Facility and Environmental Issues

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Facility and Environmental Issues

Purpose

- To review the following facility/environmental issues related to daily CCL practice:
  - Infection Control
  - Radiation Safety
  - Equipment and Maintenance
  - Information Storage and Inventory

Intended Audience

- CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, SCAI QIT Champions

Infection Control

- **All CCL and hybrid operating rooms should have sterility/infection control protocols in place**
- **Universal precautions should be followed**
- **High Risk Patients (for staff exposure)**
  - Screening for blood borne pathogens is not routinely performed
  - Wearing two pairs of gloves reduces inner glove punctures by 60% (not proven to prevent transmission of hepatitis or HIV)
  - Cap, mask, eye protection are encouraged
- **Skin Puncture or Laceration**
  - Report immediately and follow institutional guidelines
  - CDC has published guidelines for management of occupational exposure
- **Vaccination**
  - Vaccination against Hepatitis B is encouraged for all CCL employees

Chambers, CE et al. CCI 2006;67:78-86

Infection Control

Room Type	Ventilation Requirements	Patient Preparation	Operators	Ancillary Personnel	Procedure Environment
Cardiac Cath Lab / Hybrid OR	• Positive-pressure room • Air exchange >15-20 per hour	• Electric clippers for hair removal • Chlorhexidine prep to skin • Sterile drapes	• Hand washing or sanitizer • Hospital based scrub attire • Sterile gowns & gloves ***Masks, eye shield and protective caps (optional but may be required per state/institutional policy)	• Hospital based scrub attire • Cap • Gloves when in contact with sterile field • Mask, eye protection are optional	• Keep doors to CCL closed, except to allow passage of patients, equipment and essential personnel • Equipment near catheter entry site should be covered • Equipment near sterile field should have sterile covers
Hybrid OR specific (Must meet local OR guidelines)	• Positive-pressure room • Air exchange >20-25 per hour	Same as above	• Masks, eye shield and protective caps required	Same as above	• Same as above

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Infection Control

- **Cleaning**:
  - The CCL should be thoroughly cleaned once a day and spot-cleaned with trash removal between cases
  - Blood-contaminated drapes, gowns, gloves, and sponges should be discarded in containers labeled as healthcare waste
  - Sharps should be placed in puncture-proof containers
  - Consider scheduling cases with high infectious risk at the end of the day, followed by terminal clean (example- C. difficile, MRSA, VRE, patients with droplet precautions)
- **Multi-dose vials:**
  - Should be avoided, unless used with an approved device to protect against backflow

Radiation Safety

Summary of radiation doses and units			
Absorbed dose (Deterministic effect)	Amount of radiation energy absorbed by tissue per mass of tissue. Skin typically receives the highest absorbed dose.	Peak skin dose (PSD) is the absorbed dose at the skin location that has received the highest dose. This quantity is used to predict a skin injury. Not usually measured; can be estimated if needed.	Unit: Gray (Gy) 1 Gy= 1 Joule of radiation energy absorbed per unit tissue.
Effective dose (Stochastic effect)	Calculated by adding the mean dose absorbed by organ multiplied by a weighting factor for that organ (highest for bone marrow, lung, stomach, breast; least for skin).	Approximate measure of potential harm from cancer. Takes into account susceptibility of different tissues.	Unit: Sievert (Sv) Effective dose of cardiac cath is 2-16 mSv compared with 0.02 mSv for chest x-ray.
Air kerma (Ak) or Reference Ak or $K_{a,r}$	Energy per unit mass absorbed by air at assumed location of skin.	Cumulative Ak is displayed on monitor- meant to estimate patient skin dose. Non-stationary position of X-ray tube will over-estimate and lower table position will under-estimate patient dose.	Unit: milli Gray (mGy)
KERMA-area product (KAP) or Dose-area product (DAP) or P_{KA}	Total energy absorbed across entire exposed skin/incident on the patient.	Product of Ak and cross-section area of X-ray beam. Used to estimate stochastic risk such as radiation induced cancer to patient and staff.	Units: $Gy.cm^2$, $cGy.cm^{2,}$ $mGy.cm^2$

Radiation Safety

- **Follow the principle of ALARA (as low as reasonably achievable)**
- **Each facility must have a radiation safety program**
- **Staff radiation safety training and its documentation are essential**
- **Patient radiation dose must be monitored and recorded**
  - Includes fluoroscopy time, total air kerma at the interventional reference point (IRP) ($K_{a,}r$, Gy) and air kerma area product (PKA, Gy*cm2)
- **Document substantial radiation dose level (SRDL) as shown on right**

Dose metric	First notification	Subsequent notifications (increments)	SRDL
$D_{skin,max}$ [a]	2 Gy	0.5 Gy	3 Gy
$K_{a,r}$ [b]	3 Gy	1 Gy	5 Gy[b]
P_{KA} [c]	300 Gy cm^{-2d}	100 Gy cm^{-2d}	500 Gy cm^{-2d}
Fluoroscopy time	30 min	15 min	60 min

NCRP (2010) National Council on Radiation Protection and Measurements. Radiation Dose Management for Fluoroscopically Guided Interventonal Medical Procedures, NCRP Report No. 168 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

[a] $D_{skin,max}$ is peak skin dose, requiring calculations by physicist.

[b] $K_{a,r}$ is total air kerma at the reference point.

[c] P_{KA} is air kerma-area product.

[d] Assuming a 100 cm^2 field at the patient's skin. For other field sizes, the P_{KA} values should be adjusted proportionally to the actual procedural field size (e.g., for a field size of 50 cm^2, the SRDL value for P_{KA} would be 250 Gy cm^{-2}).

Chambers CE, et al. CCI 2011;77:546-56

Radiation Safety

Methods to lower patient dose	Methods to lower operator dose	Methods to lower both patient and operator dose
• Raise table height • "Spread the dose" by moving tube • Avoid high magnification (changing from 22 cm to 17 cm doubles dose rate) • Keep patient's arms away from x-ray tube • Limit beam-on time especially in obese patients • Establish "hard-stops" for elective complex PCI (e.g. CTO)	• Wear adequate protective garments (lead apron and leaded glasses) • Increase distance from x-ray tube (dose rate is proportional to the inverse of the square of the distance from the source) • Use under and over-table shielding against scatter • Lower the detector as close to patient as possible • Use robotic PCI if available	• Limit beam-on time (do not step on pedal unless looking at screen, • Use "virtual" collimation, • Last-image hold • Only "tap" on fluoro pedal if needed • Keep detector close to patient • Minimize steep angles • Limit cine- use fluoro save/store • Use lower frame rate (7.5 fps) and "Eco" dose setting • Use collimation • Keep arms/hand out of beam

Radiation Safety

Post procedure monitoring and documentation	
AK 5-10 Gy (DAP > 500 $Gy.cm^2$)	• Patients should be educated regarding potential skin changes and call the Interventionalist if seen. • Patients should be contacted at 30 days. • Phone calls may be sufficient if $A_{k,r}$ < 10 Gy, with an office visit if questions arise or adverse skin effect suspected.
AK > 10 Gy (DAP > 1,000 $Gy.cm^2$)	• Qualified physicist should promptly perform a detailed analysis to calculate PSD. • Patient should return for an office visit at 2-4 weeks with examination for possible skin effects.
PSD > 15 Gy	• Hospital risk management should be contacted within 24 hours with appropriate notification to the regulatory agencies. • This exposure represents a Joint Commission Sentinel Event.

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Essential Cath Lab Equipment

- Imaging equipment and archival storage system
- Multichannel physiologic monitoring (minimum of 2 pressure & 3 ECG channels) with real-time and archived physiologic, hemodynamic and rhythm monitoring
- X-ray system with periodic and documented preventive maintenance
  - Includes image quality, dynamic range, modulation transfer function, fluoroscopic spatial resolution, field of view size accuracy, low contrast resolution, automatic exposure control and maximum table-top exposure rate
- Adequate inventory for the scope of services provided
  - Disposable supplies
  - Equipment for management of complications and emergencies
- Daily checks and quality control to be performed (see table on right)

Cath Lab Daily Checklist
Emergency Equipment
Code Cart Checked
Temporary pacemaker & defibrillator tested
Pericardiocentesis tray in room
Check IABP & Impella consoles/catheters
Covered stents, coils, etc.
Quality Control Daily Check
ACT machine & blood gas analyzers
X-ray System
System turns on
Cine and fluoroscopy work
Table moves
Hemodynamic system turns on

Information Storage and Inventory

- Reporting system should be linked with hospital information system
- Linking inventory and billing creates a seamless interface to provide an accessible report, enhanced inventory management and can verify billing
- Compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA) is required
- Disaster recovery is essential to any archival storage system
- Image Storage
  - Compliance with HIPAA requirements include minimum of 6 years of storage, but requirements vary by state
    - https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/pprequirements.pdf?language=es
  - Link to state requirements
    - https://www.healthit.gov/sites/default/files/appa7-1.pdf

Question 1- You are performing PCI on a complex left main bifurcation lesion with a planned two-stent technique. You reviewed the diagnostic images and the view that best delineates the bifurcation is LAO 40, caudal 35. You wish to attain optimal results, while following the principle of ALARA (as low as achievable). Which of the following strategies would result in *higher* radiation dose?

A. Collimate to the region of the bifurcation.

B. Raise the table as high as possible and lower the image detector as low as possible.

C. Change the field of view from 20 cm (8 inches) to 16 cm (6 inches).

D. Use intracoronary imaging to aid in stent sizing and post-stent deployment assessment.

E. Wire the vessels and perform pre-dilation at shallow angles and move to steep LAO-caudal for stent deployment.

Answer: C

- Changing the field of view (FOV) from 20 cm to 16 cm (higher magnification) will significantly increase the radiation dose. With modern imaging systems, diagnostic image quality is often achieved at 25 cm (10 in) FOV so higher magnification than 20 cm is rarely needed. All the other choices are best practices to reduce radiation doses to the patient and operator.

Question 2- You are a high-volume operator and have received several letters from the radiation safety officer regarding your high monthly dose. Your standard practice includes using 7.5 frame/s fluoro acquisition, 25 cm (10 inch) field of view, collimation, frequent fluoro save and collimation, keeping the table at elbow height and positioning the image detector close to the patient. Which of the following is likely to reduce your recorded badge dose?

A. Change from a two-piece lead to a one piece lead apron.

B. Use a RADPAD ® scatter shield

C. Use very brief cine to store images of balloon and stent deployments.

D. Change field of view to 20 cm (8 inches).

E. Use digital subtraction angiography for femoral angiograms instead of fluoro save.

Answer: B

- This operator is already using best practices to reduce radiation dose but still has high operator dose due to high-volume.
- Using a RADPAD scatter shielding has been shown to significantly reduce operator dose in randomized controlled trial (ref: Vlastra W et al. *Circ Cardiovasc Interv.* 2017;10:e006058.)
- Choice A – the badge is worn outside the lead so this would not change the recorded dose. Also, the difference between a two-piece vs one-piece lead apron is mainly preference. The absolute thickness of the lead equivalent is typically the same.
- Choice C – brief cine to store images is a older practice that's highly discouraged, less radiation is delivered using fluoro save.
- Choice D - increasing the magnification and will increase the dose.
- Choice E – using DSA will use deliver significantly higher dose.

Question 3- You are advancing a TAVR delivery system and wish to see both the tip of the wire in the left ventricle and the valve as it traverses from the abdominal aorta to the aortic root. Which of the following is the best strategy to optimize this process and minimize radiation?

A. Use standard coronary acquisition settings and pan the table as you advance the delivery system.
B. Change the acquisition from 7.5 to 15 frames/second.
C. Drop the table height.
D. Change the field of view to a lower magnification setting.
E. Raise the image detector.

Answer: D

- By lowering the magnification, the operator can see the wire tip and the valve at the same time without needing to pan the table. This will also lower the radiation dose.
- All the other choices would increase the radiation dose unnecessarily.

Question 4- You are hired as a new director of a cath lab. You have run into several instances in which emergency equipment, such as temporary pacemakers, malfunction when they are needed. Which of the following is the appropriate strategy?

A. Purchase new equipment.
B. Assign the cath lab manager to perform a daily checklist including emergent equipment and report to you if there are issues.
C. Hire a new cath lab manager.
D. File an incident report.
E. Accept that these are expected events.

Answer: B

- Performing a daily checklist is a quality assurance practice to ensure critical equipment are functional.

Question 5- Your vascular surgery colleague notified you that he has performed a second incision and drainage for femoral access infection post cardiac catheterization in a month. Which of the following is **unlikely** to improve this problem in the future?

A. Use vascular closure device instead of manual compression.

B. Use electric clippers for hair removal instead of a razor.

C. Use chlorhexidine-based prep.

D. Instruct the technologist to prep the site at the location of the puncture first and move to the periphery with an ever-widening circular motion.

E. Use universal precautions for all cases.

Answer: A

- Using vascular closure device does not reduce infection but is associated with higher rate of infection. (Noori VJ, Eldrup-Jørgensen J. *J Vasc Surg*. 2018 Sep;68(3):887-899.)
- All the other choices are best practices to reduce access site infection.