Learning Objectives

1) Review the IAC accreditation process.
2) Review clinical carotid stenting procedures.
3) Outline relevant Medical Physics processes and responsibilities.
4) Outline physics and related requirements for a carotid stenting program.

IAC Requirements

- Volume criteria (25 facility; 15 individual physician)
- Medical and technical staff training and experience
- Procedure Log (3 years)
- Outcome data analysis
- Quality Improvement program (minimum 6 month review)

- Physicist report of the angiographic equipment
- Safety processes
- 5 procedures to include continuum of care processes and imaging

QI program requirements

- Review at a minimum every 6 months
- Outcome Measures (risk category/indications and technical)
- Administrative Processes
  - Technical (equipment)
  - Physician Performance
  - Patient and Staff Exposure
- Medical and Technical Staff Training and Experience Requirements
- A process/protocol for the performance of CAS procedures (recommended)
Why these sessions?

“Physics” reports submitted in good faith to IAC-CS did not respond to the standard.
- Facility administration not have noticed or understood than enhanced “physics” requirements are needed for IAC accreditation.
- Physicists may not have been aware accreditation or that physics is part of the application.
- Routine physics QA reports were submitted to IAC by facility administration.
  • Testing and evaluation usually included only the minimum regulatory requirements (some irrelevant).
  • These reports had been accepted by regulators.

Carotid Stenting Physics

Goal is to bring medical physics related activities up to the level of best practices.
- Carotid stenting should be performed using equipment that meets IEC interventional standards.
- Patient and staff radiation management using best practices.
- All staff should have appropriate initial and continuing radiation safety training.

Process improvement

- Technical information in this presentation is for your consideration
  - Not prescriptive
  - Starting point for implementing a facility’s program
- Medical physicists add value by understanding and appropriately contributing to relevant processes.
  - You are professionals !!

Physicists’ Clinical Knowledge

- Some first hand knowledge of clinical practice provides essential background information that will improve consultations with administrative and clinical staff.
- IAC Standard recommends observation of at least one procedure per year.

Accreditation

- Ensure high quality care by encouraging and recognizing the provision of quality imaging diagnostic evaluations.
- Facilities assess every aspect of daily operation and its impact on the quality of health care provided to patients.
- Facilities often identify and correct potential problems, revise protocols and validate QI Programs.
- Accreditation is renewed every three years; a long-term commitment to quality and self-assessment is developed and maintained.
- Reimbursement directives that require accreditation of the facility have been instituted by Medicare carriers as well as private insurers.

Adapted from IAC statement

Cartotid Stenosis - Anatomy

http://www.nhlbi.nih.gov/health/health-topics/topics/catd
Cartotid Stenosis - Therapy

http://www.nhlbi.nih.gov/health/health-topics/topics/catd

Procedure

<table>
<thead>
<tr>
<th>Initial Stenosis</th>
<th>Stent Deployment</th>
<th>Result</th>
</tr>
</thead>
</table>

Physics topics

- Training
- Facility Design
- Equipment Selection
- Equipment QA
- Patient Dose Monitoring
- Staff Radiation Protection

IAC Carotid Stenting
Program Data Summary: Complications

- Stroke and death complication rate
  - 1.99% Asymptomatic
  - 2.49% Symptomatic
- All complications
  - 3.52% Asymptomatic
  - 7.88% Symptomatic

Goal is to reduce probability of future strokes

Training: Radiation Safety

- All individuals participating in carotid stent procedures must be trained.
- Initial training is not specified by IAC.
- Recurrent training of at least 1 CME every three years.
- Documentation of training is required for accreditation.
Training – what not to present

Training – Useful topics

• Radiation risks
  – Patient
  – Staff
• Equipment configuration and function.
• Relevant image formation.
• Operational radiation safety.
• Review of facility radiation data.

Facility Design

• Interventional procedures attract a large number of participants and observers.
• Adequate space is needed in both the procedure and control rooms.
  – Control room should be designed to accommodate observers who do not have to be in the procedure room.
  – Control room should be shielded for full time occupancy by the general public.
• Clinical emergencies happen.

Medical Physicist's Qualifications

• Qualified Medical Physicist
  – Usual pathways for initial qualification
  – Eventual board certification
• Recurrent training per CAMPEP
• Recurrent clinical
  – observing one procedure per year (at each facility)

Fluoroscopic Equipment

• Should (substantially) conform to IEC 60601-2-43 (Interventional Fluoroscopes)
  – Reference point air kerma and KAP monitoring
  – Structured Dose Report Export (2nd Ed. – 2010)
  – Many other important features
• Newer systems will eventually comply with NEMA XR-27 (QA mode)
  – Manual control of system parameters during testing.
  – Output of configuration details
  – Output of “for processing” images

Equipment QA

• NY State regulatory on IAC website
  – Sample regulatory minimum
• Additional items may be added
  – Configuration documentation
  – Collimation limited to less than FOV
  – Maximum acquisition outputs
  – SID tracking
  – Integrated dosimeter accuracy
  – Effects of magnification
Clinical Configuration & Selection

Control Panel Table Side

Collimator Limits

• Restricting the maximum field size to less than the full active FOV permits continuous monitoring.
  – Most frequent QA failure
  – Service can set to approx. 95% in most systems.
  – Clinicians never comment on the small unused margin.

NY State Output Protocol

<table>
<thead>
<tr>
<th>19 mm Al</th>
<th>38 mm Al</th>
<th>38 mm Al + 0.5 mm Cu</th>
<th>38 mm Al + 2 mm Cu</th>
<th>38 mm Al + Pb or Cu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoro</td>
<td>XXXXX</td>
<td>XXXXX</td>
<td>XXXXX</td>
<td>XXXXX</td>
</tr>
<tr>
<td>Acquisition</td>
<td>XXXXX</td>
<td>XXXXX</td>
<td>XXXXX</td>
<td>XXXXX</td>
</tr>
</tbody>
</table>

• Testing should correspond to the most common clinical mode for CS
• Max output for acquisition mode is not required – typically 2 – 4 times the 2 mm Cu value
• What happens at the table-top when the SID is increased?

Beam confinement and alignment

Patient Size & SID (Info not for application)

• Clinical interventional Fluoroscope very busy clinical system
• IEC 60601-2-43 compliant
• Installed 2010
• 16 cm FOV & 15 fps

Integrated dose monitor testing

• Reliable values are the basis of dose management QA
  – Clinical decision making
  – Dosimetry review
  – Evaluation of structured dose reports.
• TG-190 protocol nearly complete
Partial procedure (AAPM TG-190 wip)

\[\approx 100\text{ kV} (\approx 8\text{ mm Cu})\]

FS at isocenter = 70 cm²

Integrate 50 – 100 mGy

Test with different dose-rates

Patient Radiation Management

- Essentially per published guidelines
  - NCRP – 168
  - SIR / CIRSE
- Integration into periodic QA
  - Clinical dose logs
  - Periodic MP statistical analysis
  - Periodic reports to clinical QA team

Geometric Effects

- Resolution vs FOV
- Resolution vs mode
- Resolution vs magnification

Staff Radiation Management

- Monitoring results
- Work habits
  based on observed procedures

HCB – effects of magnification

Situational awareness

(photos taken at monitor location)
Medical Physics goals

• Contribute to optimizing procedures.
• Staff safety
  – My camera is my best dosimeter.
• Patient safety
  – Optimized equipment configuration and performance.
  – Improved physician knowledge.
• Many CS physicians do not know who their physicist is!!!

Wrap-up

• Measurements and surveys
  -- tools to gather information
  -- not an end point
• Use professional judgment
  -- not generic protocols
• Medical Physicists are consultants
  -- to facility administration
  -- to clinical staff (have you met them?)