Clinical Implementation of a High-Dose Rate Brachytherapy Program

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Learning Objectives

- Summarize national and international safety and staffing guidelines for implementation of HDR brachytherapy
- Discuss the process of afterloader and applicator selection for gynecologic, prostate, breast, interstitial, surface treatments
- Learn about the use of an audit checklist tool to measure of quality control of a new or existing HDR program
- Describe the evolving use of checklists within an HDR program
Clinical Implementation of HDR: A New User’s Perspective

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How to start an HDR program?
How to train a Qualified Medical Physicist?

- Observation of HDR clinical cases
- Vendor training
- Familiarization with federal/state regulations
- Guidance documents (e.g., AAPM, IAEA)
- HDR planning:
  - Brachytherapy dose calculations (TG-43, TG-186)
  - Brachytherapy treatment planning (e.g., ABS guidelines)

Guidance & Regulatory documents

- AAPM Summer School (2005)
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- http://www.nrc.gov
- ASTRO White Paper: Practice Guidelines for HDR
- ASTRO Safety is No Accident
TG-59: Principles of HDR program design

- Use written documentation
- Develop a formal procedure
- Exploit redundancy
- Exploit quality improvement techniques

TG-56: Code of Practice for brachytherapy

- “It is stressed that proper brachytherapy treatment is a team effort, and communication among team members encourages quality assurance. Due to the larger degree of interdepartmental coordination needed, i.e., nursing, diagnostic imaging, surgery, etc., a higher level of cooperation compared to external beam radiotherapy must be developed.”
- “All team members should be encouraged to double check each other and identify problems without fear of retribution.”
Consolidated Guidance: NUREG-1556

Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses (NUREG-1556, Volume 9, Revision 2)

Nuclear Regulatory Commission (NRC)
NRC Regulations:
Title 10, Code of Federal Regulations

- **10CFR19:**
  - Notices, Instructions and Reports to Workers: Inspection and Investigations
- **10CFR20:**
  - Standards for Protection against Radiation
- **10CFR35:**
  - Medical Use of Byproduct Material

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10CFR19:
Notices, Instructions & Reports to Workers

- **19.11:** Posting of notices to workers.
- **19.12:** Instruction to workers.
- **19.13:** Notifications and reports to individuals.
- **19.14-17:** Inspections.
- **19.20:** Employee protection.
**10CFR20:** Standards for Protection against Radiation

- 20.1101: Radiation protection programs.
- 20.1208: Dose equivalent to an embryo/fetus.
- 20.1301: Dose limits for the public.
- 20.2001-10: Records

**10CFR35:** Medical Use of Byproduct Material

Subpart A – General Information:
- 35.12: Application for license, amendment, or renewal.

Subpart B – General Administrative Requirements:
- 35.40: Written directives.
- 35.50: Training for Radiation Safety Officer.
- 35.51: Training for an authorized medical physicist.
- 35.59: Recentness of training
10CFR35: Medical Use of Byproduct Material

Subpart H – Photon Emitting Remote Afterloader Units, etc.

- 35.604: Survey of patients treated
- 35.610: Safety procedures & instructions
- 35.615: Safety precautions
- 35.633: Full calibration measurements
- 35.643: Periodic spot-checks
- 35.647: Additional technical requirements, etc.
- 35.652: Radiation surveys.
- 35.657: Therapy-related computer systems
- 35.690: Training for use of remote afterloader units, etc.

10 CFR 35.633: Full calibration measurements

- On quarterly basis (or upon repair or following replacement of the source), check accuracy of:
  - Output to within 5%
  - Source positioning to within 1mm
  - Length of source transfer tubes
  - Length of applicators
  - Timer accuracy and linearity

- On quarterly basis (or upon repair or following replacement of the source), check function of:
  - Source retraction with backup battery upon power failure
  - Source transfer tubes plus applicators
**10 CFR 35.643:**

Period spot-checks for remote afterloader units

- **On daily basis, check function of:**
  - Electrical interlock function (door, console button, key, door button)
  - Source exposure indicator lights
  - Radiation monitors
  - Viewing/intercom systems
  - Emergency retraction system

- **On daily basis, check accuracy of:**
  - Timer
  - Clock (date and time) in computer
  - Decayed source activity in computer

### Daily QA Form ➔ Workflow

**Daily QA for HDR**

Department of Radiation and Nuclear Oncology
University of Chicago Medicine

- **QA performed by:**
- **Date:**

**HDR remote afterloader model and manufacture:**
- Varian Syringe 32 ORC200M20, Varian
- HDR remote afterloader 3D-Multidose
- License identification number: 1-03852-00320-1860-24
- **Checklist box indicates task/operation tests completed:**
- Highlighted and underlined items are performed prior to afterloader removal

### Equipment availability & Function

1. **Objective:** Ensure remote afterloader system is checked against established source opening & exposure control (current calibration found)
2. **Procedure:**
   1. Confirm availability.
   2. Confirm operational.
   3. Check exposure control.
   4. Source exposure indicator lights operational.
   5. Confirm source 
   6. Confirm interlock system.
   7. Confirm radiation system.
   8. Confirm radiation system.
   9. **Checklist:** Hourly radiation monitors should be checked (Varian).

### Accuracy of:

1. **Objective:** Ensure remote afterloader system is checked against Established check source (source accuracy - computer). Checklist must be signed.
2. **Procedure:**
   1. Confirm source aligned.
   2. Confirm source exposure
   3. Confirm source exposure
   4. Confirm source exposure
   5. Confirm source exposure
   6. Confirm source exposure
   7. Confirm source exposure
   8. Confirm source exposure
   9. **Checklist:** Daily QA Form ➔ Workflow

Amendment after “30 day operation past license renewal and safety test report” (Daily QA Form)

1. **Objective:** Confirm afterloader system is in “ready” position.
2. **Procedure:**
   1. Confirm afterloader system is in “ready” position.
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3. **Objective:** Confirm afterloader system is checked against Established check source (source accuracy - computer). Checklist must be signed.
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
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**10 CFR35.633: Full calibration measurements (applicator QA)**

- On quarterly basis, check **function** of:
  - Source transfer tubes, applicators, and transfer tube-applicator interfaces.

- On quarterly basis, check **accuracy** of:
  - Length of the source transfer tubes
  - Length of the applicators

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**AAPM TG-56: Applicator Commissioning and QA**

- “Verification of positional accuracy requires that ... the intended sequence of active sources or dwell positions is delivered to the correct position in the correct applicator.

- Often, the target source locations are identified relative to radiographic images of dummy seeds or radiographic markers which are inserted into the applicator of interest prior to simulation.

- The NRC insists on a positional accuracy criterion of 1 mm ... This more rigid standard is not realizable in a clinically meaningful sense for many applicator-source combinations.”
AAPM TG-56: Applicator Commissioning and QA

10CFR35.3045: NRC Medical Event

- Delivered dose that differs from Rx by more than:
  - 50 mSv effective dose equivalent
  - 0.5 Sv organ dose
  - 0.5 Sv shallow dose
- Total dose differs from Rx by > 20%
- Fractional dose differs from Rx > 50%
- Treatment to:
  - Wrong patient
  - Wrong site
  - Wrong mode of treatment

ASTRO White Paper: Responsibilities of Qualified Medical Physicist

- Afterloader, applicators, & TPS Checks:
  - Acceptance testing
  - Commissioning
  - Daily QA
  - Quarterly QA
  - Annual QA
- Development & implementation of quality management program
- Personnel training (initially & annually)
- Internal audit of HDR program

ASTRO White Paper: Responsibilities of Qualified Medical Physicist

- “Extensive effort is needed by the medical physicist outside of direct patient interactions to ensure that clinical procedures are fluid and performed in an accurate and timely manner with confidence by all HDR brachytherapy team members.”
Ensuring HDR Treatment Quality Control

Thomadsen et al., PRO, 2014.

Ensuring HDR Treatment Quality:
TQC Form to Parallel Workflow
ASTRO White Paper: Staffing Considerations

- For each afterloader:
  - 0.4 FTE physicist + 0.03 FTE dosimetrist
- For each treatment:
  - 0.008 FTE physicist + 0.003 FTE dosimetrist
- For 1 unit treating 50 patients/year:
  - 0.008 FTE physicist + 0.003 FTE dosimetrist = 0.8 physicist + 0.2 dosimetrist OR 1.0 physicist

- Compared to TG-59 recommendations:
  - For an average load of 10 fractions per week, 1 FTE physicist

Recommendations from a new user

- Implement an independent calculation program
- Develop workflow with staff responsibilities clearly delegated
- “Dry-run” training
- Reach out to physicists at other institutions
- Learn from past HDR errors (i.e., failure modes)
  - ASTRO White paper: most common is “length” failure
  - IAEA: “Prevention of Accidental Exposure in Radiotherapy” modules
- Automate
  - Automated Dose Point Placement for Cervical Cancer Brachytherapy Using Tandem and Ovoid Applicators (Kang et al) → Poster SU-E-T-141
Independent Calculation Check

Therapist Involvement: Treatment Time Out
Qualified Medical Physicist

- “Lead” the HDR program
- Interface with RSO & NRC/State
- Train & educate staff
- Select & purchase equipment
- Continually adapt/update your program