

APPEAL RIGHTS

1. Any NRC action may be challenged

2. Civil Penalties and Orders provide hearing rights

Any questions?

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

PEC Summary: Enclosure 3

Inspection Findings:

1) Failed to monitor occupational exposure of a worker from licensed and unlicensed sources of radiation.

2) Failed to develop and implement certain elements of the radiation protection program.

3) Failed to submit a written report to the NRC within 30 days of discovery of a situation covered under 10 CFR 20.2203, specifically an overexposure involving an adult occupational worker.

- The Licensee does not dispute these findings.

Action Plan:

Violation 1 - 10 CFR 20.1502(a)(1)

Failed to monitor occupational exposure of a worker from licensed and unlicensed sources of radiation.

The licensee reviewed responsibilities of the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). (Exhibit 1-6)

Policy changes included:

1) The licensee changed the investigation levels. (Exhibit 4, Sec VI, Table 2)
2) The licensee updated the investigation process. (Exhibit 4, Sec VI, paragraph B)
3) The licensee identified steps to contact the NRC when exposures reach 5 rem or greater. (Exhibit 4, Sec VI, paragraph B, 5)

Action Plan:

Violation 1 - 10 CFR 20.1502(a)(1)

Licensee will ensure review of radiation safety policies annually.

1) Licensee placed all radiation safety policies into PolicyStat.
2) Licensee set-up an automated review process.
3) PolicyStat will send out reminders and document the review process. (Exhibit 7)

Action Plan:

Violation 1 - 10 CFR 20.1502(a)(1)

Licensee will have Radiology Director and RSO review radiation dosimetry reports.

- The RSO has assigned the Radiology Director to review radiation dosimetry reports.

Action Plan:

Violation 1 - 10 CFR 20.1502(a)(1)

Licensee will investigate doses exceeding established quarterly Investigation Levels.

- Licensee developed an Investigation Level Action Form. (Exhibit 8)

Action Plan:

Violation 1 - 10 CFR 20.1502(a)(1)

1) Licensee developed clear action plan for individuals with radiation doses exceeding the organization's investigative levels and for doses that reach 5 rem or greater in a calendar year.
2) Policy revision outlines specified corrective action in the ALARA policy. (Exhibit 4, section VI, paragraph B, 6)

Action Plan:

Violation 2 - 10 CFR 20.2203(a)

Failed to develop and implement certain elements of the radiation protection program.

The licensee revised ALARA Policy Section V and VI. (Exhibit 4)

1) The licensee established new quarterly investigation levels.
2) Defined a process for investigating radiation doses exceeding the licensee's established investigation dose levels.
3) Defined a process for reporting radiation doses exceeding the NRC's annual limit.
4) Defined disciplinary action for individuals not following ALARA practices and concepts.

Action Plan:

Violation 3 - 10 CFR 20.1101(a)

Failed to submit a written report to the NRC within 30 days of discovery of an overexposure involving an adult occupational worker.

1. Immediate action was taken to recalculate the authorized user's radiation exposures.
2. Recalculations determined the dose of the authorized user to be 762 mrem for 2018. (Exhibit 9)
3. Revisions of the ALARA policy includes when and how to submit a written report to the NRC.

Action Plan:

Other Actions Taken to Correct or Improve Our Radiation Safety Program

1. Radiology Director conducted interviews with Cath Lab staff on radiation safety practices. (Exhibit 10)
2. ALARA practices and concept were reviewed and discussed with staff. (Exhibit 11)
3. Additions to the "Time Out" procedure were implemented. (Exhibit 12)
4. Lead apron holders were installed in the interventional radiologists' offices. (Exhibit 13)

Other Actions Taken to Correct or Improve Our Radiation Safety Program

1. The Radiology Director to perform monthly checks of "Time Out" procedures in Cath Lab. (Exhibit 14)
2. Badge calculations were adjusted for certain staff.
3. Lens dosimetry badge was ordered for interventional radiologist.

Summary

Actions taken by Licensee

- Performed recalculations of doses
- Performed interviews
- Conducted ALARA training
- Performed spot checks
- Reviewed and changed dosimetry calculations
- Ordered a lens dosimetry badge for interventional radiologist
- Reviewed responsibilities of the RSO and the RSC
- Reviewed radiation safety policies at the RSC meeting
- Setup annual policy reviews
- Installed lead apron holder for radiologist
- Incorporated lead apron & badge checks into our "Time Out" procedures
- Developed an Investigation Level Action Form

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 1

Current Status: *Active*

PolicyStat ID: *7576576*

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

Radiation Safety Committee

Policy Number: RS-1

PURPOSE:

The purpose of the Radiation Safety Committee (RSC) is to oversee the medical use of byproduct material.

POLICY:

A. ORGANIZATION:

The RSC is composed of individuals who have special expertise in the safe use of byproduct material, as required by Section 35.24 of the Nuclear Regulatory Commission Guidelines. The committee membership must include an authorized user of each type of byproduct use permitted by our license, a Radiation Safety Officer (RSO), a representative of nursing service and a representative of management who is neither an authorized user nor a RSO. Other members may be included as appropriate. The RSC will meet quarterly or more frequently as needed. To establish a quorum and to conduct business, at least one half of the Committee's membership must be present, including the RSO and management representative.

B. FUNCTION/CHARGE:

The functions of the RSC are as follows:

1. Review recommendations on ways to maintain individual and collective doses As Low As Reasonably Achievable (ALARA) and ensure that licensed material is used in compliance with NRC regulations and ALARA philosophy and program.
2. Review, on the basis of safety and with regard to the training and experience standards, and approve or deny any individual who is to be listed as an authorized user, authorized medical physicist, or the RSO, before submitting a license application, request for amendment, or renewal.
3. Review on the basis of safety, and approve with the advice and consent of the RSO and the management representative, or reject minor changes in radiation safety procedures that are not potentially important to safety and permitted under NRC regulation Part 35. This includes review of training programs, equipment, facility, supplies, procedures, and investigational levels for individual radiation exposures.
4. Review a summary of the occupational radiation dose records of all personnel working with byproduct material.

5. Review all incidents involving byproduct material with respect to cause and subsequent actions taken.
6. Review the radiation safety program annually.
7. Establish and maintain a program to ensure that all persons whose duties may require them to work in or frequent area where radioactive materials are used, are appropriately instructed and trained as required in 10 CFR Part 19.
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
9. Maintain RSC minutes as required by
10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

C. Authority: The RSC has authority, organizational freedom, and management prerogative to:

1. Identify radiation safety problems
2. Initiate, recommend, or provide corrective actions
3. Verify implementation of corrective actions
4. Meet as often as needed to conduct its business but no less than four times per year.
5. To the extent that they do not interfere with the mission of the RSC, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

D. RSC REPORTING PROCEDURE:

The minutes of each RSC meeting must include:

1. The date of the meeting
2. The members present
3. The members absent
4. Summary of deliberations and discussions
5. Recommended actions, and numerical results of all ballots
6. ALARA program reviews described in Part 35 of the NRC regulations

The minutes of each RSC meeting will be distributed to each member of the Committee, Administration, and the Hospital's Safety Committee.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 2

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

Authorized Users

Policy Number: RS-2

Responsibility of Authorized Users

The authorized user will be responsible for ensuring compliance with these procedures in areas under his/her jurisdiction. In brief, the responsibilities of the principal investigator are as follows:

1. Ascertain that the contents of these procedures are known and understood by personnel under his/her supervision who work with ionizing radiation. To see that new personnel will be instructed as to the hazards and safety precautions attendant to their work. To see that new personnel will be instructed in a course of action in emergencies. This instruction will be given by the Radiation Safety Officer at the request of the principal investigator.
2. Ascertain that proper use is made of personnel monitoring equipment assigned to those under his/her supervision.
3. Supervise the area surveying program established in his/her area by the Radiation Safety Officer.
4. Notify the Radiation Safety Officer immediately of the following circumstances:
    a. When an over-exposure to radiation is indicated
    b. When radioactive material is lost or stolen
    c. Any other situation which the principal investigator believes to be hazardous
5. Advise the Radiation Safety Officer of any substantial change in the nature of his/her experiment and/or storage and use facilities.
6. Ascertain that copies of records requested by the Radiation Safety Officer are forwarded promptly.
7. Supervise record keeping of the activity in his/her area as requested by the Radiation Safety Officer.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 3

Current Status: *Active*

PolicyStat ID: *7581471*

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

Responsibilities and Authority of Radiation Safety Officer

Policy Number: RS-3

PURPOSE:

The purpose of this policy is to outline the responsibilities and authority of the Radiation Safety Officer (RSO).

POLICY:

The RSO duties and responsibilities include ensuring radiological safety, compliance with US Nuclear Regulatory Commission (NRC) and Department of Transportation (DOT) regulations, and the conditions of the license. The RSO is responsible for implementing the radiation safety program and ensuring the radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO may delegate responsibilities as required. The RSO's duties and responsibilities include the following:

1. Stop any licensed material activities that the RSO considers unsafe.
2. Secure licensed material from unauthorized access or removal.
3. Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions.
4. Use radiation protection procedures and controls to ensure radiation exposures are maintained as low as reasonably achievable (ALARA) as defined in 10 CFR 20.1003.
5. Develop, document and implement a radiation protection program that is consistent with the scope of the activities included in the license and ensures compliance with the regulations and license conditions.
6. Review radiation protection program content and implementation annually. (10 CFR 20.1101)
7. Establish and maintain a personnel monitoring program. Provide personnel monitoring equipment to individuals who are likely to receive more than 10 percent of the allowable radiation dose limit in one year. (10 CFR 20.1501 and 20.1502)
8. Ensure individuals installing, relocating, maintaining, or repairing devices containing sealed sources are trained and authorized by a NRC or an Agreement State license.
9. Ensure staff receive annual ARARA training, education on the potential health risks, instructions on effective use of protective devices, procedures required to minimize exposures to radiation materials and

ionizing radiation, and their responsibility to promptly report any conditions that may cause unnecessary exposures.

10. Ensure radiation dosimetry monitoring devices are properly used, worn, stored, and exchanged at the proper intervals to ensure staff's occupational radiation doses are properly monitored, recorded, and maintained.
11. Ensure radiation dosimetry monitoring devices are review quarterly to ensure radiation levels are maintained within designated radiation levels set by the licensee.
12. Ensure staff review their radiation dosimetry monitoring devices annually and records are maintained properly for staff to view upon requests.
13. Develop, distribute, implement and maintain up-to-date written operating and emergency procedures.
14. Comply with the NRC or Agreement State and immediately notify the proper authorities of any radiation incident involving over exposures to ionizing radiation or radiation materials, violations of regulations, loss or theft of licensed material, damage to or malfunction of sealed sources, or medical radiation event. Follow-up with a written report that includes the corrective actions taken, preventive actions planned, and the results of any evaluation.
15. If violations of regulations, license conditions, or program weaknesses are identifies, effective corrective actions are developed, implemented, and documented.
16. Dispose, return to manufacture or transport licensed material in accordance with all applicable DOT requirements. Obtain receipts acknowledging such activities.
17. Maintain up-to-date licenses. Ensure amendment and renewal requests are submitted prior to the license expiration date.
18. Ensure all equipment used and activities performed are limited to those specified in the license, the regulations, and the manufacturer's recommendations and instructions.
19. Ensure sealed sources are being monitored and tested accordingly as specified in the license.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 4

Avera

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

ALARA Policy

Policy Number: RS-4

PURPOSE:

The purpose of this policy is to familiarize technologists, physicians, and staff with the fundamentals of radiation protection and the proper procedures for maintaining exposures As Low As Reasonably Achievable (ALARA). The following policy should be instituted to assure compliance with 10CFR35 regulations of the Nuclear Regulatory Commission (NRC) and the National Council on Radiation Protection and Measurements (NCRP).

POLICY:

I. Management Commitment

A. We, the management of this institution, are committed to the program described herein for keeping individual and collective doses as low as reasonably achievable. In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

B. We will perform a formal annual review of the radiation safety program and bring to the RSC for review, including ALARA considerations. This review will include summaries of the following: types and amounts of radioactive materials used, occupational dose reports, all license conditions and regulations as they apply, and continuing education and training provided to personnel.

C. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures, unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvement have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

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 practical level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

A. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he/she has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should follow systematized procedures to ensure ALARA and shall incorporate the use of special equipment such as syringe shields, rubber gloves, and etc.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

B. Delegation of Authority

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. If the RSC has been overruled, the committee will record the basis for its action in the committee meeting minutes.

C. 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 where 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.
3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

A. Annual and Quarterly Review

1. Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
2. Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
3. Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

B. Education Responsibilities for ALARA Program

1. The RSO or his/her designee will schedule briefings and educational sessions to inform workers of ALARA program efforts.
2. 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.

C. Cooperative Efforts for Development of ALARA Procedures.

1. Radiation workers will be given opportunities to participate in formulating the procedures they will be required to follow.
2. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
3. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of these procedures.

D. Reviewing instances of deviation from good ALARA Practices. The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the cause(s). When the cause is identifed, the RSO will implement changes in the program to maintain doses ALARA.

IV. Authorized Users

A. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for new procedure.
2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of Authorized User to Persons Under His/Her Supervision.

1. The authorized user will explain the ALARA concept and their commitment to maintain exposures ALARA to all persons under their supervision.
2. The authorized user will ensure that persons under their supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

A. The occupational exposure for the following personnel will be monitored with a personal dosimeter(s).

1. Employees who are likely to receive in one year, a dose in excess of ten percent of the occupational dose limits set forth in Table 1.
2. Declared pregnant women likely to receive, during the entire pregnancy, a dose in excess of 0.1 rem (1.0 mSv)
3. Each individual who enters a high radiation area of very high radiation.

Table 1 - Annual Occupational Dose Limits (10 CFR 20.1201)	Annual Limit
The total effective dose equivalent	5 rems (50 mSv)
The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye	50 rems (500 mSv)
Lens dose equivalent	15 rems (150 mSv)
Shallow dose equivalent	50 rems (500 mSv)

B. The total effective dose equivalent (EDE) shall be determined as the following:

1. EDE = deep dose equivalent (DDE)
2. When a protective apron is worn while working with fluoroscopic equipment and only one personal monitoring device is used, it shall located at the collar outside of the protective apron and EDE = 0.3 x DDE (EDE2)
3. When a protective apron is worn while working with fluoroscopic equipment and two personal monitoring devices are used, one shall be located at the collar outside of the protective apron and one shall be located at the waist under the protective apron and EDE $=1.5 \times DDE_{waist} + 0.04 \times DDE_{collar}$ (EDE1)

C. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

D. The worker will know what resources are available if they feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures

A. Avera St. Luke's hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table 2 below. These levels apply to the exposure of individual workers.

Table 2 - Investigational Levels	Level I	Level II
	mrem / quarter	mrem / quarter
Effective dose equivalent (EDE)	300	400
Lens dose equivalent (LDE)	900	1200
Shallow dose equivalent (SDE)	3000	4000

B. The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures", or an equivalent form (e g. Radiation Dosimetry Report), results of personnel monitoring not less than once in any calendar quarter as required by 20.401 of 10 CFR Part 20. The following action will be taken at the Investigational Levels as stated in Table 2.

1. Quarterly Exposures of Individuals Less than Investigational Level I.
   - No further action will be taken in those cases where an individual's exposure is less than Table 2 values for

Investigational Level I, except when deemed appropriate by the RSO.

2. Quarterly Exposures of Individuals Equal to or Greater Than Investigational Level I, but Less Than Investigational Level II.
   - The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I. An "Investigation Level I and II Action Form" (See Attachment) will be completed by the RSO or their designee and presented to the RSC at the first RSC meeting following completion of the review. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSC. The RSC will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RSC minutes.
3. Quarterly Exposures Equal to or Greater Than Investigational Level II.
   - The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. An "Investigation Level I and II Action Form" (See Attachment) will be completed by the RSO or their designee and presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. RSC minutes will be sent to the management of this institution for review.
4. Re-establishment of an Individual Occupational Worker's Investigational Level II to a Level Above that Listed in Table 2.
   - In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual group. Justification for a new Investigational Level II will be documented. The RSC will review the justification and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in section VI.B.3 above will be followed.
5. Action for Exposure Limits exceeding the allowable adult occupation exposures set by the NRC in 10 CFR Part 20.1201.
   a. Immediate action shall be taken to determine the root cause of an annual dose reaching 5 rem or greater. A thorough investigation will be conducted to determine if the dose is accurate and/or realistic.
      i. If determined to be accurate, the facility will notify the NRC as described below.
      ii. If determined to be inaccurate, the dose shall be recalculated by the physicist to determine the realistic dose for the period in questioned and corrected in the individuals dosimetry records to reflect the new dose.
      iii. A report of the investigation, actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.
   b. Avera St. Luke's will be required to submit a written report to the NRC within 30 days after learning of an occupational annual dose limit of 5 rem or greater. The written Report shall contain the following information.
      i. The individual's occupational annual dose on a Form 5
      ii. Type of radiation exposure (radioactive material or external radiation).
      iii. The cause of the elevated exposures, dose rate or concentrations.
      iv. Corrective steps taken or planned to ensure against a recurrence.
      v. If personal information is included in the written notice the report must be prepared so this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."
   c. The written report should be sent to NRC Regional Office located in 10 CFR Part 20, Appendix D. https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-appd.html

- USNRC, Region IV
  1600 E. Lamar Blvd.
  Arlington, TX 76011-4511
  (817) 860-8100
  (800) 952-9677
  RidsRgn4MailCenter@nrc.gov

6. Corrective Actions for Non-Compliant with ALARA Policies and Practices.
   a. Individuals that are non-compliant with ALARA practices maybe subjected to corrective action in accordance with Avera Policy: Corrective Action 736.
   b. Any plans to remove an individual from his or her duties of performing x-rays or fluoroscopy procedures will be determined by the RSO.

Avera St. Luke's, Aberdeen, S.D. NRC License #40-18000-01.

Attachments

Investigation Level I & II Action Form

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 5

Current Status: *Active*

PolicyStat ID: *7581309*

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

General Radiation Safety

Policy Number: RS-5

PURPOSE:

The purpose of this policy is to outline the General rules of Radiation Safety

POLICY:

General Rules of Radiation Safety

1. The collar dosimetry badges will be worn at collar level at all times when on duty.
2. Collimation to the minimum field size necessary for the examination is required.
3. Gonadal shielding of the patient is required in all cases where it does not interfere with the acquisition of the desired diagnostic information.
4. Whenever possible, mechanical devices **only** (e.g. tape, Velcro straps, etc.) shall be utilized to immobilize patients during radiology procedures. In those circumstances when mechanical immobilizers are impractical and human intervention is necessary, the individual restraining the patient:
    a. Shall wear a 0.25 mm lead equivalency protective apron during the x-ray exposure. If the restrainer's hands might be in the primary x-ray beam, leaded gloves (0.25 mm thick) shall also be worn.
    b. Shall wear a personnel radiation monitoring device (badge) outside the lead apron at collar level.
    c. Should maximize the distance separating him/her and the x-ray beam by stretching his/her arms as far as possible.
5. Lead aprons must be worn by all personnel present during a fluoroscopic examination. 0.35 mm lead equivalent or greater aprons are required of the fluoroscopist, and 0.25 mm lead equivalent aprons must be worn by other assisting personnel.
6. The fluoroscopist must wear a leaded glove whenever his/her hand is in the primary beam.
7. X-ray room doors **must be closed** when x-rays are being produced.
8. Always stand inside the shielded control booth when initiating an exposure.
9. Utilize lead drapes whenever possible for fluoroscopic exams.
10. Annual Radiation Safety In-service with documentation of staff attendance is required.

11. New personnel are oriented to Radiation Safety practices.

PORTABLE RADIOGRAPHY:

1. Only persons whose presence is needed during portable procedures will be in the patient room.
2. A personnel radiation monitoring device (film badge) will be worn on the radiographer during exposure.
3. A protective lead apron of at least 0.25 mm lead equivalency will be worn by the radiographer during the x-ray exposure.
4. The Radiographer shall maximize the distances separating the patient and he/she by stretching the exposure cord as far as is reasonable.

SURGICAL/ORTHOPEDIC RADIOGRAPHY:

1. Clear all unnecessary personnel from the operating room.
2. All personnel in the room must wear lead aprons. Persons standing within three feet of the patient must wear .35 mm lead equivalent aprons. All others must wear .25 mm lead equivalent aprons.
3. A qualified x-ray Technologist must be present during the x-ray procedure.
4. Minimize fluoroscopy time by utilizing image storage apparatus or image hold function.

FLUOROSCOPY SAFETY RULES:

1. Only persons whose presence is needed should be in the fluoroscopy room during the x-ray exposure.
2. Protective aprons must be worn as directed above.
3. Medical fluoroscopy shall be performed only by Physicians properly trained in fluoroscopic procedures and authorized by the Medical Director of Radiology.
4. Beam-on time shall be kept to a minimum by utilizing the "off-position" of the foot switch.
5. The hand of the fluoroscopist or any other person shall not be placed in the useful beam unless the beam is attenuated by the patient and a protective glove of at least 0.25 mm lead equivalent is worn.
6. Special care should be taken to use the 0.25 mm lead equivalent protective drape available on the image intensifier. The intensifier should be placed as close to the patient as is practicable during the procedure.
7. All personnel shall position themselves as far as practical from the image intensifier.
8. Dosimetry badges will be provided and will be worn by each individual assigned duties in the fluoroscopic room. Badges will be worn at collar level outside the lead apron when assign only one badge. Individuals that have been assigned two badges will wear the collar badge at the collar level and the chest/waist/fetal badge at the waist level under the lead apron or skirt.

CARDIOVASCULAR LAB RADIATION SAFETY:

1. All personnel must wear lead aprons. Physicians must wear wrap around aprons with .35 mm lead equivalent; others .25 mm lead equivalent wrap around aprons.
2. Room doors must remain closed during x-ray use.
3. All personnel must wear film badges at collar level.
4. Annual Radiation Safety In-services by the Radiation Physicist or other qualified trainers will be completed

and documented.

LEAD APRONS, GLOVES AND GONADAL SHIELDS:

1. All lead aprons, gloves and gonad shields are to be numbered and checked annually to ensure integrity. All lead aprons, gloves and gonad shields will be checked under fluoroscopy or by x-ray for holes, cracks, and defects. Rejecting an apron depends on the location, area size, and number of flaws. It is best to keep the number of flaws to a minimum. Radiation Safety Officer's recommendation: holes larger than a pin hole or cracks in areas in the middle or around the gonad area will be inspected by the radiology manager/director to determine if apron should be removed from service and discarded. To determine if an apron should be discarded will depend on the size, number, and located on the apron. Small holes and cracks on the outer edge of the apron maybe acceptable where as if found in the middle of the apron or in the gonad area would not be acceptable. All questionable areas should be inspected by radiology manager/director to determine if apron is acceptable or not.
2. Visual inspection should be performed prior to each wear to ensure cleanliness and functionality. Lead protection should be cleaned regularly or whenever soiled.
3. Any necessary repairs will be made as soon as possible. If unable to repair, they will be discarded and turned into facility management for disposal.
4. Records will be maintained by the Radiology Director regarding the safety of all lead protection devices.
5. Cleaning: If lead protection devises gets dirty from dirt, barium, blood or other bodily fluids, clean it as soon as possible. Use cold water and mild detergent; carefully wipe down or softly scrub with a soft brush, hang and dry. Do not use bleach or any harsh chemicals, this can deteriorate and perhaps alter the effectiveness of protection. Do not autoclave, dry-clean or machine launder x-ray aprons.
6. Storage: Don't fold, crease, drape, or sit down tightly on lead aprons. It is our policy that aprons are safely hung on a lead apron rack, hanger or equivalent storage unit. Storing aprons correctly can increase the life cycle of the lead aprons.
7. Disposal: All protective devises that contains lead must be properly disposed of. You cannot dispose in regular trash. Turn-in all lead products/devices to facility management for proper disposal.
8. This policy is followed by Avera St. Luke's Hospital and all satellite Radiology departments.

NUCLEAR MEDICINE

Radiation exposure in nuclear medicine can be broken down into two categories; External and Internal Exposure. External Exposure refers to radiation exposure from an external source, either from a radiated patient or radioactive dose or source. We practice radiation safety with external exposure with:

1. Time: Reduce time spent near radioactive sources, e.g., patients, loaded syringes, open pigs, hot lab, and therapy doses.
2. Distance: Step back from any hot source, use tongs if you have to transfer a vial, the more distance the less exposure. Inverse Square Law.
3. Shielding: Use syringe shields, lead-lined carrying cases, pigs, leaded glass shields, ect., when manipulating or transporting radiopharmaceuticals.

Internal Exposure refers to radiation exposure from within us that we may receive from ingestion, inhalation,

percutaneously or injection.

1. Ingestion: Ingestion may come from contamination of isotope on hands or working areas and transported to food or drink and we ingest it. We lessen the risk of exposure by ingestion by not permitting food, drink and cosmetics in areas where radiopharmacy is worked with or stored. These fall under rules of the hot lab.
2. Inhalation: Inhalation may come from gaseous substances such as Xe133 or liquid I131.
   We limit out exposure to inhalation by providing an external fan to create negative pressure in our room for Xe133, which we don't perform any more and we use I131 in capsule form.
3. Percutaneous: Nuclear Medicine techs can come in contact with radiopharmaceuticals on their skin or clothes. We lessen the risk of percutaneous exposure by wearing gloves, lab coats and protective eye wear. Any contamination to skin or clothes requires clothing to be removed and for skin the affected area to be washed in an attempt to reduce the exposure to background. We cover surfaces were injections are performed with absorbent chucks to lessen the chance of radiopharmaceuticals to be absorbed into pores materials like wood. We also do daily surveys and weekly wipes to search for any contaminated surfaces. Any contaminated surfaces with be cleaned in an attempt to reduce exposure to background.
4. Injection: Injection exposure is from accidental puncturing the skin with a needle that has radioactivity in or on it. We lessen the exposure of this by not recapping needles. We have a recapping devise if needed. Also by using safety needles for straight injections

To prevent unnecessary exposure to patients, the dosages must be carefully calibrated, the correct dose is utilized for the exam ordered and performed on the proper patient using extreme care to ensure the proper dose is infused into a vein or proper dose is given orally.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 6

Current Status: *Active*

PolicyStat ID: *7581494*

Origination:	*04/1991*
Effective:	*02/2020*
Last Approved:	*02/2020*
Last Revised:	*02/2020*
Next Review:	*02/2021*
Owner:	*Tony Kallas: DIRECTOR - RADIOLOGY*
Area:	*Imaging - Radiation Safety*
References:	
Applicability:	*Avera St. Luke's Hospital*

Proper Wear and Care of Individual Radiation Monitoring Devices

Policy Number: RS-6

PURPOSE:

The purpose of this policy is to give instructions and to ensure the proper wear and care of individual radiation badges

POLICY:

1. A radiation monitoring badge will be furnished by Avera St. Luke's to all persons working with and around ionizing radiation or radioactive material, in accordance with 10 CFR 20.1201. 10 CFR 20.1201 provides in part that adults likely to receive in one year a dose excess of 10 % of those limits must be provided with a monitoring dosimetry device (badge). If an individual is likely to receive more than 10% of the annual dose limit, NRC requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his /her dose.
2. Exposures should not exceed 300 mrem per calendar quarter (according to SD State Administrative Rule 44:03:01:10 para 8). Dose levels exceeding 300 mrem/qtr will be investigated by Radiation Safety Officer (RSO) and/or the Radiation Safety Committee (RSC) according to ALARA Policy RS-4.
3. If an individual or group or individuals request not to wear a radiation badge for acceptable reasons, (demonstrated that monitoring is not necessary for an individual or group of radiation workers) the individual or group/department manager must declare the request in writing. The RSO will review all written declarations and determine if declaration is appropriate or not. The RSO may accept or deny the request not to wear a radiation badge. According to NUREG-1556, vol. 9, appendix M, to demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, NRC does not require licensees to monitor radiation doses for this class of workers.
4. A record of the individual's radiation exposure status will be kept in the Radiology Director's office. These records will comply with 10CFR 19 and 20 and the State Radiation Protection Code. The personnel exposure readings will be received monthly or quarterly depending on the individual's work setting. Yearly totals of an individual's exposure are available anytime from the RSO or Radiology Director.
5. At no time will a radiation badge be exposed to radiation unless worn by the individual to whom it is issued. Any infraction of this rule may result in the loss of that person's privilege to work with radioactive

material and/or ionizing radiation at the hospital.

6. Collection and distribution of the radiation badges for routine processing will be the responsibility of the RSO or his or her designee, however, it is the responsibility of the authorized user, physician, or department manager to ensure the cooperation of personnel under his/her supervision.
7. At the discretion of the RSO, a finger TLD badge will be assigned in addition to whole body radiation badges by persons performing implant therapy, preparing radioisotopes or injecting radioisotopes for imaging or therapeutic purposes.
8. Pregnant workers are urged to declare their pregnancy to the RSO or his or her designee so that a separate waist-level fetal badge can be provided to estimate the fetal exposure.
9. The estimate dose of radiation exposure to the monitoring devices will only be correct if these rules regarding the wearing of the badges are observed:
    a. The radiation badge shall be worn at all times while working at the hospital or clinic. For O.R. or other surgical staff badges shall be worn anytime ionizing radiation is being used or there is the potential of ionizing radiation to be used.
    b. Wear the badge at collar level outside the lead apron. Pregnant workers should request an additional badge to be worn at waist-level inside the lead apron. When two badges (chest and collar badges) are required the chest badge is worn between the mid chest and waist under the lead apron and the collar badge is worn at the collar level. Individuals wearing two badges will have their doses calculated using EDE1 calculations. (See Landauer Radiation Dosimetry Reports for the different calculations.
    c. Leave the radiation badge in a safe place or on a "Control Board" in your work area when not on duty. Do not take it out of the hospital unless assigned to work outside the hospital at one of Avera's clinics.
    d. Never wear a radiation badge issued to another person.
    e. The radiation badge issued to you is your responsibility. Turn it in at the right time in exchange for a like one and take care of it.
    f. Do not tamper with the radiation badge.
    g. Report loss or damage of the badge immediately to your supervisor or the RSO.
    h. Report any other incident relative to the wearing of the radiation badge (such as possible accidental exposure when badge is not worn) to your supervisor or the RSO.
    i. The radiation badge is not to be worn while on duty at another facility. The badge is the property of Avera St. Luke's and meant to indicate the efficiency of the Avera St Luke's radiation safety program.
    j. It is the responsibility of the supervisory personnel to see that the above rules are observed and to report radiation protection problems to the RSO.
    k. Flagrant violations of this policy may result in reprimand, suspension or termination.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Radiation Safety Committee (RSC) Approval	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020
RSO	Leslie Lenter: PHYSICIAN	02/2020
	David Martin: NUCLEAR MEDICINE TECHNOLOGIST LEAD	02/2020
	Tony Kallas: DIRECTOR - RADIOLOGY	02/2020

Applicability

Avera St. Luke's Hospital

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 7

Policy Workflow

Edit Effective Date

Approval Workflow: Imaging - Radiation Safety

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 8

Investigation Level I & II Action Form **Assigned Tracking #:** _____

Avera St. Luke's hereby establishes Investigational Levels for occupational radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Office (RSO) and reported to the Radiation Safety Committee (RSC).

Table 1

Investigational Levels	Level I	Level II
	mrem / quarter	mrem / quarter
Effective dose equivalent (EDE)	300	400
Lens dose equivalent (LDE)	900	1200
Shallow dose equivalent (SDE)	3000	4000

Investigation Findings and Action Plan:

Participant Number	Level	Type	Exceeded Dose	Year Qtr	Investigation Findings and Action Taken	RSC Review Date

The Radiation Safety Officer will review personnel monitoring devices either monthly or quarter depending how often devices are exchanged. The following action will be taken at the Investigational Levels as stated above.

1. Quarterly exposures of individuals **less than Investigational Level I**: No further action will be taken in those cases where an individual's exposure is less than Table 2 values for Investigational Level I, except when deemed appropriate by the RSO.
2. Quarterly Exposures of Individuals **Equal to or Greater Than Investigational Level I, but Less Than Investigational Level II**. The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I. An "Investigation Level I and II Action Form" (See Attachment) will be completed by the RSO or their designee and presented to the RSC at the first RSC meeting following completion of the review. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSC. The RSC will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RSC minutes.
3. Quarterly Exposures **Equal to or Greater Than Investigational Level II**. The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. An "Investigation Level I and II Action Form" (See Attachment) will be completed by the RSO or their designee and presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. RSC minutes will be sent to the management of this institution for review.

☐ Action Plan Pending

Estimated date for completion: _____ Reason: _____

☐ Action Plan Completed by RSO: _____ Date: _____

☐ Date Reviewed and Action Plan Approved by RSC: _____

Avera St. Luke's

Corrective Action Plan

NRC Inspection Report 030-13778/2019-001

Exhibit 9

Avera

911 E 20th St
Suite 505
Sioux Falls, SD 57105

August 13th, 2019

Tony Kallas
Director of Radiology Services
Avera St. Luke's Hospital
305 S State St
Aberdeen, SD 57401

Dear Mr. Kallas,

A radiation exposure reconstruction for 2018 was requested for [redacted] an interventional radiologist who performs fluoroscopic services at Avera St. Luke's. The dose area product (DAP) for all interventional procedures in the interventional suite covering the full year was provided. Additionally fluoroscopy time logs were also provided for additional procedures performed in either the general fluoroscopic room or with a C-arm. Finally, Dose length product data for interventional CT procedures was also provided. The interventional room has a Siemens Artis Zee, the fluoroscopic room has a Siemens Luminos Agile Max, the C-arm is General Electric OEC 9900 Elite and the CT scanner is General Electric LightSpeed VCT. A summary of this data is given in Table 1.

Month	Interventional DAP (μGy•m²)	General Fluoroscopic Time (min)	C-Arm Fluoroscopic Time (min)	CT Interventional Procedures DLP (mGy•cm)
January	24131.1	10.2	0	3781.06
February	62263.9	7.9	3.9	3194.44
March	53641.1	13.2	3.7	6860.97
April	12534.3	4.3	3.5	5188.6
May	51095.0	2.4	2.29	1195.09
June	35282.2	1.6	0	442.41
July	32230.0	7.84	0	5913.56
August	39402.7	9.1	14.85	3260.11
September	18834.2	6.3	12.79	3226.22
October	37932.3	6.2	5.5	7056.15
November	31089.0	13.8	11.4	3408.22
December	51639.2	2.6	8.68	0
Total	450075.0	85.4	66.6	43526.83

Table 1 – Summary of 2018 fluoroscopic usage for the physician.

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A. Scatter Measurements

1. Interventional Procedures

It is expected that the amount of scatter would be most dependent upon the applied air kerma and the field size. Since DAP is simply the product of the air kerma with the field size the total scatter should be approximately proportional to the total DAP. At clinical x-ray energies, Compton scattering is the dominant interaction. Thus the scatter to DAP ratio should only be weakly dependent upon the x-ray energy as most of the energy dependence is already incorporated into the DAP measurement. In addition the scatter to DAP ratio is not expected to vary significantly between live fluoroscopy and cine loops as the prime differences are exposure rate and beam quality.

Direct measurements of scatter radiation were taken utilizing blocks of acrylic and a RaySafe X2 solid state survey meter (SN: 230047, calibrated 11/2/2018). Measurements were performed in the interventional suite with a Siemens Artis Zee system.

Exposure measurements were taken under conditions that would produce a maximal amount of scatter per DAP applied to the acrylic phantom. Measurements were taken at approximately 50 cm from the midline of the phantom both with and without the overhead protective shield. Measurements were taken at both collar and waist level with SIDs of 90 cm and 120 cm. The 42 cm field size was used and the focal spot to phantom distance was 65 cm. The results are shown in Table 2.

Collar Measurements

	With Shield			Without Shield		
SID	DAP ($\mu Gy \cdot m^2$)	Scatter (mR)	Scatter/DAP ($mR/\mu Gy \cdot m^2$)	DAP ($\mu Gy \cdot m^2$)	Scatter (mR)	Scatter/DAP ($mR/\mu Gy \cdot m^2$)
120	270	0.0108	0.00004	59.6	0.381	0.0064
90	105.7	0.0116	0.00011	62.1	0.338	0.0054

Waist Measurements

	With Shield			Without Shield		
SID	DAP ($\mu Gy \cdot m^2$)	Scatter (mR)	Scatter/DAP ($mR/\mu Gy \cdot m^2$)	DAP ($\mu Gy \cdot m^2$)	Scatter (mR)	Scatter/DAP ($mR/\mu Gy \cdot m^2$)
120	124.4	0.0145	0.00012	63.6	0.584	0.0092
90	104.1	0.0162	0.00016	55.6	0.541	0.0097

Table 2 – Scatter measurements from an acrylic phantom for the Siemens Artis Zee

2. Fluoroscopic Procedures

As only the fluoroscopic time was available for general fluoroscopy, scatter measurements were taken with a typical clinical technique and with the maximum tube output. These can be used to estimate a 'typical' occupational exposure, and a maximum occupational exposure. The largest field size was used, as that produces the most scatter.

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Direct measurements of scatter radiation were taken utilizing blocks of acrylic and a RaySafe X2 solid state survey meter (SN: 230047, calibrated 11/2/2018). Measurements were performed in the fluoroscopic room with a Siemens Luminos Agile Max. Measurements were taken at the position beside the table in-line with the x-ray tube. The Pb drapes were not equipped to provide a maximum measure of scatter. Scatter measurements with both a clinical technique of 73 kVp, 22 mA (5 mGy/min tabletop dose rate) and a maximum technique of 111 kVp, 42 mA (46 mGy/min tabletop dose rate). The results are shown in Table 3.

Technique	Scatter Rate (mR/hr)
73 kVp, 22 mA	200
111 kVp, 42 mA	1600

Table 3 – Scatter without the Pb drape

3. C-Arm Procedures

As only the fluoroscopic time was available for C-arm procedures, scatter measurements were taken with a typical clinical technique and with the maximum tube output. These can be used to estimate a 'typical' occupational exposure, and a maximum occupational exposure. The largest field size was used, as that produces the most scatter.

Direct measurements of scatter radiation were taken utilizing blocks of acrylic and a RaySafe X2 solid state survey meter (SN: 230047, calibrated 11/2/2018). Measurements were performed with a General Electric OEC 9900 Elite C-arm. Measurements were taken at 50 cm from the center of the acrylic phantom. Scatter measurements with both a clinical technique of 95 kVp, 3.0 mA (15 mGy/min reference point dose rate) and a maximum technique of 120 kVp, 6.27 mA (55 mGy/min reference point dose rate). The results are shown in Table 4.

Technique	Scatter Rate (mR/hr)
95 kVp, 3.0 mA	160
120 kVp, 6.27 mA	550

Table 4 – Scatter from a C-arm at 50 cm

4. CT Procedures

Similar to interventional fluoroscopy, the amount of scatter from a CT procedure should be approximately proportional to the dose length product (DLP). The DLP includes both components of applied kerma and the field size, both of which strongly influence the amount of scatter. In addition, most procedures are performed with a fixed x-ray energy, 120 kVp, and beam quality.

Direct measurements of scatter radiation were taken utilizing a 32 cm body CTDI phantom and a RaySafe X2 solid state survey meter (SN: 230047, calibrated 11/2/2018). Measurements were performed with a General Electric LightSpeed VCT. Measurements were taken at the collar position of an individual standing next the patient and CT gantry with an adult abdomen technique. A majority of the CT interventional work that the physician performs are in the torso. The results are shown in Table 5.

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	DLP (mGy•cm)	Scatter (mR)	Scatter/DLP (mR/mGy•cm)
Left side of gantry	58.72	3.377	0.058
Right side of gantry	58.72	3.013	0.051

Table 5 – Scatter from a CT scanner beside patient

B. Upper Bound Occupoational Exposure Estimate

An upper bound estimation for the physician's occupational exposure was performed based on the data provided along with scatter measurements performed with each fluoroscopic system. The effective dose equivalent is estimated from the estimated scatter exposure, in Roentgen. This is then convereted to an equivalent dose, or dosimeter reading (1 mR ~ 0.876 mrem). The effective dose equivalent is then estimated using Webster's formula.

Assuming the physician doesn't utilize the overhead shield, a high estimate for the scatter to DAP ratio would be 0.01 mR/μGy•m² (Table 2). Applying this factor to the DAP for all 2018 procedures yields a reasonable upper bound for the collar badge exposure obtained from interventional procedures performed in the interventional suite. It is likely that the physician was often over 50 cm from the midline of the patient during procedures, which would significantly reduce his exposure. This is shown in Table 6.

Total DAP (μGy•m²)	Maximal Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
450075.0	4501	3943	1183

Table 6 – Estimated maximum exposure from the interventional suite
*EDE was estimated using Webster's formula of 0.3 * DDE.

Since only fluoroscopic time was available for procedures in the general fluoroscopic room, an upper estimate for the physician's exposure would be from the maximal scatter (1600 mR/hr, Table 3), without the Pb drape in place. This is shown in Table 7.

Total Fluoro Time (min)	Maximal Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
85.4	2277	1995	598

Table 7 – Estimated maximum exposure from the general fluoroscopic room
*EDE was estimated using Webster's formula of 0.3 * DDE.

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Similarly, only fluoroscopic time was available for the C-arm procedures. An upper estimate for the physician's exposure was estimated from the maximal scatter at 50 cm (550 mR/hr, Table 4). This is shown in Table 8.

Total Fluoro Time (min)	Maximal Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
66.6	611	535	160

Table 8 – Estimated maximum exposure from C-arm procedures
*EDE was estimated using Webster's formula of 0.3 * DDE.

An upper bound estimate for the physician's exposure from the CT interventional procedures can be estimated by assuming the physician stands beside the patient for all CT scans. This includes the pre and post procedure helical scans. It is unlikely that physician would remain in the scan room for most of those scans. In addition, a majority of the DLP from each procedure is from those series and not the axial series utilized during the procedure. A slight larger value of 0.06 mR/mGy•cm scatter to DLP ratio than was measured (Table 5) was used for the estimate. This estimate is shown in Table 9.

CT DLP (mGy•cm)	Maximal Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
43527	2612	2288	686

Table 9 – Estimated maximum exposure from CT procedures
*EDE was calculated using Webster's formula of 0.3 * DDE.

Cumulating the maximum estimate from each source of occupational exposure yields a total of **2627 mrem** for 2018. As this is an estimate of the maximum exposure, it is reasonable to assume that the physician's actual occupational exposure was considerably less than this value. It is highly unlikely that the actual exposure exceeded 5000 mrem.

C. Realistic Occupational Exposure Estimate

An attempt can be made to derive a more realistic estimate for the physician's occupational exposure by assuming reasonable ALARA practices and more realistic patient exposures from the fluoroscopic modalities for which only time is available.

An investigation of the physician's practices in the interventional suite reveals that he does not frequently use the overhead shield. A conservative estimate of 5% usage for the overhead shield is assumed. A more reasonable average distance from the midline of the patient is also assumed to be 75 cm. Observation of other interventional radiologists demonstrate a typical of distance 75 cm to 100 cm from the patient center during fluoroscopy. The inverse square law was used to estimate the scatter at 75 cm from those taken at 50 cm. The largest scatter measurements both with and without the overhead shield are corrected for distance and shown in table 10. A composite value of the scatter per DAP was also calculated assuming 5% usage.

Scatter With Shield @ 75 cm (mR/uGy•m²)	Scatter w/o Shield @ 75 cm (mR/uGy•m²)	Composite Scatter @ 75 cm (mR/uGy•m²)
0.000071	0.0043	0.0041

Table 10 – Scatter from the interventional suite.

Using the scatter to DAP ratio of 0.0041 and estimated occupational exposure was calculated and shown in Table 11.

Total DAP (μGy•m²)	Esimated Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
450075.0	1845	1616	485

Table 11 – Estimated occupational exposure from interventional procedures
*EDE was estimated using Webster's formula of 0.3 * DDE

For a more realistic estimate of the physician's occupational exposure in the general fluoroscopic room and with the C-arm, scatter from a typical clinical technique is used. For the general fluoroscopic room, an average technique would be around 73 kVp, 22 mA at 15 pulses per second. This results in tabletop exposure rate of about 5 mGy/min. This is generally lower than most fluoroscopic systems, but typical for the Siemens system as it designed for lower exposures. The geometry for the scatter is assumed to be similar to that described in the measurement section and it is also assumed the Pb drape is not used.

For the C-arm, a typical exposure rate at the reference point is about 15 mGy/min at 95 kVp and 3.0 mA. Similar to the interventional room the physician is typically at a distance greater than the 50 cm from which the scatter was measured from the phantom. The scatter measurements were adjusted to an average distance of 75 cm from the midline of the patient. The resulting estimated occupational exposure from the general fluoroscopic room and C-arm is shown in Table 12.

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	Total Fluoro Time (min)	Estimated Scatter Rate (mR/hr)	Estimated Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
General Fluoro	85.4	200	285	249	75
C-Arm	66.6	70	78	68	20

Table 12 – Estimated occupational exposure from general fluoroscopic procedures
*EDE was estimated using Webster's formula of 0.3 * DDE

For the CT guided procedures, the DLP from the pre and post procedure helical scans were ascertained from the PACS archive and removed from the total. It assumed that the physician leaves the room during these acquisition as no patient interaction is required. The same 0.06 mR/mGy•cm scatter to DLP factor was used to estimate scatter received by the physician. The result is shown in Table 13.

CT DLP (mGy•cm)	Maximal Scatter (mR)	Dosimeter Reading (mrem)	EDE* (mrem)
11860	712	623	187

Table 13 – Estimate occupation exposure from CT procedures
*EDE was calculated using Webster's formula of 0.3 * DDE.

Combining the estimated effective dose equivalent from each modality, it is estimated that the physician received approximately **762 mrem** in 2018. This is below the annual maximum allowable of 5000 mrem.

D. Conclusion

After review of all image guided procedures performed by the physician in 2018, including those utilizing the interventional fluoroscopy suite, the general fluoroscopy room, the mobile C-arm and the CT scanner, it is estimated that the physician would likely have received an effective dose equivalent of approximately 762 mrem in 2018. The estimation was derived from scatter measurements from acrylic phantoms that approximate the size of an average patient and assuming typical practices of the physician determined from staff interviews. This estimation assumes that the physician rarely uses the overhead shield available in the interventional fluoroscopy suite. It is recommended that he utilize the shield more as procedures allow.

In addition the maximum effective dose equivalent that the physician could have received in 2018 was estimated to be 2627 mrem. It is unlikely that the physician received this dose, but it is important to note that this value is still less than the 5000 mrem maximum allowable annual effective dose equivalent.

In addition the effective dose equivalent, the physician was estimated to have likely received approximately 2556 mrem for a lens dose equivalent (LDE) in 2018. This assumes the collar dosimeter reading estimates the LDE.

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In addition, the maximum he could have received was estimated to be 8761 mrem. Both of these values are below the annual maximum of 15000 mrem.

It is recommended that the physician be assigned two dosimeters, one worn at the collar outside of the protective lead apron, and one worn at the waist under the protective lead apron. The effective dose equivalent should be reported using the two dosimeter method described in NCRP Report 122 and referenced in NRC Regulatory Guide 8.40, also referred to as the EDE1 estimation.

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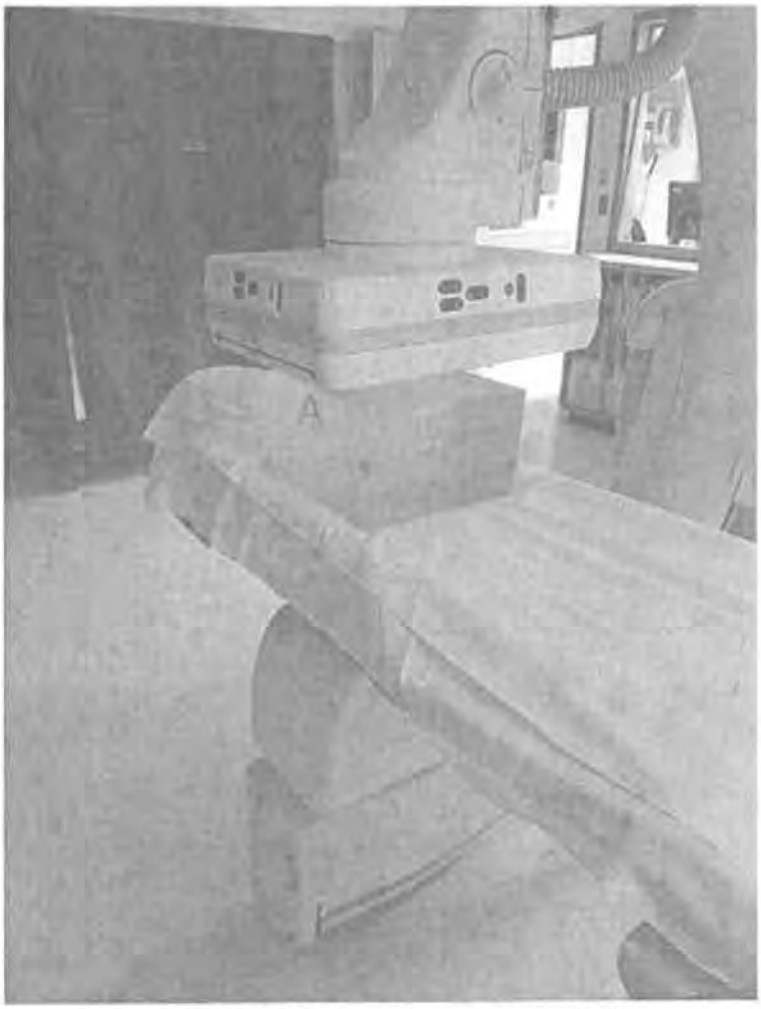
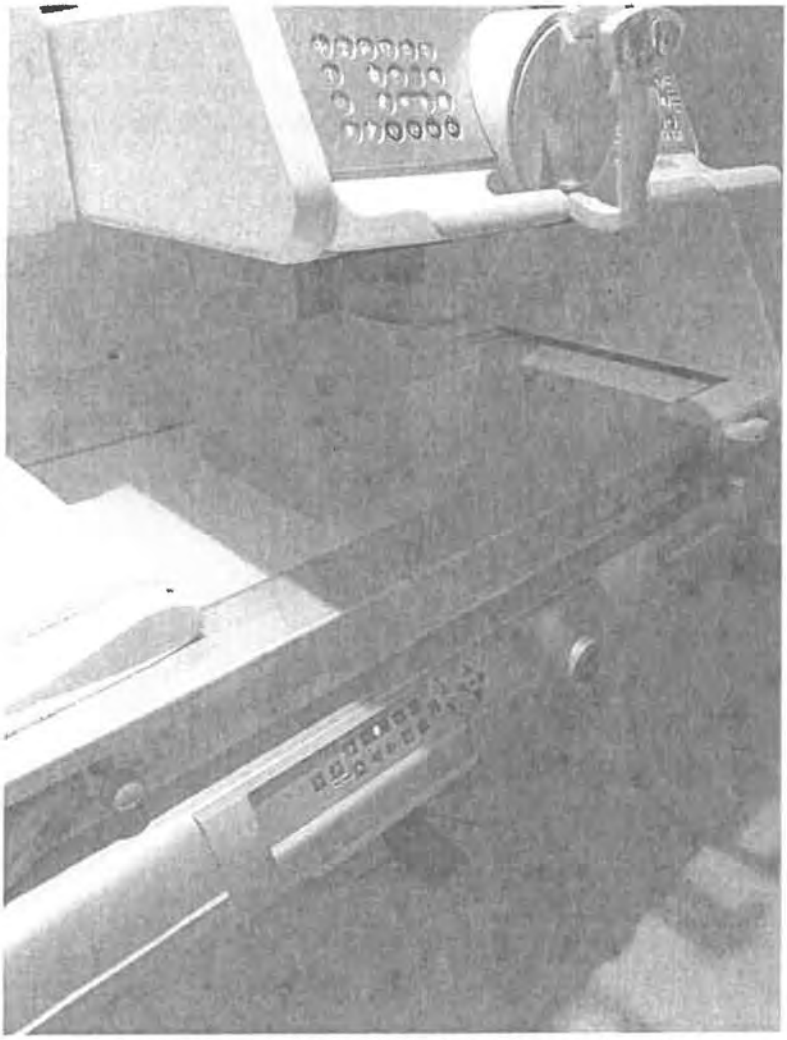
Appendix A – Scatter Measurement Set-Up



A – Scatter measurements made at the collar position

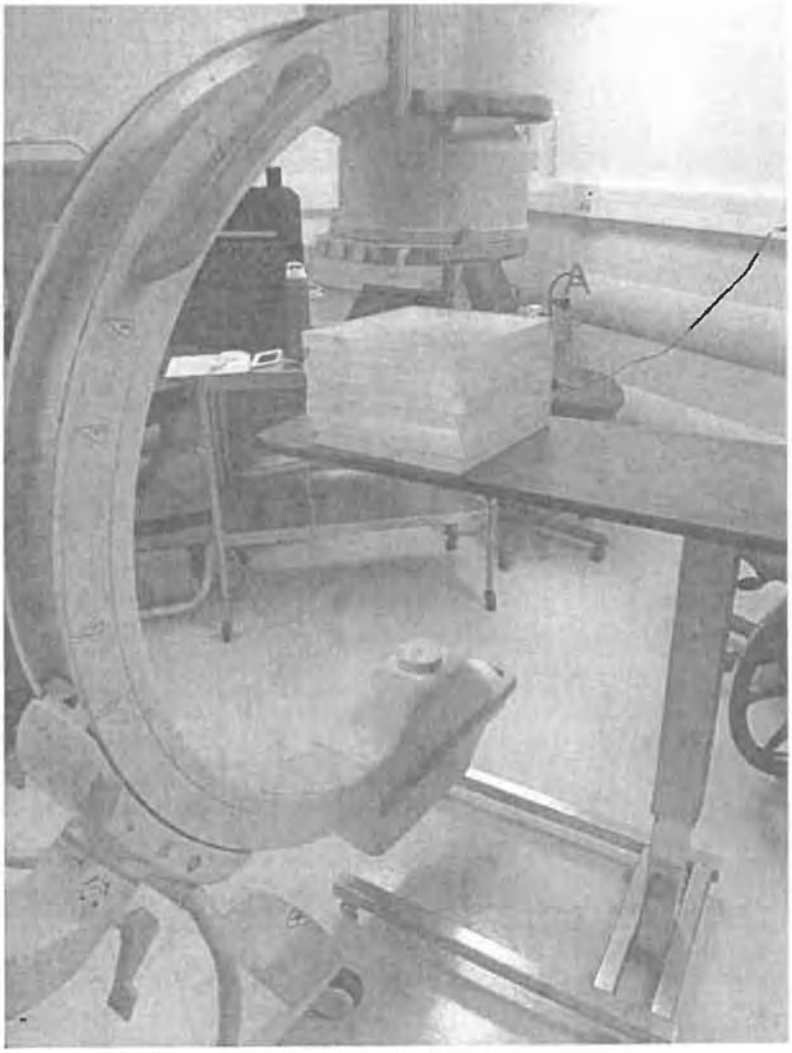
B – Scatter measurements made at the waist position

Fig 1 – Scatter Measurement Set-Up in the Interventional Suite



A – Scatter measurements position

Fig 2 – Scatter Measurement Set-Up in the General Fluoroscopic Room



A – Scatter measurements position

Fig 3 – Scatter Measurement Set-Up with the C-Arm

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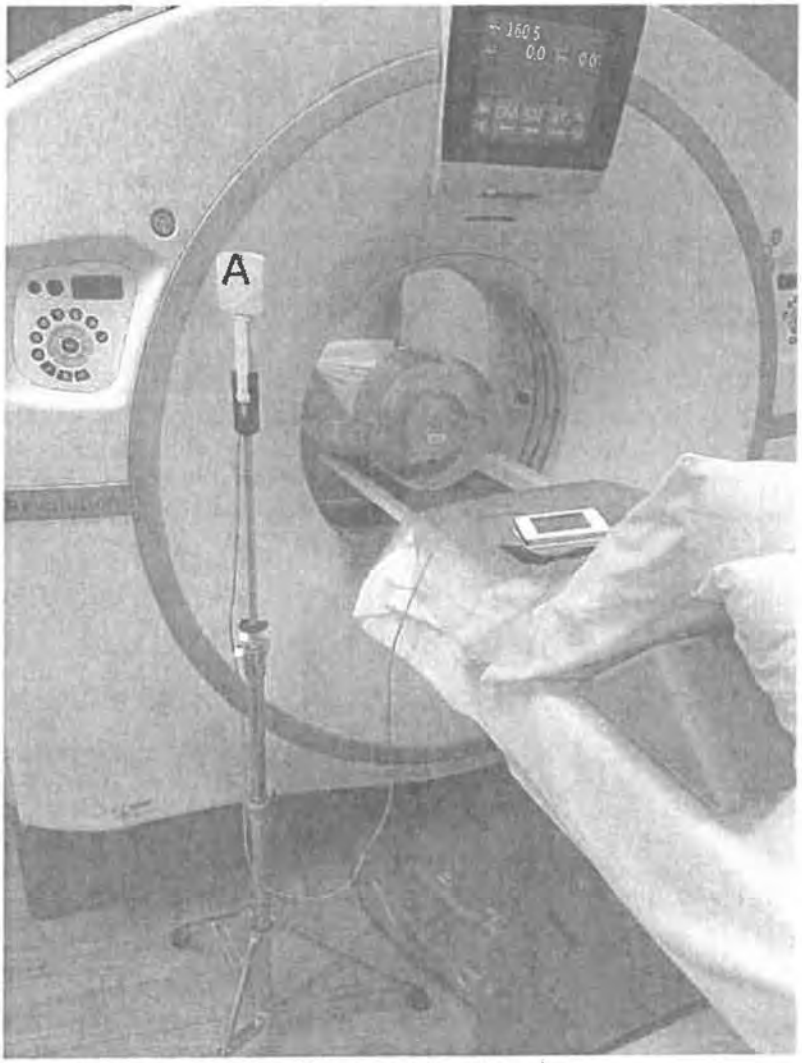

A – Scatter measurement position on the left side

B – Scatter measurement position on the right side

Fig 4 – Scatter Measurement Set-Up with the CT Scanner

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Exhibit 10

NRC Interview Questions

Staff Name: _____ Date: _____

Do you feel you have a good understanding of the ALARA concept?

Do you consistently wear your radiation dosimetry badge?

Are your aware of the radiation dose you receive each year? Did you initial 2018 radiation dosimetry report showing your annual dose?

Do you feel other cathlab staff consistently wear their radiation dosimetry badge?

Does [redacted] consistently utilize his lead apron and other lead protection when performing procedures in the cathlab?

Does [redacted] use ALARA concepts to minimize radiation exposures to staff?

What are some suggestion to reduce radiation exposures to cathlab staff or for the physicians?

What can we do to ensure staff are wearing their radiation dosimetry badges correctly?

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Exhibit 11

Annual Radiation Safety and ALARA Training

Each year we are required to perform Radiation Safety Training to staff that work with or around ionizing radiation and radioactive material. The training is to familiarize staff with the fundamentals of radiation protection and the proper procedures for maintaining exposures as low as reasonably achievable. Everyone is exposed to radiation every day. People are continuously exposed to low-level radiation found in food, soils, building materials, and the air and from outer space. For the purpose of this training we will be talking about "Occupational" exposures. To control occupational exposure the NCRP (National Council on Radiation Protection and Measurements) has adopted the concept known as ALARA "As Low As Reasonably Achievable". ALARA is simply the continuation of good radiation-protection programs and practices which traditionally have been effective in keeping individual exposures well below the limits set by the NCRP.

The concept of ALARA is not new to radiology. It began when the Nuclear Regulatory Commission in December 1977 began pushing for radiation standards that lowered the dose to patients and occupational workers. In 1994 the ALARA document became a part of title 10 the Code of Federal Regulations (10CFR35.20) which is binding on all institutions as a NRC regulation. Therefore, it must be practiced as a matter of mandate of federal code. So when the radiographer stresses the practice of ALARA it should be understood by all that it is because it is required and respectful to the patient.

As a technologist, student, physician, or nurse, how do we practice this ALARA concept? There are three Cardinal rules for Radiation Protection? Time, Distance, & Shielding

Time: Minimize the amount of time that you are exposed to the radiation source
Distance: Maximize the distance the radiation source
Shielding: Shielding should be worn or inserted between you and the radiation sources

Other things we can do to minimize radiation dose

Here are some examples or practices we use everyday that incorporate the ALARA concepts for ourselves, others, and our patients?

a. Adhere to ALARA Principle ("As Low As Reasonably Achievable")
   i. **Time:** Minimize the Time in the path of the x-ray beam. Minimize fluoro time and reduce radiation doses by using these options during fluoroscopy: Pulse Fluoro, last image hold, or image save.
   ii. **Distance:** Maximize the Distance from the x-ray source and patient. Staff shall use maximum distance between the patient and the radiation source. Only allow essential personnel needed to perform a procedure in the room. ***Stepping back one step will reduce your exposure dose by a factor of 4.***
   iii. **Shielding:** Maximize Shielding by wearing of lead aprons and standing behind a lead shield when an exposure is being made dramatically reduces approximately 95% to 100% of the dose to the protected body. Also standing behind the physician during exposure is also a recommend practice to reduce radiation exposure. Never leave your back exposed when ionizing radiation is being emitted. Utilize the lead drape on the fluoro tower or hanging lead shield in CathLab. Wear lead gloves whenever your hands maybe exposure to the primary beam
   iv. **Awareness**: Be aware of your surroundings, listening to the audio sound for the C-Arm (the beeping noise transmitted when x-ray is on), listening to for the physician requesting, x-ray or

fluoro, and watch the emitting x-ray light on top of the C-Arm monitor. All these things can help you protect yourself from unnecessary radiation exposure.

b. Maximize Source-To-Skin Distance
   i. Maximize the distance from radiation source by keeping the distance minimize from image receptor or ii
   ii. In Fluoroscopy raise the table to maximize SSD
   iii. Keep image receptor close as possible to the patient

c. Collimation and Filtration
   i. Copper filtration limits low-energy-x-rays reaching the patient
   ii. Collimate to the smallest possible (restrict x-ray field size)

d. Exposure Control
   i. Use AEC when possible
   ii. Keep fluoroscopy mA low (around 0.5 to 3 mA)
   iii. Keep kVp high (85 to 125 kVp)
   iv. Use proper exposure techniques for body part/type

e. Use Proper Protocols
   i. Establish specific protocols for specific procedures and patient age/size
   ii. Use establish protocols for specific imaging procedures
   iii. Use pediatric specific protocols for pediatric patients

f. Tube Placement
   i. Scatter radiation levels are highest at the point where the primary beam enters the body; i.e., the side of the "C" that houses the x-ray tube.
   ii. Always place the x-ray tube below the table or patient when possible. This will direct the highest levels of scatter radiation down toward the floor and away from the operator's torso, neck, eyes, and head.

B. General Guidelines
   a. Fluoroscopy should generally be performed only by a radiologist or a provider trained in fluoroscopy. C-arm fluoroscopy should only be performed by trained personnel with a physician present.
   b. Use lead shielding as much as possible for patients, especially those in childbearing years. (New guidelines are being developed by ACR and other organizations to limit shielding of patients in many situations)
   c. Whenever possible, use largest fluoroscopic imaging mode to minimize exposure levels. Mag imaging increases radiation dose exponentially.
   d. Fluoroscopic procedure require the dose summary page to be saved to PACS along with the images and the total fluoroscopy time and the total cumulative air kerma (mGy) will be required to be documented in meditech to transfer to the radiology report. In the Cathlab the dose is required to be documented in the patient's procedure record.

C. Wear of Dosimetry Badges: Who should wear dosimetry badges?
   a. Any employee who is likely to receive in one year, a dose in excess of ten percent of the occupational dose limits set forth in Table 1.

b. Declared pregnant women likely to receive, during the entire pregnancy, a dose in excess of 0.1 rem (1.0 mSv)

D. The estimate dose of radiation exposure to the monitoring devices will only be correct if these rules regarding the wearing of the badges are observed:

a. The radiation badge shall be worn at all times while working at the hospital or clinic. For O.R. or other surgical staff badges shall be worn anytime ionizing radiation is being used or there is the potential of ionizing radiation to be used.

b. Wear the badge at collar level outside the lead apron. Pregnant workers should request an additional badge to be worn at waist-level inside the lead apron.

c. Leave the radiation badge in a safe place (on the "Control Board") in your work area when not on duty. Do not take it out of the hospital unless assigned to work outside the hospital at one of Avera's clinics.

d. Never wear a radiation badge issued to another person.

e. The radiation badge issued to you is your responsibility. Turn it in at the right time in exchange for a like one and take care of it.

f. Do not tamper with the radiation badge.

g. Report loss or damage of the badge immediately to your supervisor or the Radiation Safety Officer.

h. Report any other incident relative to the wearing of the radiation badge (such as possible accidental exposure when badge is not worn) to your supervisor or the Radiation Safety Officer.

i. The radiation badge is not to be worn while on duty at another facility. The badge is the property of Avera St. Luke's and meant to indicate the efficiency of the Avera St Luke's radiation safety program.

j. It is the responsibility of the supervisory personnel to see that the above rules are observed and to report radiation protection problems to the Radiation Safety Officer.

k. Flagrant violations of this policy may result in reprimand, suspension or termination.

Table 1 - Annual Occupational Dose Limits	Annual Limit
The total effective dose equivalent	5 rems (50 mSv)
The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye	50 rems (500 mSv)
Lens dose equivalent	15 rems (150 mSv)
Shallow dose equivalent	50 ems (500 mSv)

E. How are Dosimetry Badges calculated? The total effective dose equivalent (EDE) shall be determined as follows: EDE = deep dose equivalent (DDE)
   a. When a protective apron is worn while working with fluoroscopic equipment and only one personal monitoring device is used, it shall located at the collar outside of the protective apron and EDE = 0.3 x DDE (EDE2 calculation)
   b. When a protective apron is worn while working with fluoroscopic equipment and two personal monitoring devices are used, one shall be located at the collar outside of the protective apron and one shall be located between the chest and the waist under the protective apron and EDE $=1.5 \times DDE_{waist} + 0.04 \times DDE_{collar}$ (EDE1 calculation)

F. Investigational Levels

Avera St. Luke's hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Office (RSO) and reported to the Radiation Safety Committee (RSC). The Investigational Levels that we have adopted are listed in Table 2 below. These levels apply to the exposure of individual workers.

Investigational Levels	Level I	Level II
	mrem / quarter	mrem / quarter
Effective dose equivalent (EDE)	300	400
Lens dose equivalent (LDE)	900	1200
Shallow dose equivalent (SDE)	3000	4000

The Radiation Safety Officer will review personnel monitoring devices either monthly or quarter depending how often devices are exchanged. The following action will be taken at the Investigational Levels as stated in Table 2.

Quarterly exposures of individuals less than Investigational Level I:

A. Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 2 values for investigational level I.
B. Quarterly Exposures of Individuals Equal to or Greater Than Investigational Level I, but Less Than Investigational Level II. The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSC. The RSC will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RSC minutes.
C. Quarterly Exposures Equal to or Greater Than Investigational Level II. The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. RSC minutes will be sent to the management of this institution for review. The minutes containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

Avera St. Luke's will be required to submit a written report to the NRC within 30 days after learning of an occupational annual dose limit of 5 rem or greater.

Corrective Actions for Non-Compliant with ALARA Policies and Practices.

A. Individuals that are non-compliant with ALARA practices maybe subjected to corrective action in accordance with Avera Policy: Corrective Action 736.
B. Any plans to remove an individual from his or her duties of performing x-rays or fluoroscopy procedures will be determines by the RSO.

Staff are required to review their radiation doses a least annually. Staff may review their radiation doses at any time. Dosimetry Exposure Reports are kept in the Radiology Director's office and can be viewed upon request.

The concept of ALARA is not new to radiology. It began when the Nuclear Regulatory Commission in December 1977 began pushing for radiation standards that lowered the dose to patients and occupational workers. In 1994 the ALARA document became a part of title 10f the Code of Federal Regulations (10CFR35.20) which is binding on all institutions as a NRC regulation. Therefore, it must be practiced as a matter of mandate of federal code. So when the radiographer stresses the practice of ALARA it should be understood by all that it is because it is required and respectful to the patient.

Annual Radiation Safety (ALARA) Training 2020

NAME: _____ DATE: _____

1. What does ALARA stand for?

   a. As Low As Radiation Allows
   b. As Long As Radiation Allows
   c. As Low As Reasonably Allowed
   d. As Low As Reasonably Achievable

2. What are the three Cardinal rules for Radiation Protection?

   a. Time, Distance, and Technique
   b. Time, Technique, and Filtration
   c. Distance, Filtration, and Shielding
   d. Distance, Time, and Shielding

3. Name three examples that incorporate the ALARA concept?

1.

2.

3.

4. True or False ALARA concept is just that a concept and is not binding or required to be enforced?

5. How often should you review your personal radiation doses?

6. EDE dose of 450 mrem in one quarter is considered which investigation level?

   a. Is well below the investigation level's
   b. Is considered an investigation Level I
   c. Is considered an investigation Level II
   d. Is considered an investigation Level III

7. At what dose is the licensee required to report an individual's annual does to the NRC?

   a. 1,000 mrem
   b. 3,000 mrem
   c. 5 Rem
   d. 10 Rem
   e. 50 Rem

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Exhibit 12

Notes from Patient EMR - Cath Lab flow sheet – "Time Out" procedures

Time	Procedural Comments
08:03	The patient arrived in the cath lab. See EMR for IV fluids and status. The patient was transferred to the procedure table and connected to the patient monitors. The patient was given verbal instruction regarding the procedure and was instructed on use of the pain scale. PreSedation score is 9. Mallampati score is Class 1.
08:06	An Allen's test was performed over the right radial artery and the patient remains a canidate for a radial cath. The Sa02 probe was placed on the hand of the affected extremity.The wrist was placed on a wrist support and secured to the arm board.
08:16	The physician arrived to cath lab. A "Time Out" procedure was performed per policy and including the proper wearing of radiation monitoring badges and lead aprons. The patient remains a candidate for moderate sedation.

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Exhibit 13


REVOLUTION
Interventional Radiology

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Exhibit 14

CathLab "Time Out" Monthly Review

2020 Month	Review Date	Time Out Included Lead Apron & Badge Checks	Lead Properly Worn	Badges Properly Worn	Comments	Reviewer Initials	Reviewed by RSC
Jan	1|14|20	yes	yes	yes	all staff were wearing Lead & Badges correctly	cjk	2|4|20
Feb	2|7|20	yes	yes	yes	Able to show "Time Out" documentation	cjk	
Mar							
Apr							
May							
Jun							
Jul							
Aug							
Sep							
Oct							
Nov							
Dec							

Review at Quarterly RSC Meetings

Updated: 1/13/20 ajk (Form Folder)