

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

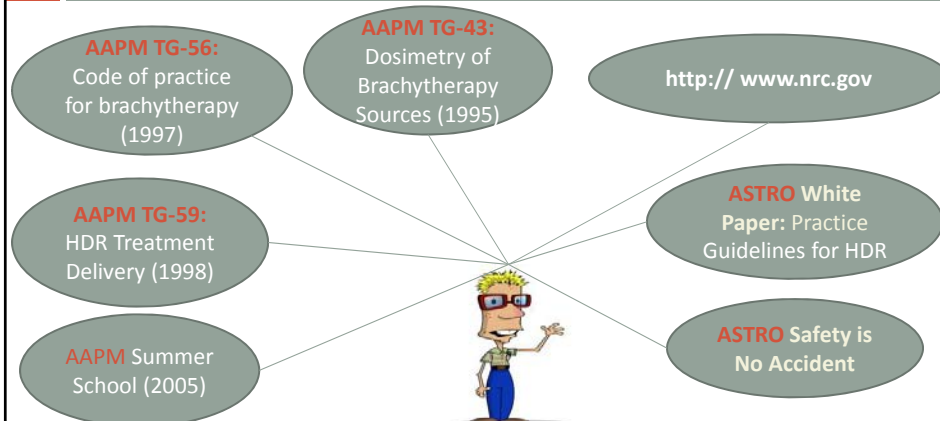
How to start an HDR program?

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



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

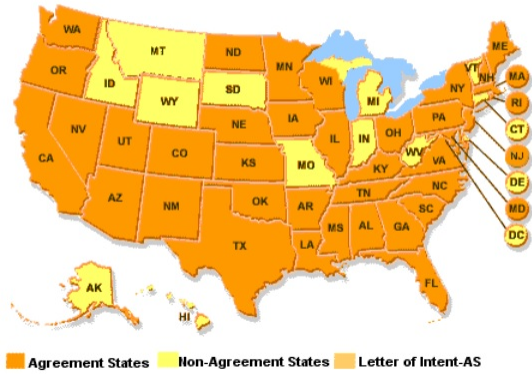
- “It is stressed that proper brachytherapy treatment is a team effort, and **communication among team members encourages quality assurance**. Due to the larger degree of interdepartmental coordination needed, i.e., nursing, diagnostic imaging, surgery, etc., a higher level of cooperation compared to 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



Nuclear Regulatory Commission (NRC)

Agreement & Non-Agreement States



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

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.
- 20.1201: Occupational dose limits for adults.
- 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 CFR35.633: 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 Cellular Oncology
University of Chicago Medicine

QA performed by: _____ Date: _____

HDR Remote afterloader model name and manufacturer: Varisource IX 320489637, Varian
HDR Remote afterloader ID: H600604
Source serial number: 02-01-6021-001-042215-11642-66

➤ Checked box indicates function/operation tests PASSED
➤ Highlighted and underlined tests can be performed prior to afterloader retrieval

Equipment availability & function

1. ☐ Hand-held survey meter checked against dedicated check source & possesses current calibration (u=mm)
2. ☐ Stopwatch available
3. ☐ TV monitor operational
4. ☐ Intercom operational
5. ☐ Emergency procedure posted
6. ☐ Contact information of AM, AMP and RSO posted
7. ☐ All individuals have personal body/ring badges
8. ☐ "HDR" switch activated outside vault
9. ☐ "Caution Radiation Area, Radioactive Materials" and "Caution High Radiation Area" signs posted on each door of treatment room
10. ☐ In-room Primameter survey meter checked against dedicated check source & possesses current calibration (u=mm)
11. ☐ Afterloader moved near to the treatment table, and wheels locked
12. ☐ Emergency tools in place (Pb pig, forceps/tongs, wire cutter, scissors, suture removal kits)
13. ☐ Exposure warning light (flash red) on the HDR afterloader visible in a TV monitor

Remote after loader operation (add fraction and deliver test plan "DailyQA")

1. ☐ Key of the afterloader turned to "treat" position
2. ☐ Transfer Guide Tube free of kinks
3. ☐ Yes/No Can source be exposed without Transfer Guide Tube properly connected to turret
4. ☐ Yes/No Can source be exposed with Transfer Guide Tube connected to turret but not to applicator
5. Connect catheter (Quick Connector attached) to turret & expose source for the following tests:
 - a. ☐ Source exposure indicator lights on the afterloader and console (flash red)
 - b. ☐ Primameter functional during source exposure
 - c. ☐ HDR "beam-on" door light operational
 - d. Emergency stops functional (i.e., source retracts when the following interlocks selected)
 - i. ☐ Console key turned off
 - ii. ☐ Console interrupt button (red button on HDR console)
 - iii. ☐ Door interrupt button (red button on HDR monitor)
 - iv. ☐ Door opened
 - v. ☐ UPS power cable unplugged (hand crank turns during retraction)
6. ☐ System correctly recovers from emergency interruption
7. ☐ Dwell time agrees with a stopwatch within 2 seconds on 30 seconds ("DwellTime" test plan) _____ sec
8. Positioning of wire within ±1mm (PVT in "source & wire" under workflow → system configuration)
 - a. 80 cm : ☐ dummy and ☐ source
 - b. 140 cm : ☐ dummy and ☐ source

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

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

TABLE II. Intracavitary source and applicator quality assurance.

Procedure	End point	Frequency
evaluate dimensions/ serial number	source identity physical length and diameter	initially
superposition of auto- and transmission radiographs	active source length and uniformity, capsule thickness accuracy of source construction	initially
source leak test	capsule integrity	see text ^a
source calibration	source strength	initially, annually
dosimetric evaluation of applicator	magnitude and geometric characteristics of shielding effect	initially
orthogonal radiographs of applicators	correct source position, mechanical integrity, internal shield positioning coincidence of dummy and radioactive source	initially, annually
measure applicator dimensions	correct diameter and length, correct diameter of all colpostat caps and cylinder segments	initially, annually
source inventory	correct source number	quarterly ^b
source preparation area survey	safety of brachytherapy personnel	as needed



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

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>

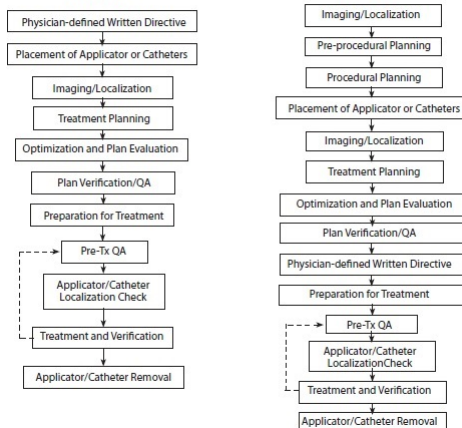
ASTRO White Paper: Responsibilities of Qualified Medical Physicist

- 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.”

Example 1



Thomadsen et al., PRO., 2014.

Ensuring HDR Treatment Quality: TQC Form to Parallel Workflow

University of Chicago Medicine
Department of Radiation and Cellular Oncology
IDR™ In Brachytherapy Treatment QA & QM review
Applicator: Single Channel Cylinder

Patient Name:	Date:	
MEN Number:		
Authorized Medical Physician (AMP):		
Physician Authorized User (AU):		
RTT:		

I. Documentation Check

Capsule is signed by _____
 Written Release (WTR) is completed and signed by AU
 Check the sequence and duration of cylinder exposure to WTS
 Treatment plan is signed by physician (AU) or RTT
 Complete loading & signed treatment document as AU
 Patient is checked into "Cylinder room" for treatment scheduling
 Treatment plan is imported to HDR computer console, and client external check plan is Reference point
 Check the image number ("Image") plan in Pinnacle software
 Only QA is performed on the IDR® applicator

II. Pre-Treatment Check

AU monitors the cylinder with the correct sequence/duration of exposures
 Hand-held survey meter and exposures are available
 Control Indicator Area, Radioactive Material, and "Control High Radiation Area" signs are posted on all doors
 Patients afterloader from locked clinic area and never enter patient suite
 Lock afterloading wheels
 Emergency equipment (Pb bucket pail, fire extinguisher, water, nurse removal kit) are in place
 Treatment plan is correctly transferred to the treatment console in Pre-Treatment report
 a) _____ Patient ID
 b) _____ Dose prescription and target
 New Post-Treatment released into PDF file
 AMP performs radiation source of patient's implant treatment time min sec
 AU monitors Outgoing Tube to the applicator & AMP inserts a new marker
 Acquire TV monitor to confirm the application
 Check the loading sequence in TRF checklist, and manually complete the treatment in Appointer scheduling
 Turn HDR L&L, reactor back at treatment entrance door to "IDCR"
 AU connects Outgoing Tube Transfer Outside Tube
 AMP measures length of Outgoing Tube plus Transfer Outside Tube to be 133.4±0.3 cm
 AMP turns the afterloader off once it reaches Transfer Outside Tube to lock & turn the wheels
 Press start release and ensure Channel 1 status LED light is green
 Two key of afterloader may "ready" multiple times
 Ensure Transfer Outside Tube does not rest on protect (skin pad)
 Confirm exposure warning light (flash red) on the back of the afterloader is visible in a TV monitor
 RTT focuses camera on patient & transfers outside tube post
 AU personnel perform body mark findings
 AU and AMP are in control area while multiple
 a) _____ starts treatment
 b) _____ Time AU pagged Time AU arrived Time treatment started

III. During Treatment Check

AU and AMP are in control area while within multiple range
 Patient is visible to video system
 Afterloader source exposure indicator light is on (a, flasher red)
 Precision timer meter is on (a, flasher red)
 Console source exposure indicator light is on (a, flasher red)
 Console timer exposure indicator light is on (a, flasher red)

IV. Post-Treatment Check

Afterloader indicator source meter & Precursor do not detect radiation
 AMP surveys radiation before the following locations:
 a) Outside the treatment room mSv h
 b) Inside the treatment room mSv h
 c) Full length of applicator & Transfer Outside Tube mSv h
 d) Patient back surface area the treatment bed mSv h
 Complete pre- and post-treatment radiation surveys
 YES/NO Radiation survey comparison indicates elevated levels?
If YES, RT is contact Health Physics and start Emergency Procedures
If NO, resume patient care per usual
 e) Top surface surface of afterloader
 YES/NO Radiation survey indicates elevated level?
If YES, RT is contact Health Physics and start Emergency Procedures
 f) _____
 New Post-Treatment released into PDF file
 Check medications given in Sentinel page

V. Treatment Completion Check

1. Another treatment will follow
 Report the procedure down Step I
 2. No more treatment for today
 Two key on afterloader wait to "lock"
 Exposure indicator is cleared position a direct, and lock direct it returns cleave keys
 Return "Control Indicator Area Radioactive Materials" and "Control High Radiation Area" signs from doors
 Remove "Control Indicator Area Radioactive Materials" and "Control High Radiation Area" signs from doors
 Turn where lock to "LED-Lock" mode
 Release the emergency stop button
 Return the keys of the emergency console, chamber, treatment console to the lock

VI. Treatment Review & Write-up

YES/NO AMP summarized deviations from the Written Procedure
 If YES, explain in detail in separate sheet
 Delivered dose is less than Pre-treatment report agrees with the planned dwell time within 1 second
 Check IGCC treatment counts is correct and treatment duration is completed, and dose has recorded in AZAR
 Upload combined CT, film, dwell dose calculation, pre- and post-treatment report into Patient Document

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

Treatment Type - HDR

Source Information - VarSource VS2000

Source Modified Date: Jan 16, 2013
 Calibration Date/Time: Oct 24, 2013, 12:11:55 PM
 Treatment Date/Time: Dec 30, 2013, 12:00:00 PM
 Total Treatment Time (sec): 394.20

Source Type: CYLINDER
 Calibration Strength (U): 45032.1484
 Treatment Strength (U): 24008.8887
 TRAK (U-sec): 9.4643e+06
 CI-sec: 2348.7

Calculation Points

Name	Coordinates (X, Y, Z) cm	Dose (cGy)	RTP Dose (cGy)	Dose or % Diff
Lt Ref Point	(4.33, 14.62, -81.47)	597.12	597.12	-0.0%
Rt Ref Point	(0.80, 14.64, -81.28)	601.37	601.42	-0.0%

Applicators (1 total)

probe (Dwell Time Sum (sec): 394.20; % of Total Time: 100.0%)

Dwell #	Coordinates (X, Y, Z) cm	Alpha (deg)	Beta (deg)	Time (sec)	Weight (%)	Dist. to Tip (cm)
1	(2.72, 14.72, -79.31)	-175.40	-1.96	61.80	15.7%	0.65
2	(2.68, 14.71, -79.81)	-175.40	-1.96	53.80	13.6%	1.15
3	(2.64, 14.69, -80.30)	-175.40	-1.96	39.40	10.0%	1.65
4	(2.60, 14.67, -80.80)	-175.40	-1.96	30.20	7.7%	2.15
5	(2.56, 14.66, -81.30)	-175.40	-1.96	25.50	6.5%	2.65
6	(2.52, 14.64, -81.80)	-175.40	-1.96	22.00	5.6%	3.15
7	(2.48, 14.62, -82.30)	-175.40	-1.96	35.10	8.9%	3.65
8	(2.44, 14.60, -82.79)	-175.40	-1.96	57.30	14.5%	4.15
9	(2.40, 14.59, -83.29)	-175.40	-1.96	69.10	17.5%	4.65

Therapist Involvement: Treatment Time Out

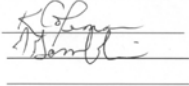
Radiation Oncologist: Yasmin Hesan MD

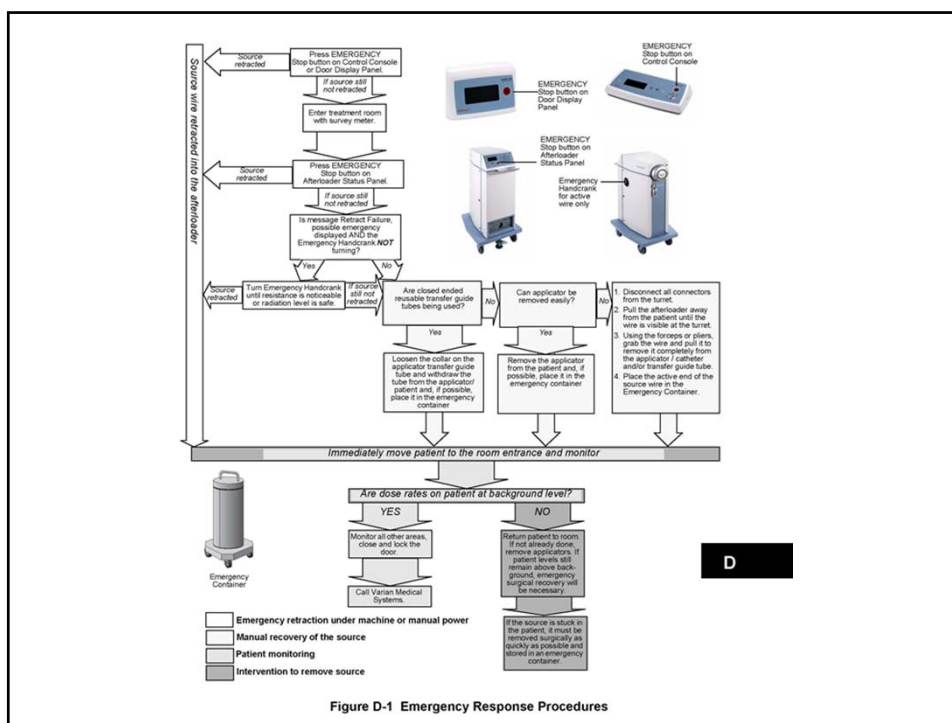
Check Procedure Type: ☒ Vaginal Cylinder, ☐ Tandem, ☐ Interstitial, ☐ IORT

Complete the HDR Treatment Timeout prior to each treatment delivery.

Verified	Process Step	Source
☒	Confirm patient ID photo	ARIA
☒	Confirm Physicians Directive prescription, HDR Brachy plan, and RadCalc are signed by the attending.	Documents
☒	Verified source strength (air kerma strength in U)	HDR Treatment unit with Radcalc
☒	Confirmed patient name and MRN	PTR with RadCalc and Brachy Plan
☒	Confirmed number of channels	PTR with HDR BrachyPlan
☒	Confirmed total scaled treatment time	PTR with RadCalc
☒	Confirmed source positions	PTR with and Brachy Plan
☒	Confirmed scaled dwell times	PRT with RadCalc
☒	Confirmed patient ID (full name and D.O.B.)	In treatment room with patient
☒	Acquired KV image	Vaginal Cylinder and Interstitial procedure
☒	Confirmed correct patient file is loaded to HDR unit prior to treatment delivery	Patient information displayed on HDR unit with Physic AU
☒	Enter HDR treatment code	14600

Staff completing 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