Nuclear Regulatory Commission Violation Response Presentation

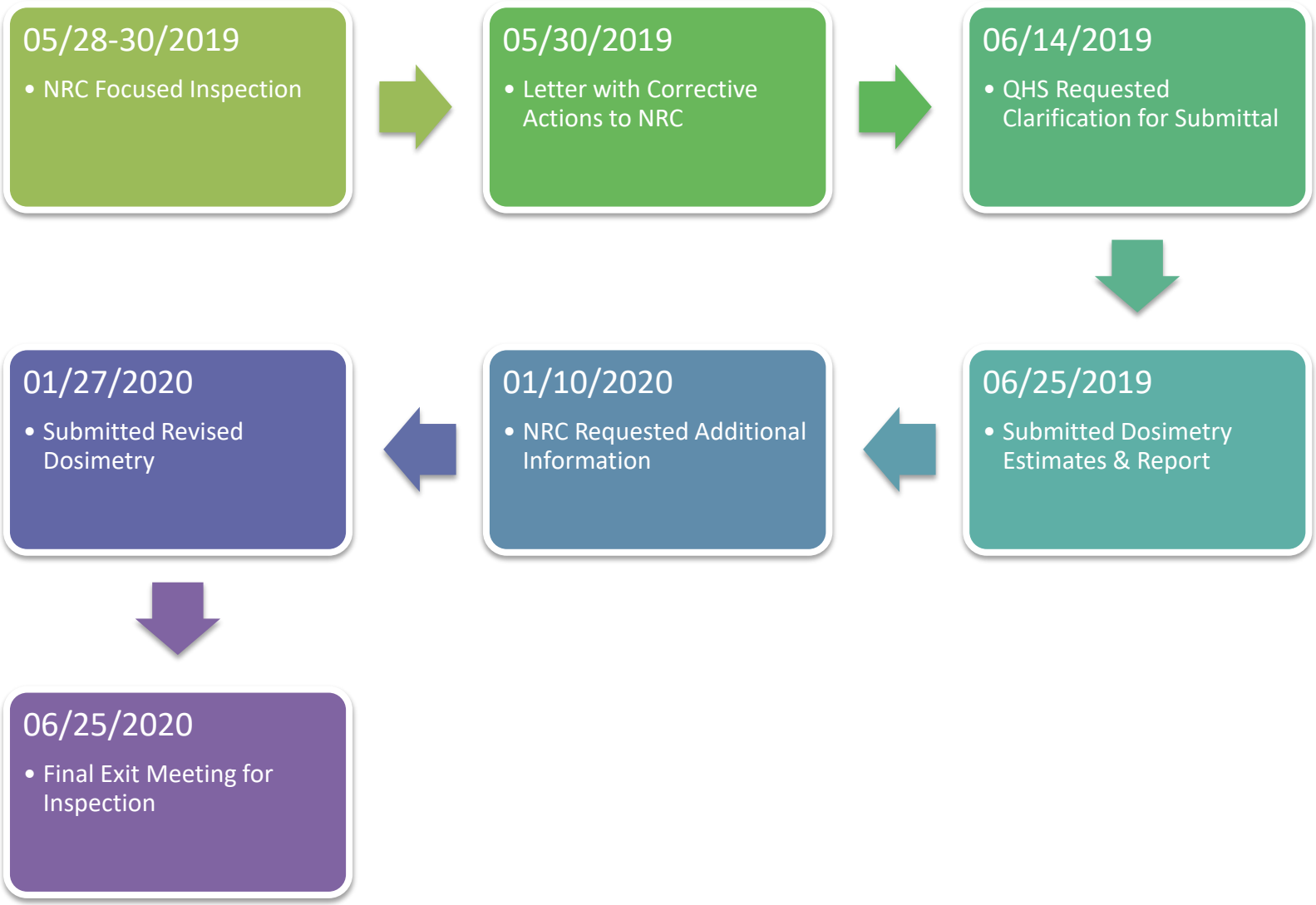
August 11, 2020

THE QUEEN'S HEALTH SYSTEMS

Opening Remarks

- The Queen's Medical Center (QMC) is committed to safe and reliable processes to assure no harm ever come to our patients, physician partners, and staff.
- We believe we have a strong radiation safety program with integrity.
- We value the input from the Nuclear Regulatory Commission (NRC) and the recommendations to help us improve our program
- Our goals are the same:
  - Safe use of radioactive material
  - Good outcomes for our patients

NRC Inspection and Follow-up



THE QUEEN'S HEALTH SYSTEMS

Apparent Violation 1

10 CFR 20.1502

"(1) monitor individuals' occupational exposure to radiation and radioactive material."

Reason for the Apparent Violation

- Lack of awareness that NRC's personnel monitoring requirements include radiation dose from both licensed and unlicensed sources of radiation.
- Exposure from Y-90 is less than the 10% threshold to require monitoring
- Instruction was provided to the Interventional Radiology (IR) physicians regarding dosimeter use but we did not take strong enough action to enforce.
- This instruction is documented in our Radiation Safety records.

Apparent Violation 1

10 CFR 20.1502

Corrective steps that have been taken:

- The Radiation Safety Plan was revised.
- Updated plan includes revision of Policy RSO-19-101
  - Clearly establishes the requirement to wear your dosimeter
  - States that reported exposures are reviewed monthly for both high exposures and compliance.
  - States that employees are subject to disciplinary action, up to termination, if they fail to wear their dosimeter.
  - States that the physicians/contractors will be reported to appropriate governing body (Medical Staff) for corrective action.
  - Includes a memo listing dosimeter responsibilities

Apparent Violation 1

10 CFR 20.1502

The current, signed policy states:

- If the Radiation Safety Officer (RSO) determines that staff have failed to wear their radiation dosimeter(s) while working with or around radiation, employee may be subject to disciplinary action, up to and including termination.
- If the RSO determines that contractors have failed to wear their radiation dosimeter(s) while working with or around radiation, the appropriate governing body within The Queen's Health Systems will be notified for appropriate action.

Apparent Violation 1

10 CFR 20.1502

"(1) monitor individuals' occupational exposure to radiation and radioactive material."

Corrective steps that have been taken:

- Radiation Safety (RS) worked closely with the Interventional Radiology (IR) physicians on procedures and verified good radiation safety practice even before inspection.
  (e.g. minimize fluoro use, use overhead shield, etc.)
- Documented discussions between RS and Interventional Radiology physicians that they are required to wear their dosimeter.
- Modified radiologist contract to include required dosimeter use.
- Radiation Safety Officer (RSO) provides physician education and training in the requirement and proper use of dosimeters.

Apparent Violation 1

10 CFR 20.1502

"(1) monitor individuals' occupational exposure to radiation and radioactive material."

Corrective steps that have been taken:

- Added dosimeter use to Interventional Radiology Time-out.

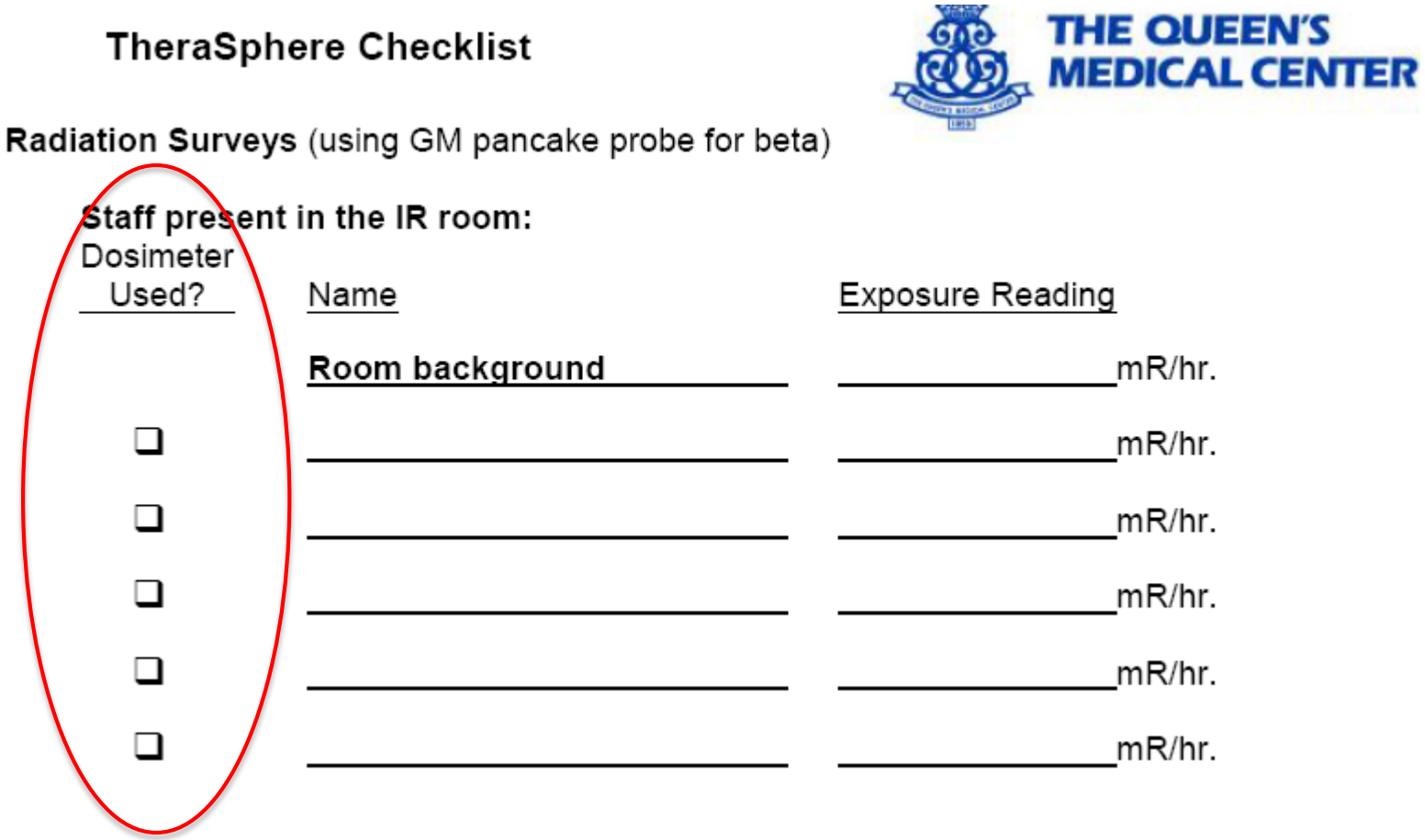
THE QUEEN'S HEALTH SYSTEMS

Six Simple Steps to Patient Safety	
Essential Elements	
Pre-Procedure Time-Out	
Proceduralist to initiate CONFIRM:	
1	Correct patient (via 2 approved patient identifiers & patient confirmation)
2	Correct procedure (via consent) and site marking
3	Drug allergies
4	Correct implants available (if applicable)
5	Special equipment available (if applicable)
6	Proceduralist to ask: Concerns / Questions from all team members **Confirm all staff in room compliant with radiation badge being worn**

Apparent Violation 1

10 CFR 20.1502

Corrective steps that have been taken:



TheraSphere Checklist

THE QUEEN'S MEDICAL CENTER

Radiation Surveys (using GM pancake probe for beta)

Staff present in the IR room:

Dosimeter Used?	Name	Exposure Reading
	Room background	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.

Apparent Violation 1

10 CFR 20.1502

THE QUEEN'S MEDICAL CENTER

Nuclear Medicine Department

LUTATHERA- Lutetium Lu 177 Dotatate injection therapy

TREATMENT # 1 **340b number DSH120001**

Pt. Name: _____ DOB: _____ MR#_____

Referring Physician:_____Diagnosis: _____

1. Written Directive For Radiopharmaceutical Administration

Exam date: _____ time: _____

Dose amount: **200 mCi**

Authorized User_____Date_____Time_____

Administered by _____Date_____Time_____

2. Written Record (to be completed by technologist)

Procedure: **Lutathera** Isotope: **Lu 177 dotatate** Route of administration: **Intravenous**

Original Assay_____ mCi Remaining Assay_____ mCi

Actual Dose_____ mCi *actual dose given is to be within 10% of the directed dose.

Technologist_____ Date_____ Time_____

Validated by_____ Date_____ Time_____

3. Documentation and verification of patient's demographics **radiopharmaceutical info**

Preinjection patient check list:

___verify patient name and ___ birthdate

___double validate amount of dose with another technologist

___written directive is complete with signed authorized user

___patient is informed with instructions and consent

❑ All Radiation Workers wearing body and finger dosimeter

_____ Staff 1

_____ Staff 2

_____ Staff 3

Lot#_____

Vial#_____

Activity@CT_____

_____

Activity@IT_____

_____

WRITTEN DIRECTIVE - Quality Management Program

This form is required for these specific Radiopharmaceuticals:

a. Sodium Iodide (I-131) - greater than 30 microcuries (µCi).

b. And any other therapeutic administration of a radiopharmaceutical.

THE QUEEN'S MEDICAL CENTER

I. WRITTEN DIRECTIVE Ins:_____ PA:_____

Patient:_____ Ph (home):_____ Ph (work):_____

Diagnosis:_____ Medications:_____

DoB:_____ THS Level:_____ Tg Level:_____ Date done:_____

Attending Physician:_____ Contact:_____ Ph:_____

Exam Date: _____ Time: _____	Route of Administration / Radiopharmaceutical
◉ Therapeutic Dose	◉ Oral / I-131 Sodium Iodide ○ Other: _____
○ Diagnostic Dose	**Directed Dosage: 0 mCi**

☐ THYROGEN

☐ CONSENT FORM SIGNED: Date:_____ Time:_____

Authorized User:_____ Date:_____ Time:_____

Is this patient admitted? Coordinate the date of the Therapy with the patient and:

Bedcontrol (4389):_____ PX (487-0814):_____ Dosimetry: (x4771):_____

II. WRITTEN RECORD (To be completed by the assayng Technologist)

*The actual dose given is to be in agreement within 10% or 15 µCi of the directed dose

Initial Assay	Residual Assay	*Actual Dose
		0.0 mCi

Technologist:_____ Date:_____ Time:_____

Validated by:_____ Date:_____ Time:_____

III. DOCUMENTATION OF RELEASE CRITERIA

1. Patients with administered activity of I-131 below 33 mCi can be release immediately. If the administered activity exceeds 7.0 mCi, instructions on precautions to take must be given to the patient.

I have received written instructions to this radioactive treatment.

Patient Signature:_____ Date:_____

TIME-OUT (Confirm before administering the dose)

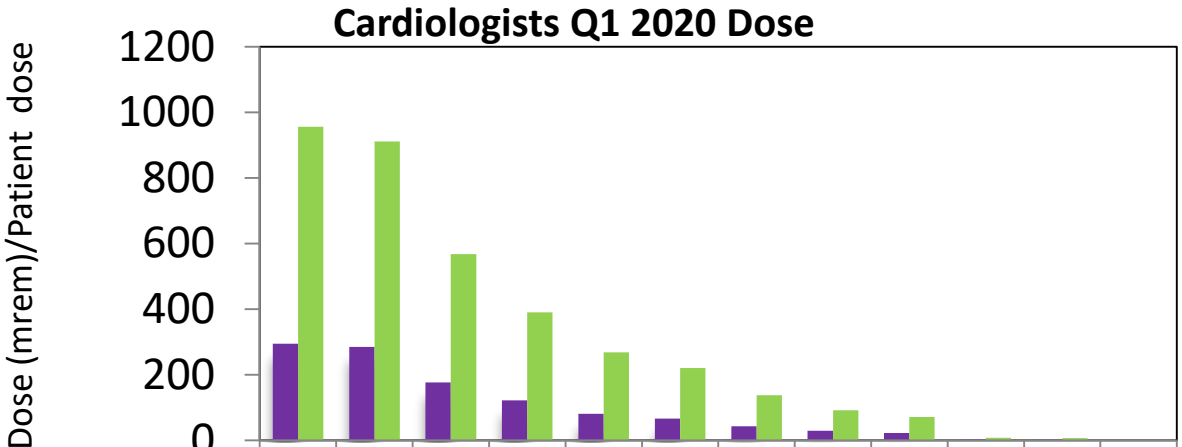
[ ] NAME [ ] BIRTHDATE OR [ ] SOCIAL SECURITY NUMBER

[ ] Staff are wearing dosimeter, both wholebody and extremity.

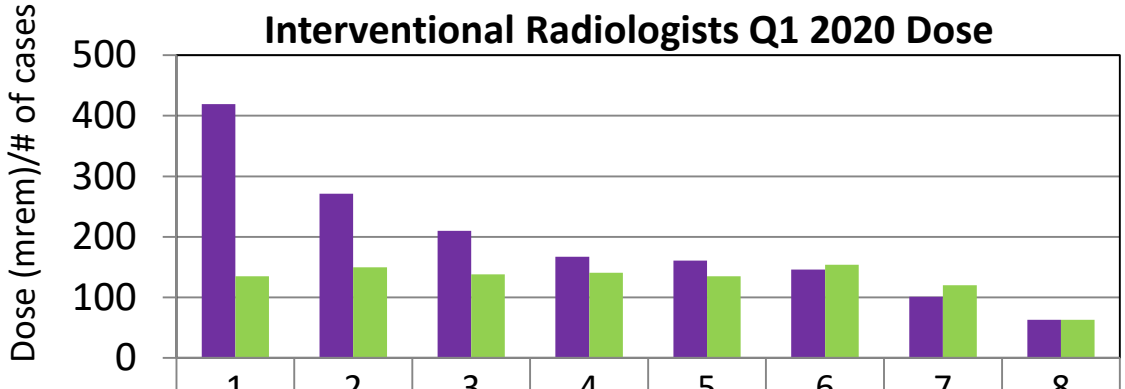
Is the patient pregnant? Yes / No Is the patient breast feeding? Yes / No

Apparent Violation 1

10 CFR 20.1502



	1	2	3	4	5	6	7	8	9	10	11	12
DDE (mrem)	295	285	177	122	81	67	43	29	23	3	2	0
Patient Dose (cGy)	956	911	568	390	268	221	138	92	71	8	7	0



	1	2	3	4	5	6	7	8
DDE	419	271	210	167	161	146	101	63
# of Cases	135	150	138	141	135	154	120	63

THE QUEEN'S HEALTH SYSTEMS

Apparent Violation 1

10 CFR 20.1502

Summary for Apparent Violation 1

- We self-identified the issue
- We implemented corrective actions
- We had success in physician dosimeter compliance
- We could have done better with stronger enforcement

Apparent Violation 1

10 CFR 20.1502

"(1) monitor individuals' occupational exposure to radiation and radioactive material."

Corrective steps that will be taken:

- Commit to annual, independent audits by Consultant of our Radiation Safety program
- Increase the frequency of radiation safety training for Interventional Radiology physicians to every 6 months.
- Continue to verify dosimeter use by film badge report audits.

Date that full compliance will be (was) achieved

- October 1, 2019

Apparent Violation 2

10 CFR 20.1101a

"(2) implement a radiation protection program commensurate with the scope and extent of licensed activities"

- No remedial action to correct deficiencies identified in the Radiation Safety Program.
- *Radiation Safety Guidelines Regarding Personnel Monitoring* (Policy RSO-19-101) and it's *Radiation Safety Plan*, failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

Apparent Violation 2

10 CFR 20.1101a

Reason for the Apparent Violation

- Radiation Safety Committee (RSC) was focused on exposures that exceeded ALARA Level 2
- Memos are routinely sent to individuals that exceed ALARA 2
- RSC was under the belief that we were not required to sum licensed and unlicensed dose to determine the 10% (500 mrem) threshold for dose monitoring.

Apparent Violation 2

10 CFR 20.1101a

Corrective steps that have been taken:

- On June 17, 2019 RSC meeting held to approve updates to the Radiation Safety plan.
- Plan now includes remedial action to correct deficiencies
- Updated plan included revision of Policy RSO-19-101
  - States that employees can be terminated if they fail to wear their dosimeter.
  - States that contactors will be reported to appropriate governing body (Medical Staff) for corrective action.
- Requirement to wear radiation dosimeters is now included in Interventional Radiologist physician contract as follows:
  - “Physician is required to wear radiation dosimeter during working hours when onsite at MEDICAL CENTER or MGH.”

Apparent Violation 2
10 CFR 20.1101a

Corrective steps that have been taken:

- Current Radiologist Contract

XI. Other Duties.

A. Physician will be available in assigned department as a resource for the technical staff. This includes formal or informal sessions regarding protocols and image quality.

B. Physician is responsible for obtaining informed consent from the patient and leading Time Outs, with staff and patient participation.

C. Physician is responsible to provide guidelines for required labs and preps. MEDICAL CENTER staff is responsible to ensure appropriate labs and preps on each patient.

D. Physician is required to wear radiation dosimeter during working hours when onsite at MEDICAL CENTER or MGH.

E. Contractor will require one (1) Physician to participate on the Radiation Safety Committee.

F. If PACS or PowerScribe are not available, MEDICAL CENTER shall send images directly from modality to StatRad. StatRad shall interpret images. Contractor shall provide MEDICAL CENTER with StatRad's rate sheet and invoice for such

25

[redacted]
PSA for Radiology
10.01.19 to 09.30.24

Apparent Violation 2
10 CFR 20.1101a

Corrective steps that will be taken:

- Continue to provide dosimeter training for all new radiation workers
- Hire a 3rd medical physicist to standardize and conduct audits
- Commit to annual, independent audit of our RS program.

Date that full compliance will be (was) achieved.

- December, 2019
- This is the date that all signatures were acquired for the policy update.

Apparent Violation 3

10 CFR 19.12(a)(3)

"(3) provide instruction to occupationally exposed individuals."

We do have a strong instruction program.

- All Interventional Radiology physicians were trained by our Y-90 vendor
- All staff participate in annual online training that includes radiation safety.
- All staff who handle byproduct material participate in annual Radiation Safety (RS) training.
- Ancillary staff are included in annual RS training
- In 2019, we trained all staff in Cyclotron, PET, Nuclear Medicine, Housekeeping, Security, as well as nurses that assist in written directives procedures.

Apparent Violation 3
10 CFR 19.12(a)(3)

"(3) provide instruction to occupationally exposed individuals."

Reasons for apparent violation

- Radiation Safety was not aware that Interventional Radiology (IR) physicians participating in the Y-90 program are regulated under 10 CFR 19.12(a)(3)
  - Our IR physicians are not on our NRC license
  - Our IR physicians receive <100 mrem from licensed material
- Interventional Radiology physicians were trained by Y-90 vendor
- We considered dosimeter use as common knowledge, especially for ABR certified radiologists, so we didn't train them in this topic.
- RSC was under the belief that we were not required to sum licensed and unlicensed dose to determine the 100 mrem threshold for training.

Apparent Violation 3

10 CFR 19.12(a)(3)

Corrective steps that have been taken:

- All Interventional Radiology physicians were given the occupationally exposed worker training by 6/26/2019.
- The refresher training was provided again to occupationally exposed workers on 7/2/2020 to all but 1 Interventional Radiology physician.
  - This training also included proper radiation dosimeter use.
  - This training also included instructions to wear the radiation dosimeter at collar level outside the lead apron.
- The final Interventional Radiologist was given the training on 7/8/2020 when he returned from vacation.

Apparent Violation 3
10 CFR 19.12(a)(3)

Corrective steps that have been taken:

- Supplement on Safety (SOS) training, for all hospital staff and contractors, has been revised to include the proper use and the requirement to wear your assigned dosimeter.

Additional content in SOS training for all physicians and staff.

Radiation Dosimeter

Physicians and staff that are exposed to larger amounts of radiation, (i.e. personnel that work regularly in interventional cardiology, radiology, nuclear medicine, cyclotron, etc.) are issued radiation dosimeters to track the amount of radiation they are exposed to. Physicians and staff that are issued radiation dosimeters are required to wear these dosimeters. Normal dosimeter location is at collar level outside of the lead apron. Failure to wear a radiation dosimeter, if issued by QMC, will result in disciplinary action.

Apparent Violation 3

10 CFR 19.12(a)(3)

"(3) provide instruction to occupationally exposed individuals."

Corrective steps that will be taken:

- The training will include the proper use of radiation dosimeters
- Requirement to wear radiation dosimeters, if issued, will continue to be included in physician's contracts. Current contracts have been amended.
- Increase the frequency of radiation safety training for Interventional Radiology physicians to every 6 months.

Date that full compliance will be (was) achieved:

- Full compliance was achieved on 6/26/2019 when all physicians were trained as occupationally exposed workers.
- Training logs are located within radiation safety records

Attachments

Attached for your review

- Radiation Safety Plan
- Policy *Radiation Badge Monitoring Responsibilities RSO-19-101_All*
- TheraSphere procedure with checklist
- Radiation Safety Training for Interventional Radiology

Mahalo

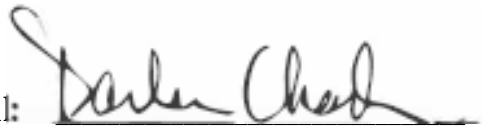
RADIATION SAFETY PLAN

THE QUEEN'S HEALTH SYSTEM

April 15, 2020

Contents

I. Approvals

A. Management Approval:  3/2/2020

Darlena Chadwick, VP, Patient Care — Date

B. RSO Approval: Dale Schippers 2/26/2020

Dale Schippers, Medical Physicist / RSO — Date

C. RSC Approval:  3/4/2020

Frank Goerner, Ph.D. Medical Physicist — Date

D. Effective Date: 4/15/2020

E. Date(s) when staff were trained in the new plan:

PET, Punchbowl (PB)	2/25/2020	Cyclotron	NA
Nuclear Medicine, PB	2/25/2020	Angiography	NA
Nuclear Medicine, West	4/10/2020	Radiation Therapy	3/31/2020
Nuclear Medicine, NHCH	3/30/2020	Security	3/30/2020

Must include a copy of previous plan and the changes to this plan.

II. Revision History:

Original plan: most recent plan available appears to be a draft plan and was dated July 2014.

6/18/2019

This update includes reformatting for clarity with only minor changes or revisions to radiation safety practices. The revisions include:

1. The table of contents added.
2. Frequency of types of audits were added for clarity
3. The introduction now contains a section on how to change the radiation safety plan.
4. Management commitment to ALARA program section was modified. Two paragraphs were removed.
5. High Exposure Level was added to the ALARA levels and each ALARA level was clarified with what actions will be taken.
6. Radiation Safety Officer and Authorized User sections under ALARA were deleted.
7. Dosimetry section was added to clarify the use of radiation badge monitors.
8. Item 17, under Rules for Safe Use of Radiopharmaceuticals was removed.
9. Radiation survey instrument capabilities were clarified in Area survey procedures
10. The training program section was changed to reflect the training that new employees and nursing staff receive. The article that was photocopied into the manual after the training section was deleted.
11. The Radiological Rooms, Radiation Safety Guidelines for Portable x-rays, Lead Apron Evaluation Program and Radioactive Trash In-service sections were removed because these are all addressed in QMC policies.
12. The Radiation Accident Protocol section was removed since the Spill Procedures section was added and covers most of this information.
13. The policies at the end of the radiation safety program were removed since these have all been revised.
14. Survey instrument calibration section was added.
15. Waste disposal section was added.

12/1/2019

1. Waste disposal section was modified to incorporate previous waste disposal policy
2. Bioassay section was added

4/15/2020

1. Update the isotope delivery instructions in Procedure for Receiving and Opening Radioactive Packages.

III. Purpose

A. Providing safe and effective use of radiation for patients, employees, medical staff, and visitors.

IV. Responsibilities

A. Radiation Safety Committee (RSC) – Administers the plan, meets quarterly.
B. Radiation Safety Officer (RSO) – Manages the program, conducts Compliance Audits.
C. Management – Evaluate Annual Review of Program.
D. Employees – Reports any unsafe conditions or events to the RSO.

V. Audits

A. Personnel Monitoring - Quarterly.
B. Radiation Therapy – Quarterly.
C. Nuclear Medicine – Quarterly.
D. Cyclotron - Quarterly
E. Radiology – Annually.

VI. Radiation Safety Program

A. Introduction
    1. It is the policy of The Queen's Medical Center (QMC) that exposures to ionizing radiation are to be kept as low as reasonably achievable (ALARA) to all employees, patients, and visitors to QMC. Toward that end, QMC has established the Radiation Safety Committee (RSC) to oversee the radiation safety practices at QMC. Furthermore, the committee has appointed a Radiation Safety Officer (RSO) to ensure the safe use of radiation. He/she will be responsible for managing the Radiation Safety Program, identifying radiation safety problems, and implementing corrective action when needed. He/she will also be responsible to ensure compliance with the United States Nuclear Regulatory Commission (NRC), State of Hawaii, and The Joint Commission (TJC) requirements.

2. Sources of radiation include x-ray machines in Radiology, Surgery, and the Dental Clinic, as well as linear accelerators in Radiation Therapy. In Nuclear Medicine, radioactive drugs are used for imaging and treatment. Finally, certain patients on the nursing floors and in angiography are treated with radioactive sources for cancer therapy. The benefits of using radiation in medicine are great, and this program is designed to minimize the risks.
3. If you have any questions or concerns regarding radiation, please call the RSO at 691-4884 during normal working hours. For urgent requests, he/she can also be contacted through the QMC operator.
4. Changes to Radiation Safety Program
    a) All changes to the Radiation Safety Program must be reviewed and approved in writing by the RSO and management.
    b) Individuals affected by changes to the Radiation Safety Program will be instructed on the revised program before the changes are implemented.
    c) A record of each change to the Radiation Safety Program will be maintained for 5 years. The record will include a copy of the old and new procedures, the effective date of the change, and the signatures of the RSO and management representative that reviewed and approved the change (§ 35.2026).
    d) Any change requiring a license amendment according to 10 CFR 35.13 must be submitted to the Nuclear Regulatory Commission for approval.

B. Duties of the Radiation Safety Committee/Radiation Safety Officer
1. The Radiation Safety Committee shall:
    a) Ensure that licensed material will be used safety. This includes review, as necessary, of training programs, equipment, facility, supplies, and procedures.
    b) Ensure that licensed material is used in compliance with NRC regulations and the institutional license.
    c) Ensure that the use of licensed material is consistent with the ALARA philosophy and program.
    d) Establish a table of investigational levels for individual occupational radiation exposures.
    e) Identify program problems and solutions.
2. Responsibilities of the Radiation Safety Committee include:

a) Be familiar with all pertinent NRC regulations, the license application, the license, and any and all amendments.
b) Review the training and experience of the proposed authorized users, the RSO, and the Authorized Medical Physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license.
c) Review of the basis of safety and approve or deny, consistent with the limitations of the regulations, the license and the ALARA philosophy, all requests for authorization to use radioactive material within the institution.
d) Prescribe special conditions that will be required during a proposed method of use of radioactive material, such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
e) Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
f) Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., Nursing, Security, Housekeeping) are appropriately instructed as required in 19.12 of 10 CFR Part 19.
g) Review at least annually the RSO's summary report of the entire Radiation Safety Program (RSP) to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, and results of NRC inspections, written safety procedures, and the adequacy of the management control system.
h) Recommend remedial action to correct any deficiencies identified in the RSP.
i) Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken.
j) Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies and procedures, and personnel.

3. Administrative Information:

a) The Committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter (four times yearly).

b) Membership must include one authorized user of each type of use authorized by the license, the RSO, a nursing representative and a representative of management who is neither an authorized user nor an RSO. Management, and the RSO, may appoint alternate members to participate in meetings in the case of absence of principal members.

c) To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

d) To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities, such as x-ray radiation safety, quality assurance (QA) oversight, and research project review and approval.

C. ALARA Program

1. Management Commitment

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

b) We will perform a formal annual review of the RSP, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the Radiation Safety Staff or outside consultants.

2. Radiation Safety Committee

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 methods of use for which application has been made to ensure that the applicant will be able to take appropriate measure 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.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses of radiation will be ALARA.

(4) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the ALARA levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA Program's quality and to decide if action is warranted when investigational levels are exceeded.

(5) ALARA Levels

	ALARA Level I 10% of MPD	ALARA Level II 30% of MPD	High Exposure Level 1/12 of MPD	Annual Limit (MPD)
Body Dose (DDE /EDE2)	125 mrem/qtr.	375 mrem/qtr.	400 mrem/mth	5 rem
Lens of Eye (LDE)	375 mrem/qtr.	1125 mrem/qtr	1250 mrem/mth	15 rem
Extremities (SDE)	1875 mrem/qtr.	5625 mrem/qtr.	4000 mrem/mth	50 rem
LDE limits per ICRP		150 mrem/qtr		2 rem

(a) ALARA Level I: No investigation is required but the RSO will watch for a trend.

(b) ALARA Level II: The RSO will ask the individual to reply to a High Exposure memo.

(c) High Exposure Level: The RSO will ask the individual to reply to a High Exposure memo.

(6) The RSO will review and record, on NRC Form 5 or equivalent, a summary of personnel monitoring on an annual basis.

VII. Quality Management Program

A. Objective

1. To provide high confidence that byproduct material will be administered as directed by the Authorized User (AU).

B. Requirements

1. Prior to administration, a Written Directive (WD) will be completed and signed by an AU for the following procedures:
   a) Any therapeutic administration of a radiopharmaceutical
   b) Any administration of I-125 or I-131 greater than 30 □Ci
   c) Brachytherapy and High Dose Rate (HDR) procedures

2. Annual Audit to include:
    a) The compliance rate of having a WD prior to administration of a radiopharmaceutical or radiation in those cases where WD is required.
    b) The content of the written directive is as required.
    c) A comparison of what was administered versus what was prescribed in the WD.

VIII. Dosimetry (Personnel Radiation Monitoring).

1. Monitoring of occupational exposure to radiation from licensed and unlicensed radiation sources under licensee control will be supplied and require the use of individual monitoring devices by:
    a) Adults likely to receive greater than 10% of the annual limits in § 20.1201(a) [10% of annual limit is 500 mrem].
    b) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
    c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and
    d) Individuals entering a high or very high radiation area.
2. All individuals who are likely to receive greater than 5 rem skin dose (10% of skin dose limit) from handling radioactive material will be issued, and are required to wear, a film, TLD, or OSL extremity dosimeter.
3. Prior exposure history will be requested from the most recent employer, when applicable.
4. Staff shall report any lost, damaged, or accidentally exposed badges to the Radiation Safety Officer.
5. Employees and contractors (including physicians) must wear a dosimeter when performing procedures that involve ionizing radiation unless they have documentation to verify that they are not likely to receive greater than 10% of the annual dose limits.
6. In the event that your dosimeter is lost or temporarily displaced you may participate in a procedure involving ionizing radiation but you must report your lost dosimeter and/or lack of dosimeter use to Radiation Safety. The form for this report is included in appendix A.
7. Failure to wear your assigned radiation dosimeter will result in the following disciplinary actions:

a) Consistent neglect in wearing your dosimeter, as indicated by an unusually low reported exposure relative to your workload, will result in the loss of privileges to work with ionizing radiation. For more information, please see policy *Radiation Badge Monitoring Responsibilities* (RSO-19-101-All).

IX. Procedures for Radiopharmaceuticals and Sealed Sources

A. Rules for Safe Use of Radiopharmaceuticals

1. Wear laboratory coats or other protective clothing in areas where radioactive material is used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor your hands for contamination in a low-background area with a survey meter either after each procedure or before leaving the area.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (.e.g., through use of a butterfly needle).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe test by-product storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
12. With a radiation detection survey meter, survey the generator storage (if applicable), kit preparation, injection areas and trash daily for

contamination. If necessary, decontaminate or secure the area for decay, as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the amount of the compound, and the date and time of receipt or preparation. A log book or computer software should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, the measured activity or each patient dosage, and any other appropriate information.
14. Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.
15. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 20 percent off from the prescribed dosage, except for prescribed dosages of less than 1 mCi. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
16. Always keep flood sources, syringes, waste, and other radioactive material(s) in shielded containers.

B. Bioassays

Bioassays determine the quantities, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, called in vivo counting, or by analysis and evaluation of materials excreted from the human body. Individuals who handle large amounts of easily ingested radionuclides may be required to participate in a bioassay monitoring program. Bioassays may also be ordered by the Radiation Safety Officer (RSO) after a spill, an unusual event, or a procedure that might result in an uptake.

C. Radiation Surveys.

1. Surveys will be performed at the end of each day of use for all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms should be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 µCi). Special care will be taken to remove all paraphernalia from patient rooms where

diagnostic administrations are occasionally made. Patient rooms will not be surveyed.

Surveys of ambient radiation exposure rates should be performed at the end of each day of use for all radiopharmaceutical elution, preparation, assay and administration areas (excluding patient rooms). Daily surveys are consistent with our ALARA philosophy, Part 20 requirements and will ensure that radioactive material is not inadvertently disposed in the normal trash.

2. All areas where radiopharmaceuticals are eluted, prepared, assayed and administered will be surveyed weekly for ambient radiation exposure rates and for removable contamination.
3. All radiopharmaceutical use, storage and waste storage areas will be surveyed weekly for ambient radiation exposure rates and for removable contamination.
4. All sealed source and brachytherapy source storage areas will be surveyed quarterly for ambient radiation exposure rates.
5. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect at least 0.05 mR/hour.
6. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm (200 dpm for isotopes of iodine).
7. Survey results greater than the trigger levels (Table R.1 from NUREG 1556 vol9, rev2) will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to less than the trigger levels on repeat surveys.

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr
All trash	All areas	Background

8. A record shall be kept of all survey results. The record will include:
   a) Location, date, and type of equipment used;
   b) Initials of the person conducting the survey;
   c) Drawing of the area surveyed;
   d) Trigger levels keyed to the location on the drawing;
   e) Measured dose rates in mR/hr or contamination levels in dpm/100 cm2, as appropriate;
   f) Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.
9. The RSO will be notified immediately if the trigger levels are exceeded.

D. Procedure for Receiving and Opening Radioactive Packages

1. Packages must be delivered directly to NM or Radiation Therapy and not left in Receiving Department.
   a) Vendors (e.g. radiopharmacies) for after-hour, weekend and holiday deliveries.
      (1) Check in with RepTrax
      (2) Courier is escorted by Security to/from NM or Radiation Therapy department
      (3) Security unlocks Hot Lab or department door and leaves package
      (4) Security insures that door is locked
   b) Federal Express (non-vendors)
      (1) Delivers packages directly to NM or Radiation Therapy and leaves the package with staff member.
      (2) Staff member secures the package in a locked room.
2. For all packages containing radioactive materials licensed per 10 CFR 35, the following procedure will be performed.
   a) Put on gloves to prevent hand contamination
   b) Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
   c) Measure the exposure rate at the package surface. The surface exposure rate should not exceed 0.5, 50 and 200 mR/hr for "White I", "Yellow II" and "Yellow III" packages, respectively. If it is higher than expected, stop and notify the RSO. The Transportation Index (TI) is the radiation level, measured at 1 meter, in Sieverts (TI:
   d) Determine the removable contamination level on the exterior of the package. Wipe an area of 300 cm^2 with an absorbent material. The contamination cannot exceed or 173.443:
      (1) 240 dpm/cm^2 for beta and gamma emitters.
      (2) Contamination (in dpm) = cpm / (300 cm^2 x efficiency)
      (3) Use the measured efficiency or 0.10 (10%) if unknown.
   e) Open the package with the following precautionary steps:
      (1) Remove the packing slip.
      (2) Open the outer package following the supplier's instructions, if provided.
      (3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquids, condensation, or discoloration of the packing material.

f) If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (It is required that the sample be assayed using a Nal Well Counter, and the results recorded in disintegrations per minute). Take precautions against the potential spread of contamination.

g) Check the user request to ensure that the material received is the material that was ordered.

h) Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in normal trash.

i) Make a record of the receipt. The receipt survey records must be kept on file for three years. The record of receipt (i.e. bill of lading, radiopharmaceutical incoming labels) must be kept as long as the licensee retains possession of the material and for three years following the transfer or disposal of the material.

10. The monitoring required by paragraph (2) shall be performed as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

E. Survey Instrument Calibration

1. General Requirements

a) Survey instruments, for example GM survey meters, ionization chambers and NaI(Tl) scintillator probes, are required for performing various surveys (see Radiation Surveys). NUREG-1556, Volume 9, Section 8.17, states that the "instruments should be available for use at all times when byproduct material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125 (I-125), palladium-103 (Pd-103)] if they become dislodged in the operating

room or patient's room. The Radiation Protection Program that licensees are required to develop, document, and implement in accordance with NRC 10 CFR 20.1101 must include provisions for survey instrument calibration. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured." The NRC in NRC 10 CFR 35.61 requires the "calibration of survey instruments used to show compliance with NRC 10 CFR 35 and NRC 10 CFR 20 before first use, annually, and following a repair that affects the calibration." (Battery changes are not considered "servicing.")

2. Calibrating Survey Instruments
    a) Survey meters used for quantitative measurements will be calibrated on an annual basis using the services provided by calibration laboratories, a survey instrument vendor or a consultant.
    b) An alternative method to perform calibration of our own survey instruments may be used, as discussed by Pat Zanzonico in a 2008 Journal of Nuclear Medicine review article. Further information is available in NUREG-1556, Volume 9, Section 8.17 and Appendix K. Note that the NRC states that, as an operational check, each day before use perform a check (with a dedicated check source) as well as a battery check. A record of each survey instrument calibration must be retained for three years in accordance with NRC 10 CFR 35.2061.

F. Waste Disposal

Radioactive material waste can come in the form of a solid, liquid or gas. The disposal method for these forms is described below.

1. Conventional Waste
    a) Byproduct material with a physical **half-life of less than or equal to 120 days** can be disposed of in the normal trash following decay-in-storage if
        (1) Survey at the surface demonstrates that its radioactivity cannot be distinguished from the background radiation level when monitored with an appropriate radiation survey meter set on its most sensitive scale and with no interposed shielding; and
        (2) All surface radiation labels are removed or obliterated.
    b) Byproduct material with a physical **half-life of more than 120 days** must be disposed of using a certified radioactive material disposal service.

c) Storage and disposal records of all radioactive waste will be maintained for 3 years following disposal.

2. Sewer Waste
   a) Material must be readily soluble and dispersible in water.
   b) Excreta from individuals undergoing medical diagnostic or therapeutic procedures with radioactive materials are exempt from any limitations.
   c) Radionuclides other than the above must be disposed in accordance with 10 CFR 20.2003. There are daily and monthly limits based on the total sanitary sewage release of the medical center. In each case, record the date, radionuclide, estimated activity, and designation of the sink or toilet at which the material was released.
3. Effluent Waste
   a) Limits on permissible concentrations of effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR 20. These limits apply at the boundary of the restricted area.
   b) All radioactive effluents at this facility are sufficiently diluted to meet NRC standards.

G. Spill Procedures

1. Contamination control is the responsibility of every individual using radioactive material. Proper preparation based on its physical state, drip pans, splash guards, backed absorbent paper and similar inexpensive provisions greatly reduce the need for decontamination. Well-channeled ventilation, good housekeeping, and frequent use of survey meters are investments which will be well repaid.
2. Minor Contamination Events
   a) Minor contamination events are those events typically identified through routine surveys that involve removable contamination levels greater than the action limit, but less than ten times the action limit.
   b) Minor contamination events can be easily decontaminated without the need for strict adherence to a step-by-step procedure.
   c) Minor contamination events require judgment on the part of the individuals responding to determine the scope and extent of the contamination and to assess their ability to respond effectively.
   d) In order to prevent the spread of contamination, coworkers should be notified if decontamination of the area will be delayed.
   e) Notification of the RSO is not required.

3. Spilled activity that exceeds the values listed in this table should be considered a Major Spill (NUREG 1556 vol 9 rev 2 & draft rev 3).

F-18	100 mCi		In-111	10 mCi		Lu-177	1 mCi
Ga-67	10 mCi		Lu-177	1 mCi		Ra-223	*
I-123	10 mCi		P-32	1 mCi		Y-90	10 mCi
I-125	1 mCi		Tc-99m	100 mCi			
I-131	1 mCi		Tl-201	100 mCi			

* any spill of isotopes that are primarily alpha emitters should be considered major

4. The Radiation Safety Office should be notified as soon as possible whenever a spill (major or minor) occurs.
   Meanwhile, the primary considerations are:
   a) Prevent spread of contamination. If liquid spill, use absorbent material to prevent flow and seal cracks in floor, workbench, etc. Use decontamination solution (e.g. radiac wash) and wipe the contaminated area with absorbent material. If airborne, close windows, doors, vents, turn off ventilation, seal doors with masking tape.
   b) Post radiation warning signs and allow no one to enter contaminated area unaware.
   c) Decontaminate personnel using the following steps:
      (1) Surface contamination - Persons splashed with active solutions should wash immediately with ample quantities of water. A mild soap should be used for a "surgical scrub" with light brushing. If the body contamination after this scrubbing remains more than two times background, the laboratory supervisor and the Radiation Safety Officer must be notified so that further steps can be taken.
      (2) Internal contamination (ingestion) - Any radioactive material swallowed should be evaluated immediately by the Radiation Safety Officer and a physician knowledgeable in radiation safety, e.g., a nuclear medicine physician.
   d) The Radiation Safety Office must be notified and may render assistance in decontamination. All personnel affected will be monitored and shall follow the recommendations regarding decontamination.
5. A complete history of the spill and subsequent remedial or protective measures must be submitted to the Radiation Safety Office via a Spill Report (Appendix B).

X. Personnel Protection

See the following policies available at The Queen's Medical Center intranet, eww.queens.org/RadTx/policies.html

A. Radiation Badge Monitoring Responsibilities. RSO-19-101-All
B. Radiation Safety Guidelines for Fetal Protection

XI. Training

A. Annual General In-service to QMC Staff.
B. Initial Training for New Employees working with radiation may include the following as applicable
    1. Review Dosimetry Requirements as listed in section VII.
    2. Review policies for procedures that require a Written Directive
    3. Review Personnel Protection policies listed in section IX.
    4. A training checklist will be used to document initial radiation safety training. The checklist must be signed by the employee and approved by the RSO.
C. Specific Instructions
    1. Nursing
        a) Initial and annual radiation safety instruction will be provided to personnel caring for patients who cannot be released under § 35.75. The instruction will be commensurate with the nurse's duties and include (§ 35.310):
            (1) Patient or human research subject control;
            (2) Visitor control, including—
                (a) Visitation to hospitalized individuals will be limited in an effort to maintain the public dose to < 100 mrem (§ 20.1301)
                (b) In special cases, the dose to the public may exceed 100 mrem, but must be < 500 mrem. The Authorized User must determine that the visit is appropriate;
            (3) Contamination control;
            (4) Waste control; and
            (5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.
    2. Nuclear Medicine

a) Initial and annual radiation safety instruction will be provided and cover the training requirements in 10 CFR 19.12, 20 and 35.

3. Radiation Therapy
   a) Emergency procedures for High Dose Rate brachytherapy
   b) Radiation Safety for brachytherapy

In the event that your dosimeter is lost or temporarily displaced you may participate in a procedure involving ionizing radiation only if another person is unable to take your place and you report the details of the procedure to the RSO within 3 days.

Also, if your dosimeter is not returned to Radiation Safety within 60 days of the end wear date, the RSO will estimate your exposure from your, or similar users, dose history. To properly assign the dose, we need the information requested below. If you have any questions contact the RSO at 691-4884.
Complete this form and return via email or inter-department mail to:

Dale Schippers, RSO
Nae'a - Radiation Therapy Department or dschippers@queens.org

Last Name	First Name

Department/Series Code:	phone / ext.

Begin Wear Date: _____ (or first use date)

End Wear Date: _____ (date badge was lost)

Type of badge: [Body]  [Ring]  [Other] _____

Briefly describe your duties around radiation sources.

Were there any circumstances during the period which might have caused an increase or decrease in your typical reading? (i.e. Unusually high workload, vacation/sick days off)

_____ _____
Signature Date

Radiation Safety Use Only Date:

Name: _____ Series Code: _____ Badge # _____

Previous exposure reading (mrem)

MONTH					
DDE					
LDE					
SDE					

Spare Badge Assigned?
Yes / No

millirem to be assigned: DDE _____ LDE _____ SDE _____

_____ _____
Radiation Safety Officer Date

THE QUEEN'S HEALTH SYSTEM

INFORMATION AND RESPONSIBILITIES FOR BADGED RADIATION WORKERS

(Do not return with badge application – please keep for your record.)

Radiation Monitoring Badges Are Required to be worn if you are exposed to more than 10% of the annual dose limit for radiation workers. The Radiation Safety Officer (RSO) will help you determine whether or not you are required to wear a radiation monitoring badge.

If the RSO determines that you are required to wear a radiation monitoring badge, it is MANDATORY that you wear the badge when you work with or around radiation. If the RSO determines that you are not regularly wearing your radiation badge when working with or around radiation, the following disciplinary action will result:

- Consistent neglect in wearing your dosimeter, as indicated by an unusually low reported exposure relative to your workload, will result in the loss of privileges to work with ionizing radiation. Consistent neglect is defined as 3 months of unexplained low exposures, relative to workload, in a 12 month period.

It is important that you wear your radiation monitoring badge for the following reasons:

1. **For your own safety related to radiation.**
   Exposure data will help the radiation safety office to better determine if the work environment you are in protects you from unnecessary radiation and if you are using radiation safely and adhering to ALARA.
2. **For the safety of your co-workers.**
   Your radiation exposure data can be helpful in estimating the exposure for other staff in the room.
3. **For the safety of patients.**
   Your radiation exposure can be an indication of the radiation the patient received and if the user is consistently using radiation in the safest manner possible.
4. **It's a requirement of Federal, State and regulatory agencies.**

Radiation Badge Monitoring Wearer's Responsibility Code:

I understand that in conjunction with my application submission for and issuance of a personnel radiation monitoring badge, I will comply with the following:

- Wear my badge whenever I am working in the vicinity of radiation or with radioactive material
- Return my old badge at the end of the wear period
- Wear my badge according to the appropriate type:
  1. Collar Badge – wear on collar, outside of lead apron (if a lead apron is worn)
  2. Waist Badge – wear on waist, underneath lead apron (if a lead apron is worn)
     If assigned a collar and waist badge, the waist badge must be worn underneath lead apron
  3. Fetal Badge – wear low in center of abdomen, underneath lead apron
     The fetal badge will be exchanged monthly, even if your chest badge is exchanged quarterly
     Note: Pregnant radiation workers should review the Declared Pregnant Worker information.
  4. Ring Badge – wear on dominant hand, under gloves, facing source of radiation
- The badge reading is a legal record and must reflect occupational exposure only:
  - Badge shall be worn only by the person to whom it was assigned
  - Badge shall not be worn during exposure I receive as a medical patient
  - Badge shall not be worn at institutions outside of The Queen's Medical Center
- If I lose my badge, I will report it on the Lost Dosimeter Form and request a replacement
- Failure to return my badge when it is due may result in disciplinary action
- Know and adhere to the Radiation Safety Program Manual and any associated policies and procedures specific to radiation safety that are applicable to my work, including 10 CFR 19.12 training requirements.

Radioactive Spill Report

Enter values in all red cells

THE QUEEN'S MEDICAL CENTER
HONOLULU, HAWAII

Date of spill:	
Time of spill:	

Personnel Present	contamination results (items)

Radioisotopes present or suspected in spill		
Isotope: F-18	Activity:	Minor Spill

Description of the event

Follow up actions taken

Person recording form:	

Contamination Results

Meter used:	Select a counter from dropdown

Location description	Pre-clean survey	Post clean		
		survey	wipe test	
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm
			cpm	dpm

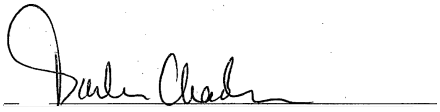
RADIATION SAFETY PLAN

THE QUEEN'S MEDICAL CENTER

December 2019

Contents

I. Approvals

A. Management Approval:  11/20/2019

Darlena Chadwick, VP, Patient Care — Date

B. RSO Approval: Dale Schippers 11/13/2019

Dale Schippers, Medical Physicist / RSO — Date

C. RSC Approval:  11/18/2019

Frank Goerner, Ph.D. Medical Physicist — Date

D. Effective Date: 12/1/2019

E. Date(s) when staff were trained in the new plan:

PET, Punchbowl (PB)	11/25/2019	Cyclotron	11/26/2019
Nuclear Medicine, PB	11/27/2019	Angiography	NA
Nuclear Medicine, West	11/27/2019	Radiation Therapy	11/25/2019
Nuclear Medicine, NHCH	11/27/2019		

Must include a copy of previous plan and the changes to this plan.

II. Revision History:

Original plan: most recent plan available appears to be a draft plan and was dated July 2014. It is attached as Appendix C.

6/18/2019

This update includes reformatting for clarity with only minor changes or revisions to radiation safety practices. The revisions include:

1. The table of contents added.
2. Frequency of types of audits were added for clarity
3. The introduction now contains a section on how to change the radiation safety plan.
4. Management commitment to ALARA program section was modified. Two paragraphs were removed.
5. High Exposure Level was added to the ALARA levels and each ALARA level was clarified with what actions will be taken.
6. Radiation Safety Officer and Authorized User sections under ALARA were deleted.
7. Dosimetry section was added to clarify the use of radiation badge monitors.
8. Item 17, under Rules for Safe Use of Radiopharmaceuticals was removed.
9. Radiation survey instrument capabilities were clarified in Area survey procedures
10. The training program section was changed to reflect the training that new employees and nursing staff receive. The article that was photocopied into the manual after the training section was deleted.
11. The Radiological Rooms, Radiation Safety Guidelines for Portable x-rays, Lead Apron Evaluation Program and Radioactive Trash In-service sections were removed because these are all addressed in QMC policies.
12. The Radiation Accident Protocol section was removed since the Spill Procedures section was added and covers most of this information.
13. The policies at the end of the radiation safety program were removed since these have all been revised.
14. Survey instrument calibration section was added.
15. Waste disposal section was added.

12/1/2019

1. Waste disposal section was modified to incorporate previous waste disposal policy
2. Bioassay section was added

III. Purpose

A. Providing safe and effective use of radiation for patients, employees, medical staff, and visitors.

IV. Responsibilities

A. Radiation Safety Committee (RSC) – Administers the plan, meets quarterly.
B. Radiation Safety Officer (RSO) – Manages the program, conducts Compliance Audits.
C. Management – Evaluate Annual Review of Program.
D. Employees – Reports any unsafe conditions or events to the RSO.

V. Audits

A. Personnel Monitoring - Quarterly.
B. Radiation Therapy – Quarterly.
C. Nuclear Medicine – Quarterly.
D. Cyclotron - Quarterly
E. Radiology – Annually.

VI. Radiation Safety Program

A. Introduction
    1. It is the policy of The Queen's Medical Center (QMC) that exposures to ionizing radiation are to be kept as low as reasonably achievable (ALARA) to all employees, patients, and visitors to QMC. Toward that end, QMC has established the Radiation Safety Committee (RSC) to oversee the radiation safety practices at QMC. Furthermore, the committee has appointed a Radiation Safety Officer (RSO) to ensure the safe use of radiation. He/she will be responsible for managing the Radiation Safety Program, identifying radiation safety problems, and implementing corrective action when needed. He/she will also be responsible to ensure compliance with the United States Nuclear Regulatory Commission (NRC), State of Hawaii, and The Joint Commission (TJC) requirements.
    2. Sources of radiation include x-ray machines in Radiology, Surgery, and the Dental Clinic, as well as linear accelerators in Radiation Therapy. In Nuclear Medicine, radioactive drugs are used for imaging and treatment. Finally, certain patients on the nursing floors and in angiography are treated with radioactive sources for cancer therapy. The benefits of using

radiation in medicine are great, and this program is designed to minimize the risks.

3. If you have any questions or concerns regarding radiation, please call the RSO at 691-4884 during normal working hours. For urgent requests, he/she can also be contacted through the QMC operator.
4. Changes to Radiation Safety Program
    a) All changes to the Radiation Safety Program must be reviewed and approved in writing by the RSO and management.
    b) Individuals affected by changes to the Radiation Safety Program will be instructed on the revised program before the changes are implemented.
    c) A record of each change to the Radiation Safety Program will be maintained for 5 years. The record will include a copy of the old and new procedures, the effective date of the change, and the signatures of the RSO and management representative that reviewed and approved the change (§ 35.2026).
    d) Any change requiring a license amendment according to 10 CFR 35.13 must be submitted to the Nuclear Regulatory Commission for approval.

B. Duties of the Radiation Safety Committee/Radiation Safety Officer
1. The Radiation Safety Committee shall:
    a) Ensure that licensed material will be used safety. This includes review, as necessary, of training programs, equipment, facility, supplies, and procedures.
    b) Ensure that licensed material is used in compliance with NRC regulations and the institutional license.
    c) Ensure that the use of licensed material is consistent with the ALARA philosophy and program.
    d) Establish a table of investigational levels for individual occupational radiation exposures.
    e) Identify program problems and solutions.
2. Responsibilities of the Radiation Safety Committee include:
    a) Be familiar with all pertinent NRC regulations, the license application, the license, and any and all amendments.
    b) Review the training and experience of the proposed authorized users, the RSO, and the Authorized Medical Physicist to determine that their qualifications are sufficient to enable the individuals to perform their

duties safely and are in accordance with the regulations and the license.

c) Review of the basis of safety and approve or deny, consistent with the limitations of the regulations, the license and the ALARA philosophy, all requests for authorization to use radioactive material within the institution.

d) Prescribe special conditions that will be required during a proposed method of use of radioactive material, such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

e) Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.

f) Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., Nursing, Security, Housekeeping) are appropriately instructed as required in 19.12 of 10 CFR Part 19.

g) Review at least annually the RSO's summary report of the entire Radiation Safety Program (RSP) to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, and results of NRC inspections, written safety procedures, and the adequacy of the management control system.

h) Recommend remedial action to correct any deficiencies identified in the RSP.

i) Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken.

j) Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies and procedures, and personnel.

3. Administrative Information:

a) The Committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter (four times yearly).

b) Membership must include one authorized user of each type of use authorized by the license, the RSO, a nursing representative and a

representative of management who is neither an authorized user nor an RSO. Management, and the RSO, may appoint alternate members to participate in meetings in the case of absence of principal members.

c) To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

d) To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities, such as x-ray radiation safety, quality assurance (QA) oversight, and research project review and approval.

C. ALARA Program

1. Management Commitment

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

b) We will perform a formal annual review of the RSP, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the Radiation Safety Staff or outside consultants.

2. Radiation Safety Committee

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 methods of use for which application has been made to ensure that the applicant will be able to take appropriate measure 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.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses of radiation will be ALARA.

(4) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the ALARA levels are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an

index of the ALARA Program's quality and to decide if action is warranted when investigational levels are exceeded.

(5) ALARA Levels

	ALARA Level I 10% of MPD	ALARA Level II 30% of MPD	High Exposure Level 1/12 of MPD	Annual Limit (MPD)
Body Dose (DDE /EDE2)	125 mrem/qtr.	375 mrem/qtr.	400 mrem/mth	5 rem
Lens of Eye (LDE)	375 mrem/qtr.	1125 mrem/qtr	1250 mrem/mth	15 rem
Extremities (SDE)	1875 mrem/qtr.	5625 mrem/qtr.	4000 mrem/mth	50 rem
LDE limits per ICRP		150 mrem/qtr		2 rem

(a) ALARA Level I: No investigation is required but the RSO will watch for a trend.

(b) ALARA Level II: The RSO will ask the individual to reply to a High Exposure memo.

(c) High Exposure Level: The RSO will ask the individual to reply to a High Exposure memo.

(6) The RSO will review and record, on NRC Form 5 or equivalent, a summary of personnel monitoring on an annual basis.

VII. Quality Management Program

A. Objective

1. To provide high confidence that byproduct material will be administered as directed by the Authorized User (AU).

B. Requirements

1. Prior to administration, a Written Directive (WD) will be completed and signed by an AU for the following procedures:
   a) Any therapeutic administration of a radiopharmaceutical
   b) Any administration of I-125 or I-131 greater than 30 □Ci
   c) Brachytherapy and High Dose Rate (HDR) procedures
2. Annual Audit to include:
   a) The compliance rate of having a WD prior to administration of a radiopharmaceutical or radiation in those cases where WD is required.
   b) The content of the written directive is as required.
   c) A comparison of what was administered versus what was prescribed in the WD.

VIII. Dosimetry (Personnel Radiation Monitoring).

1. Monitoring of occupational exposure to radiation from licensed and unlicensed radiation sources under licensee control will be supplied and require the use of individual monitoring devices by:
   a) Adults likely to receive greater than 10% of the annual limits in § 20.1201(a) [10% of annual limit is 500 mrem].
   b) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
   c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and
   d) Individuals entering a high or very high radiation area.
2. All individuals who are likely to receive greater than 5 rem skin dose (10% of skin dose limit) from handling radioactive material will be issued, and are required to wear, a film, TLD, or OSL extremity dosimeter.
3. Prior exposure history will be requested from the most recent employer, when applicable.
4. Staff shall report any lost, damaged, or accidentally exposed badges to the Radiation Safety Officer.
5. Employees and contractors (including physicians) must wear a dosimeter when performing procedures that involve ionizing radiation unless they have documentation to verify that they are not likely to receive greater than 10% of the annual dose limits.
6. In the event that your dosimeter is lost or temporarily displaced you may participate in a procedure involving ionizing radiation but you must report your lost dosimeter and/or lack of dosimeter use to Radiation Safety. The form for this report is included in appendix A.
7. Failure to wear your assigned radiation dosimeter will result in the following disciplinary actions:
   a) Consistent neglect in wearing your dosimeter, as indicated by an unusually low reported exposure relative to your workload, will result in the loss of privileges to work with ionizing radiation. For more information, please see policy *Radiation Badge Monitoring Responsibilities* (RSO-19-101-All).

IX. Procedures for Radiopharmaceuticals and Sealed Sources

A. Rules for Safe Use of Radiopharmaceuticals

1. Wear laboratory coats or other protective clothing in areas where radioactive material is used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor your hands for contamination in a low-background area with a survey meter either after each procedure or before leaving the area.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (.e.g., through use of a butterfly needle).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe test by-product storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
12. With a radiation detection survey meter, survey the generator storage (if applicable), kit preparation, injection areas and trash daily for contamination. If necessary, decontaminate or secure the area for decay, as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the amount of the compound, and the date and time of receipt or preparation. A log book or computer software should be used to record the preceding information and total

prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, the measured activity or each patient dosage, and any other appropriate information.

14. Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.
15. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 20 percent off from the prescribed dosage, except for prescribed dosages of less than 1 mCi. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
16. Always keep flood sources, syringes, waste, and other radioactive material(s) in shielded containers.

B. Bioassays

Bioassays determine the quantities, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, called in vivo counting, or by analysis and evaluation of materials excreted from the human body. Individuals who handle large amounts of easily ingested radionuclides may be required to participate in a bioassay monitoring program. Bioassays may also be ordered by the Radiation Safety Officer (RSO) after a spill, an unusual event, or a procedure that might result in an uptake.

C. Radiation Surveys.

1. Surveys will be performed at the end of each day of use for all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms should be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 µCi). Special care will be taken to remove all paraphernalia from patient rooms where diagnostic administrations are occasionally made. Patient rooms will not be surveyed.

   Surveys of ambient radiation exposure rates should be performed at the end of each day of use for all radiopharmaceutical elution, preparation, assay and administration areas (excluding patient rooms). Daily surveys are consistent with our ALARA philosophy, Part 20 requirements and will

ensure that radioactive material is not inadvertently disposed in the normal trash.

2. All areas where radiopharmaceuticals are eluted, prepared, assayed and administered will be surveyed weekly for ambient radiation exposure rates and for removable contamination.
3. All radiopharmaceutical use, storage and waste storage areas will be surveyed weekly for ambient radiation exposure rates and for removable contamination.
4. All sealed source and brachytherapy source storage areas will be surveyed quarterly for ambient radiation exposure rates.
5. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect at least 0.05 mR/hour.
6. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm (200 dpm for isotopes of iodine).
7. Survey results greater than the trigger levels (Table R.1 from NUREG 1556 vol9, rev2) will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to less than the trigger levels on repeat surveys.

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr
All trash	All areas	Background

8. A record shall be kept of all survey results. The record will include:
   a) Location, date, and type of equipment used;
   b) Initials of the person conducting the survey;
   c) Drawing of the area surveyed;
   d) Trigger levels keyed to the location on the drawing;
   e) Measured dose rates in mR/hr or contamination levels in dpm/100 cm2, as appropriate;
   f) Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.
9. The RSO will be notified immediately if the trigger levels are exceeded.

D. Procedure for Receiving and Opening Radioactive Packages

1. Packages must be delivered directly to NM or Radiation Therapy and not left in Receiving Department.
   a)

2. For all packages containing radioactive materials licensed per 10 CFR 35, the following procedure will be performed.
   a) Put on gloves to prevent hand contamination
   b) Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
   c) Measure the exposure rate at the package surface. The surface exposure rate should not exceed 0.5, 50 and 200 mR/hr for "White I", "Yellow II" and "Yellow III" packages, respectively. If it is higher than expected, stop and notify the RSO. The Transportation Index (TI) is the radiation level, measured at 1 meter, in Sieverts (TI:
   d) Determine the removable contamination level on the exterior of the package. Wipe an area of 300 cm^2 with an absorbent material. The contamination cannot exceed or 173.443:
      (1) 240 dpm/cm^2 for beta and gamma emitters.
      (2) Contamination (in dpm) = cpm / (300 cm^2 x efficiency)
      (3) Use the measured efficiency or 0.10 (10%) if unknown.
   e) Open the package with the following precautionary steps:
      (1) Remove the packing slip.
      (2) Open the outer package following the supplier's instructions, if provided.
      (3) Open the inner package and verify that the contents agree with the packing slip.
      (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquids, condensation, or discoloration of the packing material.
   f) If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (It is required that the sample be assayed using a Nal Well Counter, and the results recorded in disintegrations per minute). Take precautions against the potential spread of contamination.
   g) Check the user request to ensure that the material received is the material that was ordered.
   h) Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in normal trash.

i) Make a record of the receipt. The receipt survey records must be kept on file for three years. The record of receipt (i.e. bill of lading, radiopharmaceutical incoming labels) must be kept as long as the licensee retains possession of the material and for three years following the transfer or disposal of the material.

10. The monitoring required by paragraph (2) shall be performed as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

E. Survey Instrument Calibration

1. General Requirements

a) Survey instruments, for example GM survey meters, ionization chambers and NaI(Tl) scintillator probes, are required for performing various surveys (see Radiation Surveys). NUREG-1556, Volume 9, Section 8.17, states that the "instruments should be available for use at all times when byproduct material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125 (I-125), palladium-103 (Pd-103)] if they become dislodged in the operating room or patient's room. The Radiation Protection Program that licensees are required to develop, document, and implement in accordance with NRC 10 CFR 20.1101 must include provisions for survey instrument calibration. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured." The NRC in NRC 10 CFR 35.61 requires the "calibration of survey instruments used to show compliance with NRC 10 CFR 35 and NRC 10 CFR 20 before first use, annually, and following a repair that affects the calibration." (Battery changes are not considered "servicing.")

2. Calibrating Survey Instruments

a) Survey meters used for quantitative measurements will be calibrated on an annual basis using the services provided by calibration laboratories, a survey instrument vendor or a consultant.

b) An alternative method to perform calibration of our own survey instruments may be used, as discussed by Pat Zanzonico in a 2008 Journal of Nuclear Medicine review article. Further information is available in NUREG-1556, Volume 9, Section 8.17 and Appendix K. Note that the NRC states that, as an operational check, each day before use perform a check (with a dedicated check source) as well as a battery check. A record of each survey instrument calibration must be retained for three years in accordance with NRC 10 CFR 35.2061.

F. Waste Disposal

Radioactive material waste can come in the form of a solid, liquid or gas. The disposal method for these forms is described below.

1. Conventional Waste

a) Byproduct material with a physical **half-life of less than or equal to 120 days** can be disposed of in the normal trash following decay-in-storage if

(1) Survey at the surface demonstrates that its radioactivity cannot be distinguished from the background radiation level when monitored with an appropriate radiation survey meter set on its most sensitive scale and with no interposed shielding; and

(2) All surface radiation labels are removed or obliterated.

b) Byproduct material with a physical **half-life of more than 120 days** must be disposed of using a certified radioactive material disposal service.

c) Storage and disposal records of all radioactive waste will be maintained for 3 years following disposal.

2. Sewer Waste

a) Material must be readily soluble and dispersible in water.

b) Excreta from individuals undergoing medical diagnostic or therapeutic procedures with radioactive materials are exempt from any limitations.

c) Radionuclides other than the above must be disposed in accordance with 10 CFR 20.2003. There are daily and monthly limits based on the total sanitary sewage release of the medical center. In each case, record the date, radionuclide, estimated activity, and designation of the sink or toilet at which the material was released.

3. Effluent Waste
    a) Limits on permissible concentrations of effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR 20. These limits apply at the boundary of the restricted area.
    b) All radioactive effluents at this facility are sufficiently diluted to meet NRC standards.

G. Spill Procedures

1. Contamination control is the responsibility of every individual using radioactive material. Proper preparation based on its physical state, drip pans, splash guards, backed absorbent paper and similar inexpensive provisions greatly reduce the need for decontamination. Well-channeled ventilation, good housekeeping, and frequent use of survey meters are investments which will be well repaid.
2. Minor Contamination Events
    a) Minor contamination events are those events typically identified through routine surveys that involve removable contamination levels greater than the action limit, but less than ten times the action limit.
    b) Minor contamination events can be easily decontaminated without the need for strict adherence to a step-by-step procedure.
    c) Minor contamination events require judgment on the part of the individuals responding to determine the scope and extent of the contamination and to assess their ability to respond effectively.
    d) In order to prevent the spread of contamination, coworkers should be notified if decontamination of the area will be delayed.
    e) Notification of the RSO is not required.
3. Spilled activity that exceeds the values listed in this table should be considered a Major Spill (NUREG 1556 vol 9 rev 2 & draft rev 3).

F-18	100 mCi		In-111	10 mCi		Lu-177	1 mCi
Ga-67	10 mCi		Lu-177	1 mCi		Ra-223	*
I-123	10 mCi		P-32	1 mCi		Y-90	10 mCi
I-125	1 mCi		Tc-99m	100 mCi			
I-131	1 mCi		Tl-201	100 mCi			

* any spill of isotopes that are primarily alpha emitters should be considered major

4. The Radiation Safety Office should be notified as soon as possible whenever a spill (major or minor) occurs.
   Meanwhile, the primary considerations are:

a) Prevent spread of contamination. If liquid spill, use absorbent material to prevent flow and seal cracks in floor, workbench, etc. Use decontamination solution (e.g. radiac wash) and wipe the contaminated area with absorbent material. If airborne, close windows, doors, vents, turn off ventilation, seal doors with masking tape.

b) Post radiation warning signs and allow no one to enter contaminated area unaware.

c) Decontaminate personnel using the following steps:

(1) Surface contamination - Persons splashed with active solutions should wash immediately with ample quantities of water. A mild soap should be used for a "surgical scrub" with light brushing. If the body contamination after this scrubbing remains more than two times background, the laboratory supervisor and the Radiation Safety Officer must be notified so that further steps can be taken.

(2) Internal contamination (ingestion) - Any radioactive material swallowed should be evaluated immediately by the Radiation Safety Officer and a physician knowledgeable in radiation safety, e.g., a nuclear medicine physician.

d) The Radiation Safety Office must be notified and may render assistance in decontamination. All personnel affected will be monitored and shall follow the recommendations regarding decontamination.

5. A complete history of the spill and subsequent remedial or protective measures must be submitted to the Radiation Safety Office via a Spill Report (Appendix B).

X. Personnel Protection

See the following policies available at The Queen's Medical Center intranet, eww.queens.org/RadTx/policies.html

A. Radiation Badge Monitoring Responsibilities. RSO-19-101-All

B. Radiation Safety Guidelines for Fetal Protection

XI. Training

A. Annual General In-service to QMC Staff.

B. Initial Training for New Employees working with radiation may include the following as applicable

1. Review Dosimetry Requirements as listed in section VII.
2. Review policies for procedures that require a Written Directive
3. Review Personnel Protection policies listed in section IX.
4. A training checklist will be used to document initial radiation safety training. The checklist must be signed by the employee and approved by the RSO.

C. Specific Instructions

1. Nursing
   a) Initial and annual radiation safety instruction will be provided to personnel caring for patients who cannot be released under § 35.75. The instruction will be commensurate with the nurse's duties and include (§ 35.310):
      (1) Patient or human research subject control;
      (2) Visitor control, including—
         (a) Visitation to hospitalized individuals will be limited in an effort to maintain the public dose to < 100 mrem (§ 20.1301)
         (b) In special cases, the dose to the public may exceed 100 mrem, but must be < 500 mrem. The Authorized User must determine that the visit is appropriate;
      (3) Contamination control;
      (4) Waste control; and
      (5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.
2. Nuclear Medicine
   a) Initial and annual radiation safety instruction will be provided and cover the training requirements in 10 CFR 19.12, 20 and 35.
3. Radiation Therapy
   a) Emergency procedures for High Dose Rate brachytherapy
   b) Radiation Safety for brachytherapy

Effective Date: December 2019

System-Wide Radiation Services Policies and Procedures of The Queen's Health System

Subject: RADIATION BADGE MONITORING RESPONSIBILITIES

This policy applies to all employees and contractors of the following entities, (collectively "Queens"):

☒ The Queen's Health Systems	☐ Queen's Development Corporation
☒ The Queen's Medical Center	☒ Diagnostic Laboratory Services, Inc.
☒ Molokai General Hospital	☐ Queen's Insurance Exchange, Inc.
☒ North Hawaii Community Hospital, Inc.	☐ CareResource Hawaii
☐ Queen Emma Land Company	☐ All Entities, and any other current or future subsidiaries

THE QUEEN'S MEDICAL CENTER

Dale Schippers, RSO
Medical Physicist
The Queen's Medical Center

Darlena Chadwick, MSN, MBA, FACHEE
Vice President, Patient Care
The Queen's Medical Center - Punchbowl

Susan R. Murray, FACHE
QHS Sr. VP, West Oahu Region
COO, The Queen's Medical Center – West Oahu

NORTH HAWAII COMMUNITY HOSPITAL, INC.

Cindy Kamikawa, RN, MS
President, North Hawaii Community Hospital

MOLOKAI GENERAL HOSPITAL

Janice Kalanihuia
President, Molokai General Hospital

Submitted for Revision by:	Date
Most Recent Revision Info	10/2019
Previous Revision Info	04/2014

SCOPE

Distribution: Available via the Queen's Medical Center Intranet and to Medical Staff Members upon request. The master, signed original document is located in the office of the identified guardian.

Individuals likely to receive 10% of the annual radiation dose limit (500 mrem/year is 10%), will be provided with and **MUST WEAR** radiation dosimeters when working with or around ionizing radiation. Radiation safety staff will determine which individuals or groups require monitoring. This includes personnel (employees and contractors) who work with radioactive material or x-ray equipment at The Queen's Medical Center.

PURPOSE

1. To ensure the safety of patients, staff and contractors at Queen's Medical Center that are exposed to ionizing radiation.
2. To ensure that staff and contractors are compliant with personnel monitoring procedures.

POLICY COMPLIANCE

The Radiation Safety Officer (RSO) or a delegate will review all dosimeter reports for high level exposures which will follow guidelines listed in the Radiation Safety Program. Additionally, dosimeter reports will be reviewed to ensure that staff are compliant in wearing their radiation badge dosimeters when working with or around ionizing radiation. If the RSO determines that staff have failed to wear their radiation dosimeter(s) while working with or around radiation the following corrective actions will be taken:

1. If the RSO determines that staff have failed to wear their radiation dosimeter(s) while working with or around radiation, employee may be subject to disciplinary action, up to and including termination. If the RSO determines that contractors have failed to wear their radiation dosimeter(s) while working with or around radiation, the appropriate governing body within The Queen's Health Systems will be notified for appropriate action to be taken.

PROCESS

1. To obtain a Radiation badge for occupational dose monitoring, radiation workers must submit a completed "Application for Personal Dosimetry" form (Appendix A) to the RSO.

2. If your radiation dosimeter is lost, misplaced, damaged or contaminated you must notify the RSO within 3 days. A "Lost Dosimeter Form" (Appendix B) must be completed and submitted to the RSO.

3. To obtain a Fetal Radiation badge for occupational fetal dose monitoring, radiation workers must notify the RSO. A "Declaration of Pregnancy" form (Appendix C) must be completed and submitted to the RSO for approval.

If you have any questions, please contact Dale Schippers, MS, RSO or Frank Goerner, PhD at 691-4884 or 691-7063, dschippers@queens.org , fgoerner@queens.org

Appendix A
RSO-19-101_All

THE QUEEN'S HEALTH SYSTEM
REQUEST FOR PERSONAL DOSIMETRY
RADIATION MONITORING BADGE

Type or print legibly all information requested.

1. Full Name: _____
   Last First Middle (Maiden)

2. Last 4 digits of your Social Security Number: _____ 3. Sex: ☐ Male ☐ Female

4. Department: _____ 5. Telephone No. / ext.: _____

6. Position/Title: _____

7. a. Have you previously been issued a radiation monitoring badge by QMC? ☐ Yes ☐ No

   b. If "Yes", complete the following:

   (1) Department: _____

   (2) Dates of Employment: From _____ To _____

8. Previous exposure history - OTHER THAN AT QMC.

   a. Have you been enrolled in a dosimetry program before? ☐ Yes ☐ No

   b. Have calculations and/or analysis been made of external radiation received, and/or radioactive materials deposited in your body? ☐ Yes ☐ No

   c. If answer to "a" or "b" above is "Yes", complete the following:

Note: This section only applies to the individual who has worked with radiation-producing devices or radioisotopes in a permanent status. List only those employers for whom you worked with radiation.

NAME OF EMPLOYER **AND** DEPARTMENT	ADDRESS (Street address, city, state, zip code)	FROM Month / Year	TO Month / Year

- Under the provisions of Title 10, Code of Federal Regulations, Part 19.13 (10CFR19.13), I authorize former employers to release my history of occupational radiation exposure to The Queen's Medical Center, Radiation Safety Officer.

- I have read and understand the form "Information and Responsibilities for Badged Radiation Workers" and agree to wear my radiation dosimetry badge any time I am using or around radiation while performing work duties at The Queen's Medical Center.

Signature: _____ Date: _____

RADIATION SAFETY USE ONLY

Series Code: _____

a. Monitoring badge required ☐ Whole-body Type _____ ☐ Ring Size _____

b. Frequency ☐ Monthly ☐ Quarterly

Date badge ordered: _____ Begin Wear Date: _____

Issue spare badge? ☐ Yes ☐ No Spare badge date: _____ Spare badge #: _____ Date Issued: _____

Radiation Safety
1301 Punchbowl Street
Honolulu, HI 96813
808 691-4884

THE QUEEN'S HEALTH SYSTEMS

_____
Date

_____
Institution where previous exposure occurred

_____
Department

_____
Address

_____
City, State, Zip

SUBJECT: Occupational Radiation Exposure History Request

Please supply us with the external exposure history on the following person for the employment period at your institution. Return by mail or email.
If this individual has been exposed to isotopes controlled by the U. S. Nuclear Regulatory Commission, we will also need information regarding radiation dose from internal exposures. This dose information should be provided on NRC Form 4 or an equivalent form containing all of the information required by NRC Form 4.

Name: _____ Soc. Sec. #:_____

DOB:_____ Department: _____

Dates of Employment: _____ to _____
start date end date

I hereby authorize the release of my radiation exposure history:

_____
signature

Thank you for your cooperation in this matter. Please return this form with your reply via email or US mail.

Sincerely,

Dale Schippers, M.S.
Radiation Safety Officer
dschippers@queens.org

THE QUEEN'S HEALTH SYSTEM

INFORMATION AND RESPONSIBILITIES FOR BADGED RADIATION WORKERS

(Do not return with badge application – please keep for your record.)

Radiation Monitoring Badges Are Required to be worn if you are exposed to more than 10% of the annual dose limit for radiation workers. The Radiation Safety Officer (RSO) will help you determine whether or not you are required to wear a radiation monitoring badge.

If the RSO determines that you are required to wear a radiation monitoring badge, it is MANDATORY that you wear the badge when you work with or around radiation. If the RSO determines that you are not regularly wearing your radiation badge when working with or around radiation, the following disciplinary action will result:

- Consistent neglect in wearing your dosimeter, as indicated by an unusually low reported exposure relative to your workload, will result in the loss of privileges to work with ionizing radiation. Consistent neglect is defined as 3 months of unexplained low exposures, relative to workload, in a 12 month period.

It is important that you wear your radiation monitoring badge for the following reasons:

1. **For your own safety related to radiation.**
   Exposure data will help the radiation safety office to better determine if the work environment you are in protects you from unnecessary radiation and if you are using radiation safely and adhering to ALARA.
2. **For the safety of your co-workers.**
   Your radiation exposure data can be helpful in estimating the exposure for other staff in the room.
3. **For the safety of patients.**
   Your radiation exposure can be an indication of the radiation the patient received and if the user is consistently using radiation in the safest manner possible.
4. **It's a requirement of Federal, State and regulatory agencies.**

Radiation Badge Monitoring Wearer's Responsibility Code:

I understand that in conjunction with my application submission for and issuance of a personnel radiation monitoring badge, I will comply with the following:

- Wear my badge whenever I am working in the vicinity of radiation or with radioactive material
- Return my old badge at the end of the wear period
- Wear my badge according to the appropriate type:
  1. Collar Badge – wear on collar, outside of lead apron (if a lead apron is worn)
  2. Waist Badge – wear on waist, underneath lead apron (if a lead apron is worn)
     If assigned a collar and waist badge, the waist badge must be worn underneath lead apron
  3. Fetal Badge – wear low in center of abdomen, underneath lead apron
     The fetal badge will be exchanged monthly, even if your chest badge is exchanged quarterly
     Note: Pregnant radiation workers should review the Declared Pregnant Worker information.
  4. Ring Badge – wear on dominant hand, under gloves, facing source of radiation
- The badge reading is a legal record and must reflect occupational exposure only:
  - Badge shall be worn only by the person to whom it was assigned
  - Badge shall not be worn during exposure I receive as a medical patient
  - Badge shall not be worn at institutions outside of The Queen's Medical Center
- If I lose my badge, I will report it on the Lost Dosimeter Form and request a replacement
- Failure to return my badge when it is due may result in disciplinary action
- Know and adhere to the Radiation Safety Program Manual and any associated policies and procedures specific to radiation safety that are applicable to my work, including 10 CFR 19.12 training requirements.

In the event that your dosimeter is lost or temporarily displaced you may participate in a procedure involving ionizing radiation only if another person is unable to take your place and you report the details of the procedure to the RSO within 3 days.

Also, if your dosimeter is not returned to Radiation Safety within 60 days of the end wear date, the RSO will estimate your exposure from your, or similar users, dose history. To properly assign the dose, we need the information requested below. If you have any questions contact the RSO at 691-4884.
Complete this form and return via email or inter-department mail to:

Dale Schippers, RSO
Nae'a - Radiation Therapy Department or dschippers@queens.org

Last Name	First Name

Department/Series Code:	phone / ext.

Begin Wear Date: _____ (or first use date)

End Wear Date: _____ (date badge was lost)

Type of badge: [Body]  [Ring]  [Other] _____

Briefly describe your duties around radiation sources.

Were there any circumstances during the period which might have caused an increase or decrease in your typical reading? (i.e. Unusually high workload, vacation/sick days off)

_____ _____
Signature Date

Radiation Safety Use Only Date:

Name: _____ Series Code: _____ Badge # _____

Previous exposure reading (mrem)

MONTH					
DDE					
LDE					
SDE					

Spare Badge Assigned?
Yes / No

millirem to be assigned: DDE _____ LDE _____ SDE _____

_____ _____
Radiation Safety Officer Date

DECLARATION OF PREGNANCY

Employee Name: _____ **Department** _____

I have declared my pregnancy and wish to continue to work in my present capacity at The Queen's Medical Center. Currently, my work involves occupational radiation exposure.

The Radiation Safety Officer has provided me the following documents:

1) Radiation and Pregnancy: A Fact Sheet for the Public
2) Radiation Safety Guidelines for Fetal Protection

I understand that the additional risk from occupational exposure during my pregnancy is less than that for most occupational groups.

The approximate date of conception is _____.

A fetal radiation badge will be issued to monitor fetal radiation exposure. **This badge is to be worn at my waist and under the lead apron when one is being worn**.
I understand that the fetal dose will not be allowed to exceed the 500 mrem limit during the entire monitoring period.

_____ _____
Employee sign Date

_____ _____
Manager sign Date

Reviewed:

_____ _____
Radiation Safety Officer / medical physicist Date

TheraSphere Radioembolization of Hepatic Malignancies

Effective Date:	February 1, 2016
INDICATIONS:	Candidates for radioembolization are patients with unresectable primary or metastatic hepatic disease with liver-dominant tumor burden and a life expectancy >3 months. Yttrium-90 microspheres are glass beads embedded with Y-90. Y-90 emits a beta particle with maximum energy 2.28 MeV, mean energy 0.937 MeV, average soft-tissue range 2.5 mm. It has a physical half-life of 64.2 hours. Hospitalization is not required for the administration of Y-90 TheraSpheres.
CONTRA-INDICATIONS/ PRECAUTIONS:	Contraindications for radioembolization therapy may include: 1. pretreatment 99mTc macro-aggregated albumin (MAA) scan demonstrating the potential of ≥30 Gy radiation exposure to the lung or flow to the gastrointestinal tract resulting in extrahepatic deposition of 99mTc MAA that cannot be corrected by catheter embolization techniques, 2. excessive tumor burden with limited hepatic reserve, 3. elevated total bilirubin level (>2 mg/dL) in the absence of a reversible cause, and 4. compromised portal vein, unless selective or super-selective radioembolization can be performed. Patients with prior radiotherapy involving the liver should be carefully reviewed on a case-by-case basis. It is unclear whether capecitabine chemotherapy treatments represents a contraindication to Y90 treatment. **Pre-treatment High Risk Factors include:** • infiltrative tumor type • "Bulk disease" (tumor volume > 70% of the target liver volume, or tumor nodules too numerous to count) • AST or ALT > 5 times ULN • bilirubin > 2 mg/dL • tumor volume > 50% combined with an albumin < 3 g/dL
ISOTOPE:	Yttrium-90 microspheres (TheraSpheres)
DOSE:	The usual administered dose of Y-90 microspheres is 130 Gy (normal range is 80 – 150 Gy). The dose calculation for total injected radioactivity is performed using the following equation:

$$\text{Activity Desired (GBq)} = \frac{\text{Desired Dose (Gy)} \cdot \text{Liver Mass (kg)}^{*}}{50(1 - F)}$$

* Liver mass is the perfused liver mass.

F is the lung fraction determined from MAA scan.

Note: 1 cc liver is 1.03 g (conversion factor volume is 1.03g/cc)

Guidelines for measuring the amount of Yttrium -90 to be administered:

PATIENT PREPARATION:

Prior to administration of Y-90 TheraSpheres, the patient must be evaluated for shunting to the lungs and small bowel.

The typical plan for patients referred for possible Y-90 TheraSphere treatment includes:

- Mapping angiogram in Interventional Radiology
- Assessment of shunting to the lungs and small bowel using Tc-MAA
- Dosimetry using lung shunt and treatment volume. The treatment volume is measured using ultrasound or CT exam.

MAPPING ANGIOGRAM PROCEDURE:

The mapping angiogram will identify the anatomy and feasibility for treatment using Y-90 TheraSpheres.

1. Aortogram to delineate overall vascular anatomy
2. Celiac arteriogram to assess left gastric, right gastric, phrenic, falciform and esophageal arteries.
3. Superior mesenteric arteriogram to assess replaced right hepatic-supraduodenal branches and anatomic variants.
4. Prophylactic embolization, if necessary
5. Injection of Tc-MAA for assessment of shunting.

Tc-MAA SHUNT PROCEDURE:

DOSAGE:

The usual adult administered activity is 150 MBq (4 mCi).

For the assessment of lung shunting fraction, unilobar or whole liver injection of MAA may be performed. Irrespective of the location of MAA injection, it is imperative that the MAA be delivered with flow rates and catheter position that mimic the anticipated Y-90 infusion rate. Whole liver or unilobar infusions of Y-90 may be considered at the discretion of the treating team, according to tumor characteristics and location. Scintigraphy should be performed within 1 h of injection of MAA to prevent false-positive extrahepatic activity due to free technetium.

IMAGING:

Planar images should be obtained in both anterior and posterior projections to include the lungs, liver and small bowel. The detector distance, relative to the

table, should be the same for each view. DO NOT adjust the detector to be closer to the patient after the initial anterior or posterior image.

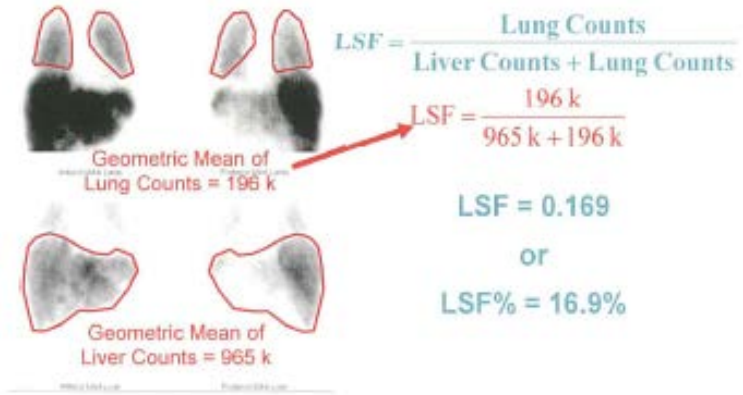
View:	Anterior & Posterior images of the lungs, liver and small bowel.	SPECT
Collimator:	High Resolution	Ultra High Res.
Acq. Time:	3 minutes/image (goal > 1M counts)	20 sec./proj. (22 min. total)
Frames:	1	64 / 180° 2 heads
Matrix:	256^2	128^2
Zoom:	1	1

IMAGE PROCESSING:

Lung Shunt Fraction (LSF) is calculated using the geometric mean of counts from the lungs and liver using the following formula.

$$\text{Lung Shunt Fraction (LSF)} = \frac{\text{Net Lung Counts}}{\text{Net Liver Counts} + \text{Net Lung Counts}}$$

1. Draw region of interests over each lung in both anterior and posterior images.
2. Draw background ROI for the lungs near thyroid if thyroid visible or near the dome of the left lung. Draw background ROI for the liver near the base of anterior medial segment.
3. Net Lung counts = Total lung cts – (bkg cts/pixel x Total lung pixels)
4. Net Liver counts = Total liver cts – (bkg cts/pixel x Total liver pixels)
5. Calculate the geometric mean using net counts as $= \sqrt{Anterior \times Posterior}$ and then calculate the LSF.



6. Note: If abdominal shunting is present or kidneys are observed, the apparent shunt will be significantly greater than the real shunt. To correct for this situation, include the entire abdomen in ROI for the liver.

7. Create a Savescreen showing the ROIs and LSF calculation.
8. Send the images to PACS.

Y-90 THERASPHERE PROCEDURE:

1. Calculate the dose to the treatment volume and to the lungs.
   The dose for Y-90 TheraSpheres is calculated as:

$$\text{Activity Desired (GBq)} = \frac{\text{Desired Dose (Gy)} \cdot \text{Perfused Liver Mass (kg)}}{50\,(1 - \text{LSF})(1 - R)}$$

$$\text{Perfused Liver Mass (kg)} = \frac{\text{Perfused Liver Volume (cm}^3) \cdot 1.03\text{g/cc}}{1000\,g/kg}$$

2. The lung dose must be limited to 30 Gy or shunted activity of less than 0.6 GBq.

$$\text{Lung Dose (Gy)} = \frac{50 \cdot \text{Injected Activity (GBq)} \cdot \text{LSF} \cdot (1 - \text{R})}{1Kg}$$

   R is the residual activity; LSF is the Lung Shunt Fraction

3. Desired activity and dose calculations are verified by a second, independent person.
4. Vial radioactivity and Treatment Activity Desired is determined using Excel spreadsheet named, “Dose calculator for TheraSpheres.xls.”
5. The desired dose is ordered by completing the, “TheraSphere® Order Form” (Appendix A) and faxing or emailing to BTG.
6. Prior to administration, a written directive (Appendix B) will be prepared which contains the following information:
   a. the patient or human research subject’s name
   b. pre-administration
      i. date
      ii. signature of the authorized user
      iii. treatment site
      iv. radionuclide including the physical form
      v. prescribed dose/activity; and, if appropriate for the type of microsphere used, identify the manufacturer and include the statement “or dose/activity delivered at stasis”
      vi. maximum dose(s)/activity(ies) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract)
   c. post-administration but before the patient or human research subject leaves the post-procedural recovery area
      i. date
      ii. signature of the authorized user

iii. total dose/activity delivered to the treatment site. If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated.

d. Prior to administration, patient's identity must be verified by more than one method as individual named in the written directive by the person administering the radiopharmaceutical.

7. Preparation and administration of the Y-90 TheraSpheres will follow the TheraSphere Checklist (Appendix C).
   a. The Authorized User must sign the written directive and be immediately available during the procedure.
   b. Nuclear Medicine and/or medical physics staff will be present in the IR room during the infusion to assist with radiation safety issues including surveying of all staff prior to leaving the room.
   c. Technologist verifies that the specific details of administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the Written Directive. If any portion of Written Directive is unclear to technologist, the authorized user will be consulted for clarification.

ADDITIONAL INFORMATION

Instructions for Patients

1. Common adverse events
   a. Fatigue
   b. Mild abdominal pain or discomfort
   c. Fever/Night Sweats
2. Rare adverse events secondary to GI Ulceration/Gallbladder Injury
   a. Severe abdominal pain
   b. Significant nausea/vomiting
   c. Weight loss
   d. Anorexia
3. Radiation Safety

REPORTING:

Deviations from the prescribed dose (in the Written Directive) shall be reported for any event, except for an event that results from intervention of a patient or human research subject, in which:

2. the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
3. the administration of Y-90 microspheres results in a dose:
   a. that differs from the prescribed dose, as documented in the pre-administration written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed

dose/activity, as documented in the pre-administration written directive, by 20 percent or more; or

b. that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or

c. to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the pre-administration portion of the written directive

REFERENCES:	Recommendations for Radioembolization of Hepatic Malignancies Using Yttrium-90 Microsphere Brachytherapy: A Consensus Panel Report from the Radioembolization Brachytherapy Oncology Consortium. Andrew Kennedy M.D., Subir Nag M.D., et al. April 19, 2007 Package Insert, TheraSphere® Yttrium-90 Glass Microspheres FSME-08-075, Standard License Conditions for the Yttrium-90 (Y-90) Microsphere Radiotherapy Licensing Guidance. October 8, 2008; U.S. NRC web site
REVISIONS:	Checklist updated July 10, 2020
TECHNOLOGIST INITIALS:	

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TheraSphere Checklist

THE QUEEN'S MEDICAL CENTER

Patient Name _____ ***Med Rec Number*** _____

Date of Treatment _____ ***DOB:***_____ ***Treatment Lobe***_____

TheraSphere Lot Number_____ ***Labeled Quantity***_____***GBq***

Catheter Information:
(Place catheter sticker in the space provided below)
Microcatheter inner diameter must be ≥0.5mm (0.020 inch)

*****Previous Treatment:** None

1. ***Dose Calculations verified by two individuals***
   - ❑ ***Treatment volume calculated by:*** _____, _____
   - ❑ ***Lung Shunt calculated by:*** _____, _____
   - ❑ ***Final Dose calculation by:*** _____, _____

2. ***Materials Required for TheraSphere Administration:***

   - ❑ Signed Written Directive Form (patient prescription for TheraSphere)
   - ❑ Ionization Survey Meter
   - ❑ GM Contamination Meter
   - ❑ Spill Kit
   - ❑ Drape for floor – apply under cart in angiography suite
   - ❑ Place a sterile drape on the cart.
   - ❑ Place the following items on the draped cart:

Sterile side of cart:	***Non-sterile side of cart:***
❑ Needle Holder (Non-Snugging) ❑ Scissors ❑ Steri-strips ❑ Towels ❑ Gauze ❑ Saline Bag (250 ml) → open and place on cart. ❑ 20 mL syringe ❑ Administration Set → open and remove from the sterile blister pack. (includes 20 mL syringe, 20 mL vial) ❑ Prep Bowl Set	❑ TheraSphere Acrylic Box → remove top shield and fully extend stainless steel arm. ❑ Bag hook → install on acrylic box. ❑ Electronic dosimeter (RADOS RAD 60R or equivalent) → turn on, set to **mR/h**, clip to bracket on acrylic box. ❑ 2L Nalgene waste container → remove lids. ❑ Leave beta shield outside the room ❑ TheraSphere Dose Vial (in lead pot) → Gently rock the lead pot back and forth to wet any microspheres on the vial septum. Place lead pot inside acrylic box holder. ❑ Alcohol Swabs

3. ***Angio Time-out*** *(by Medical Physics staff or NM tech.)*

- ❑ All radiation workers present are wearing their assigned dosimeter. Verify now or with Invasive procedure time-out. (document each person on survey page)
- ❑ Verify Patient ID by two methods and the treatment lobe.

4. ***Pre- Prep*** *(by Medical Physics staff or NM tech.)*

- ❑ Measure and record the initial radiation field for the patient, using an ionization survey meter. _____ mR/hr
- ❑ Verify that the Written Directive (WD) is signed by AU.
- ❑ Verify correct dose vial (matches the WD)
- ❑ Tilt the dose vial (in its lead pot) back-and-forth, and tap it firmly on a hard surface to dislodge any spheres that may be attached to the rubber septum.
- ❑ Place dose vial in the beta shield

5. ***Administration Set Priming*** *(by IR Technologist, IR physician or Physics staff)*

- ❑ Use either a normal 20 cc syringe or the 20 cc syringe included with the administration set to flush the tubing.
- ❑ Insert the large non-vented white piercing spike (Large CAP) into the saline bag
- ❑ Insert the small white vented spike (Small CAP) into the empty 20mL vial.
- ❑ Remove the (RED RUBBER) shield cap from the Needle Injector Assembly and place the Needle Injector Assembly on a sterile towel or a basin.
- ❑ Slowly fill and vigorously discharge the syringe to remove air from the Administration Set tubing and syringe. Continue priming until there are no bubbles in the lines and there are continuous streams of saline flowing out of both needle holes in the Needle Injector Assembly. Tap the tubing at point A since this is a common location for air bubbles.
- ❑ Fill the syringe when priming is complete.
- ❑ Install the (RED RUBBER) shield cap on the Needle Injector Assembly to maintain sterility.

Note: See **Troubleshooting Guidance** on last page to resolve priming issues. **STOP HERE UNTIL IR IS READY FOR DOSE**

- ❑ Call Nuclear Medicine AU to IR suite when ready for administration.
- ❑ Remove the lead pot lid and place it upside down on a non-sterile surface.

6. ***Dose Vial Preparation*** *(by IR physician or Medical Physics staff)*

- ❑ Use a needle holder to remove the purple seal from the top of the dose vial acrylic shield. Discard the seal in the Nalgene waste container.
- ❑ Use a Steri-strip to remove the acrylic shield plug. Discard the plug and Steri-strip in the Nalgene waste container.
- ❑ Use an alcohol swab and a needle holder to disinfect the dose vial septum. Discard the swab in the Nalgene waste container.
- ❑ Double check to make sure no bubbles are in the administration set.
- ❑ Remove red rubber shield cap

- ❑ Insert the Needle Injector Assembly into the acrylic dose vial shield. Press on the GREEN cap to lock in place. **You will hear or feel a click or snap.**
- ❑ Close the pinch clamp on outlet tubing near label 'E'.
- ❑ Place the empty 20 mL vial in holder on the acrylic box and push the relief valve tube into gripper clip 'A'.
- ❑ Hold the Needle Injector Assembly and place inlet line through slot 'B' in the acrylic box, and outlet line through slot 'D'.
- ❑ Loop tubing around the side and slide connection firmly into slot 'C'.

7. Dose Delivery and Time Out *(by IR staff or IR physician)*

- ❑ Time Out to verify details of the Written Directive
  - Verify Patient ID, radiopharmaceutical, dosage, and route of administration
  - Document the Time out on Written Directive

8. ***Final Assembly*** (*by IR physician)*

- ❑ Push the YELLOW tabs all the way down, locking the needles into the dose vial. **You will hear or feel a click or snap at the bottom of travel.**
- ❑ Place the top shield on the acrylic box with the sloped shield towards the catheter. Ensure tubing is not pinched or kinked.
- ❑ Record the dosimeter initial reading:

Dose Vial
mR/hr.

- ❑ Move the cart close to patient. Lower the bed to lowest position.
- ❑ Place a sterile towel under the extension arm holder 'E'.
- ❑ Place a sterile towel across the gap between the acrylic box and the patient.
- ❑ Interventional Radiologist (IR) flushes catheter to ensure flow. Inspect the visible portion of the catheter for kinks or damage. Replace the catheter if it is damaged or does not have satisfactory flow.

ATTENTION: DO NOT USE A CATHETER EXTENSION OR EXTRA FITTINGS. REPLACE A CATHETER WHICH IS TOO SHORT.

- ❑ Disconnect the outlet line labeled 'E' from the priming line at holder 'C'. Firmly *wet connect the outlet line 'E' to the catheter.
  *(wet connect means to drip saline onto the catheter connection)
- ❑ Wipe micro-catheter connection to remove any liquid.
- ❑ Place the catheter connection into the slotted holder 'E' at end of extended arm. Outlet line 'E' will be above the holder, and the catheter hanging vertically below.
- ❑ IR to verify catheter position.
- ❑ **Release the pinch clamp from the outlet line**
  (and massage tubing to remove dent)
- ❑ Loosen Touhy-Borst valve to allow flow through the micro-catheter (if needed)

9. TheraSphere Administration (by IR physician)

ATTENTION: BETA RADIATION FIELDS CAN BE VERY HIGH DURING MICROSPHERE TRANSFER. STAND BEHIND BETA SHIELDING OR MAINTAIN DISTANCE.

- ❑ Record starting time of the administration: _____
- ❑ Infuse TheraSphere Y-90 glass microspheres using steady pressure on the syringe plunger. Infuse continuously until syringe is empty (20 mL).

  NOTE: If the pressure applied to the syringe is over 30 psi, excess fluid will drip into the vented empty vial. If this occurs, reduce the pressure being applied on syringe until no flow is seen going into the vented vial.

  See **Troubleshooting Guidance** on last page to resolve any issues.

- ❑ Observe the outlet line and catheter for proper operation. If a problem is observed, inform team and take corrective action.
- ❑ Re-fill syringe for subsequent flushes by pulling back the syringe plunger.
- ❑ Minimum 3 flushes are recommended. Continue flushes until desired dosimeter reading is achieved.
- ❑ Record the number of flushes completed: _____
- ❑ Record the time treatment was completed: _____
- ❑ Record the dosimeter final reading:

Dose Vial
mR/hr.

10. Disassembly (by IR physician)

- ❑ Reengage the pinch clamp at point E.
- ❑ Cut the inlet line at indicated position.
- ❑ Remove the acrylic box top shield and side shield.
- ❑ Lift the catheter connection out of the extended holder 'E'.
  Do not disconnect the catheter from the outlet line.
- ❑ IR to pull the micro-catheter tip into the base catheter and then remove from the patient. Use gauze or a small towel to handle the catheters and control the tip.
- ❑ Place contaminated waste into the Nalgene waste container:
  - catheters and attached tubing and towels/gauze
  - dose vial with attached Needle Injector Assembly (lift lead pot and dump out dose vial)
  - contaminated items - gauze, towels and IR's outer gloves.
- ❑ IR to remove outer gloves

12. *Surveys* *(by Medical Physics staff)*

- ❑ Measure and record the final radiation field for the patient using an ionization survey meter.

  _____ mR/hr (Surface Exposure at Liver) _____ mR/hr (Exposure at 1 meter)
- ❑ Survey all staff leaving the room with the GM contamination meter.
- ❑ Remove patient from the room (survey any staff leaving with the patient).
- ❑ Use a GM contamination meter to check IR's hands for contamination.

13. *Cleanup and Waste Disposal* *(by Medical Physics staff)*

- ❑ Use GM contamination meter to check for contamination on the cart, lead pot, equipment, and the areas under the catheter connection and cart.

  NOTE: Radiation from fluoroscopy, the patient, and the waste container will affect the ability to detect and measure contamination.

- ❑ Decontaminate or dispose of items (tubing, lead pot, etc.) as appropriate.
- ❑ Seal the cap of the Nalgene waste container and place the lid on the beta shield. Remove for measurements to determine % delivery and for disposal.
- ❑ Remove dosimeter from the side of the acrylic shield and turn it off.
- ❑ Clean the TheraSphere acrylic box with mild soap, water and a clean soft cloth. In case of blood contamination, alcohol wipes may be used minimally (alcohol may degrade the acrylic adhesive after extended time).
  Do not use cleaner wipes, ammonia (do not use Windex) or abrasives to clean the acrylic parts of the Accessory Kit.
- ❑ Place top and side shields back on acrylic box. Retract the extension arm and remove the bag hook. Turn off the dosimeter. Store the kit.

Revision History

July 10, 2020	Added responsibilities
	Added Troubleshooting guidance
	Added verification of dosimeter use

Radiation Surveys (using GM pancake probe for beta)

Staff present in the IR room:

Dosimeter Used?	Name	Exposure Reading
	Room background	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.
❑	_____	_____ mR/hr.

Room Survey:

Item or Area	Exposure Reading
Base catheter	_____ mR/hr
Drape on Floor	_____ mR/hr
Sterile towels	_____ mR/hr
Acrylic box and cart	_____ mR/hr
_____	_____ mR/hr
_____	_____ mR/hr
_____	_____ mR/hr

Notes and Comments:

THE QUEEN'S MEDICAL CENTER

Troubleshooting Guidance

1. *Difficulty priming the Administration Set.*
- Verify that the tubing in the Administration Set is not pinched or kinked.
- Verify that the pinch clamp is not closed.
- The first priming flush should be performed very slowly to prevent small bubbles from forming in tubing and fittings. Subsequent priming flushes should be vigorous with full pressure.
- If saline leakage is observed, ensure connections are tight.
- If the issue cannot be identified and corrected, replace the Administration Set with a new one. Notify the manufacturer of the problem.

2. *Leakage that may contain microspheres.*
Attention: Any leakage from the dose vial, injector assembly, tubing 'D' through 'E', or the catheter connection at 'E' is likely to contain microspheres.
- Assess the extent of the leak. Ensure that the needle injector is properly inserted into the dose vial. If warranted, abort the infusion, disassemble the Administration Set and commence decontamination procedures. During decontamination, investigate the cause of the leak.

3. *Leakage of saline during infusion.*
- Leakage observed from the syringe, the saline bag/bottle, or tubing lines 'A', 'B' and 'C' will only contain saline. If saline leakage is observed during TheraSphere®
Administration, maintain steady pressure on the syringe.
Do not stop the flush. At the end of the flush, address the saline leakage. Ensure that priming tube 'C' is clamped. Ensure connection to the syringe is tight. Adjust the saline bag or bottle connection.

4. *Blood begins to flow back to the TheraSphere® dose vial, when the catheter is connected and the syringe is not being pushed.*
- This indicates that one of the fittings or the TheraSphere® dose vial septum is compromised. The procedure should be aborted if the issue cannot be identified and corrected. If issue has been identified and corrected, continue with administrations and observe the system for possible leaks
(see Problem 2).

5. *Excessive fluid flow resistance is experienced during infusion or Difficulty achieving the desired dosimeter reading.*
- Verify that the white pinch clamp is open. Verify that the tubing between the syringe and dose vial are not pinched or kinked. Verify that the tubing between the dose vial and catheter are not pinched or kinked. Verify that the yellow tabs are pushed all the way down.
- Apply sufficient pressure on the syringe to cause fluid to flow into the pressure relief vial.
- Apply and release pressure on the syringe several times rapidly. This may clear a collection of microspheres at the tip of the outlet needle.
- Close the white pinch clamp before performing any actions with the catheter. Verify that there is no blood coagulation or damage in the catheter.

Attention: There may be microspheres in the outlet line and catheter. Use standard radiation safety methods to assess the components before handling. Use remote handling tools as appropriate.

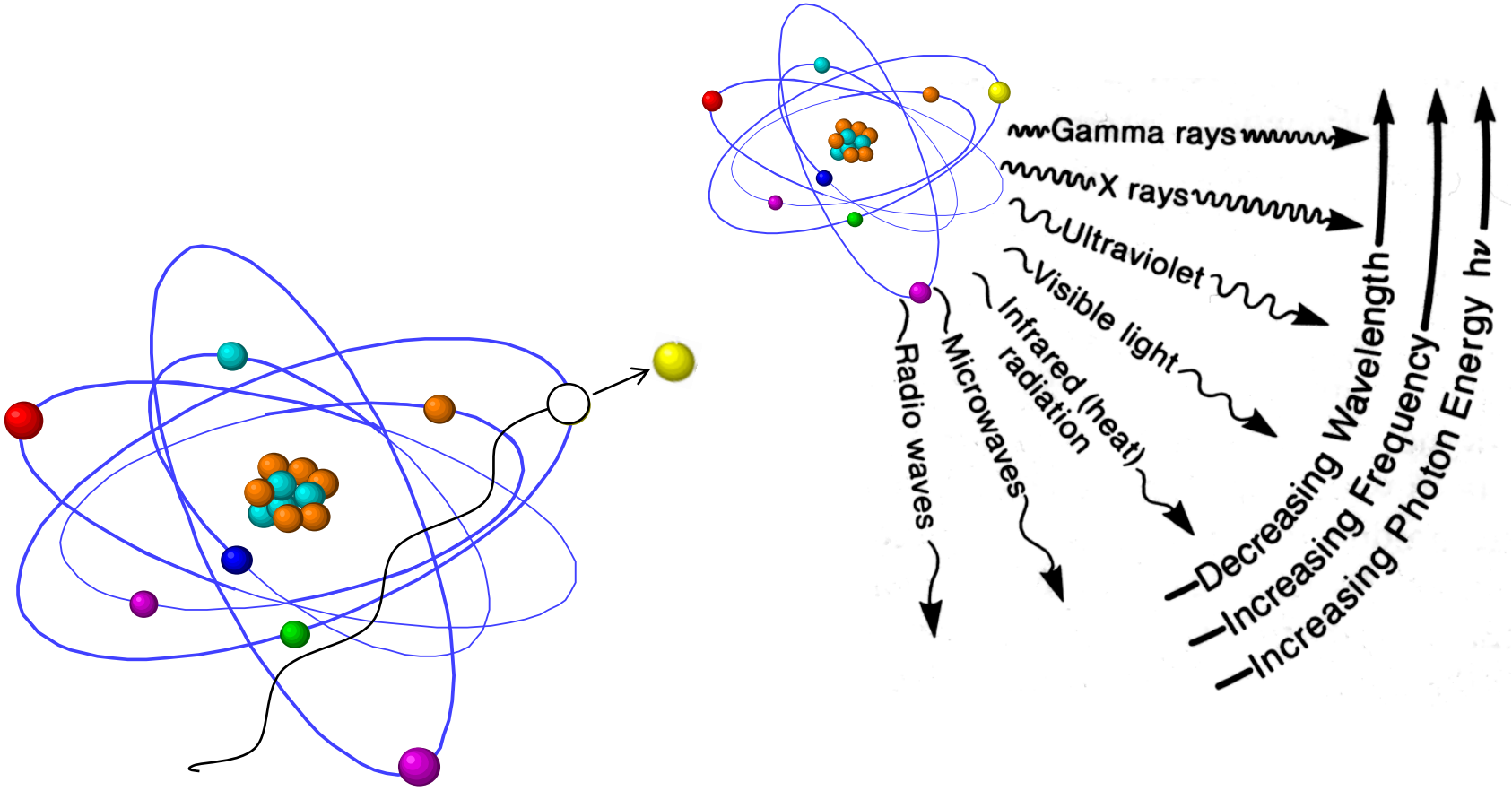
Annual Fluoro/NM Training

Dale Schippers, MS

Frank Goerner, PhD

What is Radiation?

- Light with enough energy to create charged particles (ionizing radiation)



Effects of Radiation on People

- There are two primary ways radiation can negatively effect people :
  - Stochastic- these are effects like cancer, radiation can increase the likelihood (not the severity) you will get it but there is not a threshold dose at which you are guaranteed to get it. Also at doses below 50-100 mGy the evidence is not clear as to whether there is increased risk, decreased risk or neutral risk.
  - Deterministic- these are effects that do have a threshold dose and the severity will increase with more dose. Some deterministic effects include lymphocyte (around 100 mGy) depression and local tissue effects (around 3000 mGy).
- In fluoroscopy we want to reduce stochastic effects and eliminate deterministic effects.
- The patient is primarily at risk of experiencing a deterministic effect and the operator of experiencing a stochastic effect.

Deterministic Risks to Skin

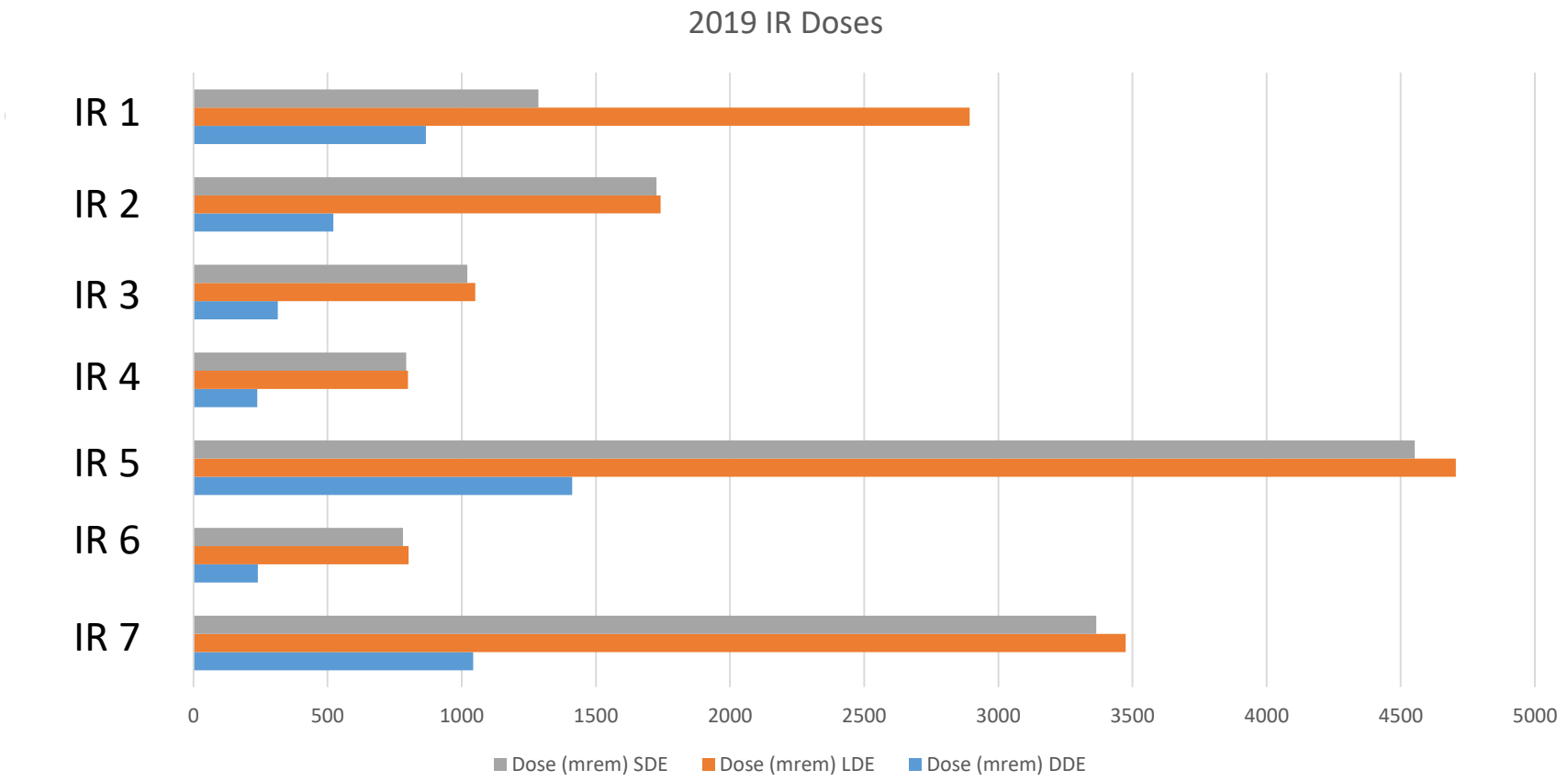
Threshold skin doses for different skin injuries (Data adopted from Wagner, Eifel and Geise, 1994 and modified on data from John Hopewell, oral communication, 1999).

EFFECT	Single-Dose Threshold (Gy_t)	Onset
Early transient erythema	2	Hours
Main Erythema	6 (600 rads)	~10 days
Temporary epilation	3	~3 wk
Permanent epilation	7	~3 wk
Dry desquamation	14	~4 wk
Moist desquamation	18	~4 wk
Secondary ulceration	24	>6 wk
Late erythema	15	~6 – 10 wk
Ischemic dermal necrosis	18	>10 wk
Dermal atrophy (1^{st} phase)	10	>14 wk
Dermal atrophy (2^{nd} phase)	10	>1 yr
Induration (Invasive Fibrosis)	10	
Telangiectasia	10	>1 yr

Hair Loss > 3 Gy (300 rads or 300,000 mrem)

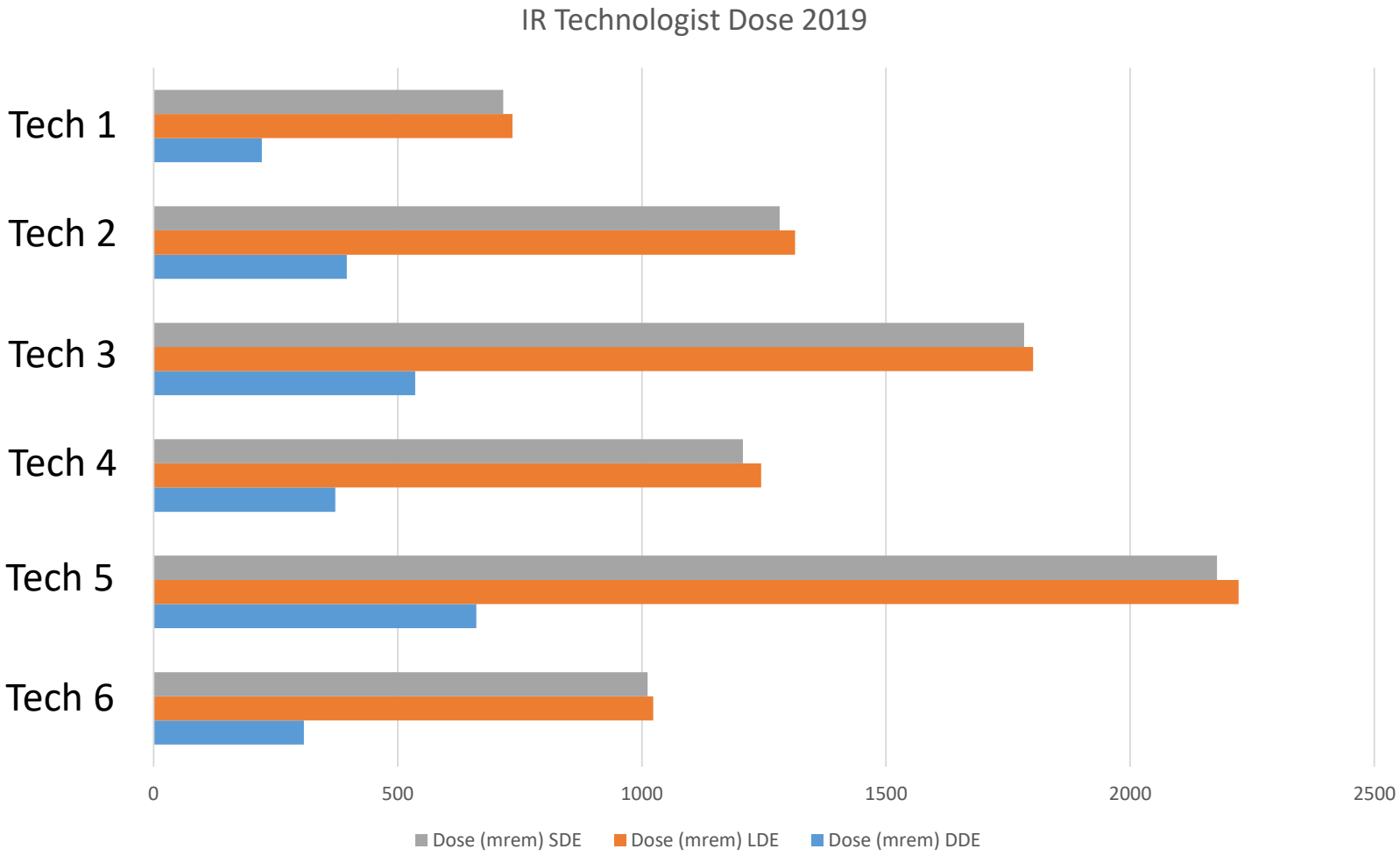
Physician Dosimetry

Hair Loss > 3 Gy (300 rads or 300,000 mrem) or
500 x more dose than typical IR



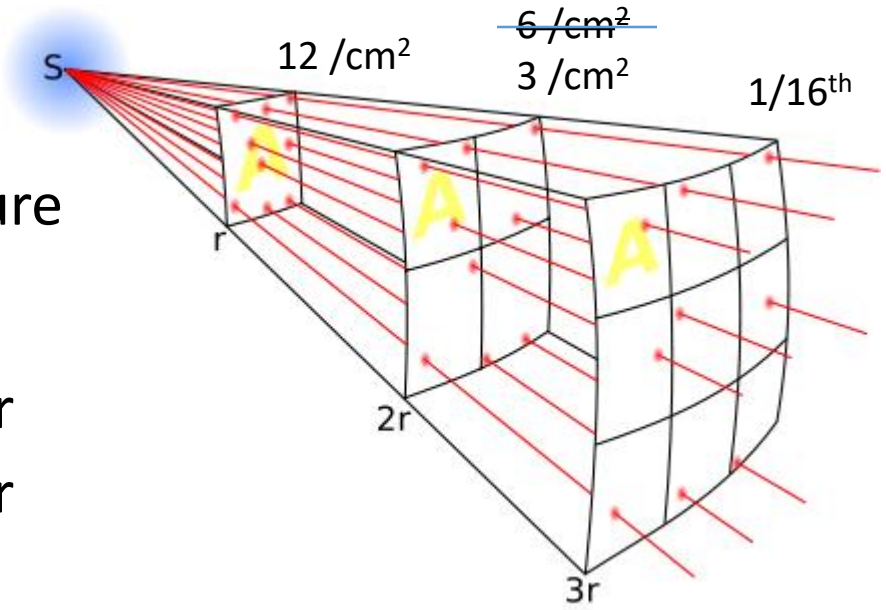
1 rem = 1 cGy = 0.01 Gy

Technologist Dosimetry

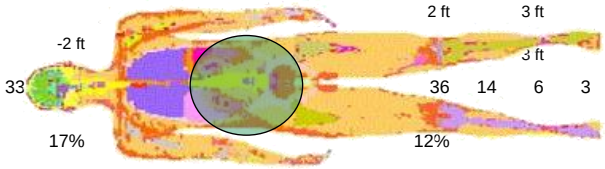


Dose Reduction for Staff

- Time
  - ½ the time = ½ the exposure
- Distance
  - Exposure @ 1 ft = 8 mR/hr
  - Exposure @ 2 ft = 2 mR/hr
- Shielding
  - Lead aprons reduce exposure by 20 x
  - State regulations require everyone in the room to wear lead aprons.

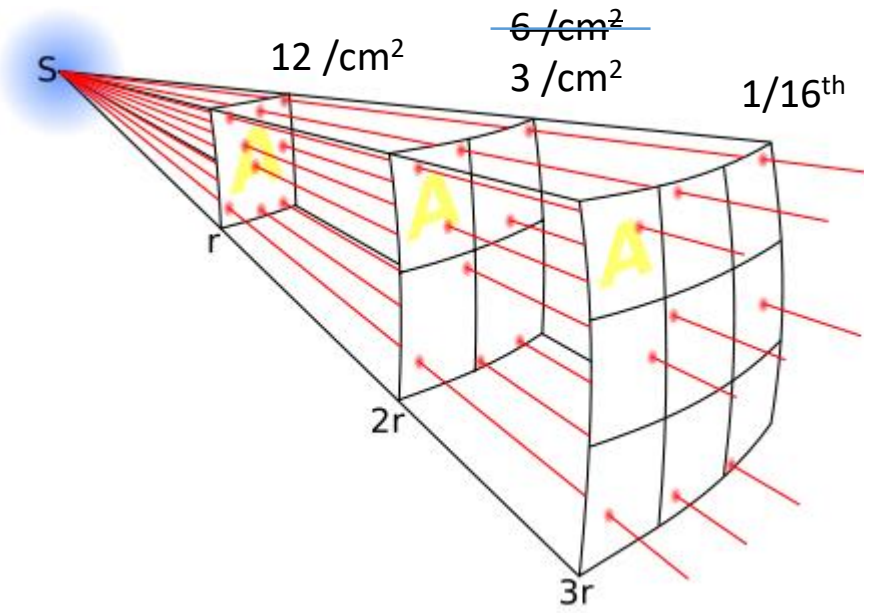


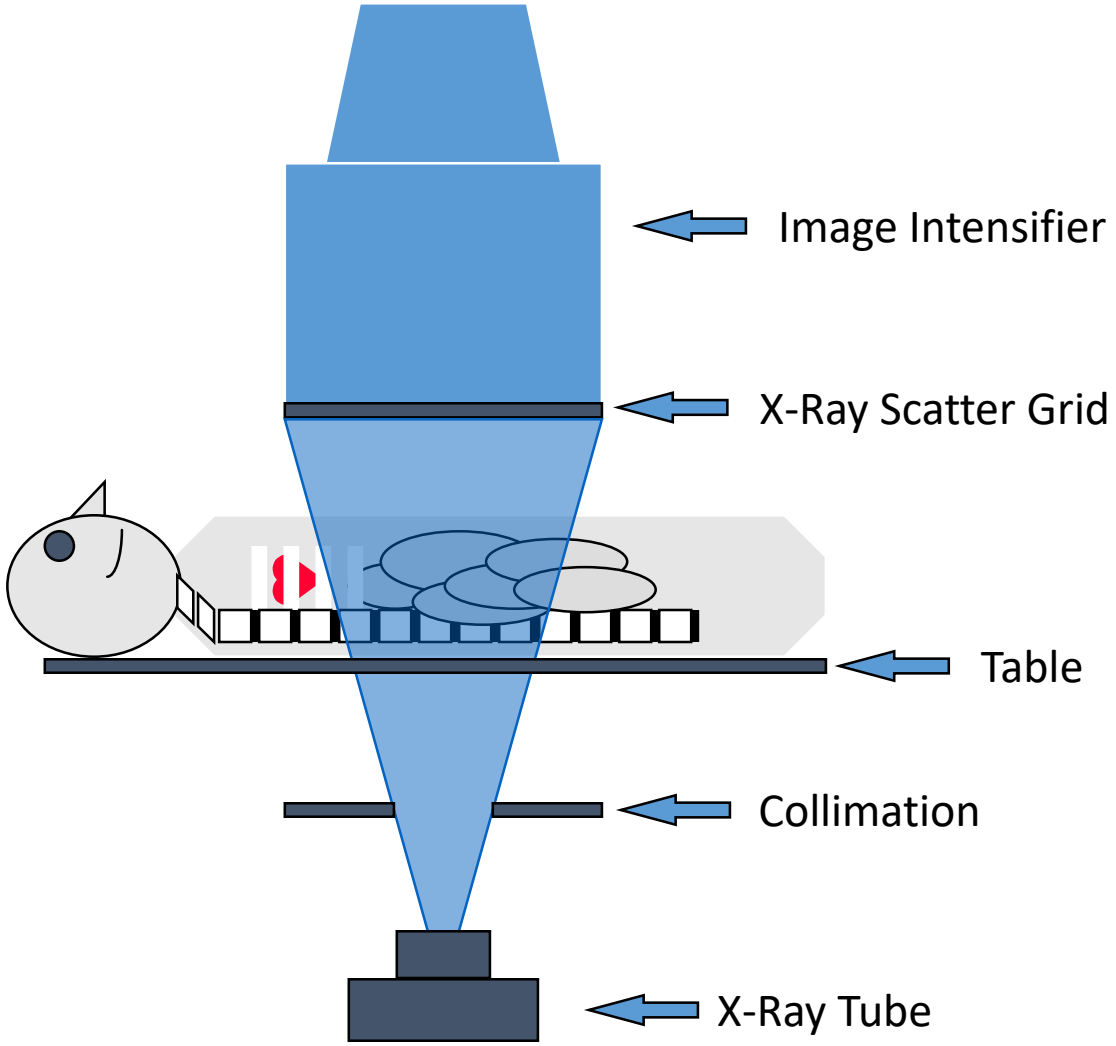
Exposure in mR/hr



Fraction of lateral exposures

Fluoroscopy Components





What is Radiation Dose?

- Radiation dose is the amount of radiation absorbed by a person (patient or operator)
- The unit of radiation dose is typically given in gray (Gy)
- Methods of quantifying dose that concern the typical fluoroscopy operator:
  - Air Kerma
  - Dose Area Product (DAP)
  - Equivalent Dose

Air Kerma (old unit was Roentgen)

- This is the dose displayed on almost all fluoroscopy equipment and is a good indicator of what the dose to the patient is. Typically this number is displayed in either Gray (Gy) or milliGray (mGy)
- If this number starts to climb to over 5000 mGy or 5 Gy the patient may experience skin irritation (erythema). The irritation will be worse as the Air Kerma rises. Anything over 15 Gy or 15,000 mGy could result in a life long skin injury.
- Skin doses > 15 Gy is a Sentinel Event by Joint Commission Standards

Radiation Dose

- There are three main different ways you will likely see radiation dose displayed in fluoroscopy:
- Air Kerma (Gy or mGy)- Patient dose to the Reference Point
- Dose Air Product (DAP) (mGy*cm^2)- This is also displayed on most fluoroscopy units but it is more difficult to determine if the dose to the patient is harmful. It needs to be divided by the area of the field incident on the patient's skin.
- Equivalent Dose (mrem)- This dose is often used to report dose to the operator and can be seen on badge reports. An annual dose limit is 5000 mrem (5 cGy) whole body and 15,000 mrem to the eye and 50,000 to the extremity.

19.12 Instructions to Workers for Radioactive Material

- 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--
    1. Kept informed of the storage, transfer, or use of radiation and/or radioactive material;
    2. Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
    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;
    4. Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;
    5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and
    6. Advised as to the radiation exposure reports which workers may request pursuant to § 19.13. (Annual dose report is required if > 100 mrem or if requested)

Y-90 Workflow

- Lung Shunt (AU)
- Liver Volume (Interventional Radiologist)
- Dose plan (IR/Physics)
- Dose Order (NM Technologist)
- Dose Receipt (NM)
- Dose Verification (NM/Physics)
- Sign Written Directive (Authorized User)
- Dose Administration (IR)
- Residual Calculation (Physics)

Y-90 Checklist Reminders

- IR Tech/Physics or IR Physician flushes line
- IR Physician administers dose
- Physics reads checklist
- Roles added to checklist for clarity
- Tips for issues with administration added to checklist
- Two people check for air bubbles IR Tech and IR Physician

Y-90 Therapies

- Measure dose with 2 people to verify activity
- Be especially careful if 2 or more doses are on hand.
- Requires SIGNED Written Directive
- Issues with dose delivery or a spill
  - Contain the spill
  - Call Radiation Safety
  - Survey staff thoroughly to avoid spread.
  - Clean up or cover spill to avoid spread.

Dosimeter Requirements

- 10 CFR 20.1502
- At a minimum, each licensee shall monitor 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 by adults likely to receive > 500 mrem/year.
- Your film badge is assigned to your collar.
- Should be worn outside of your lead apron
- Must be exchanged on the 1st of each month
- Must be worn for every x-ray procedure and every byproduct exam.