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?

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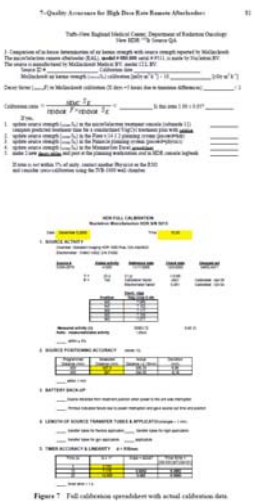
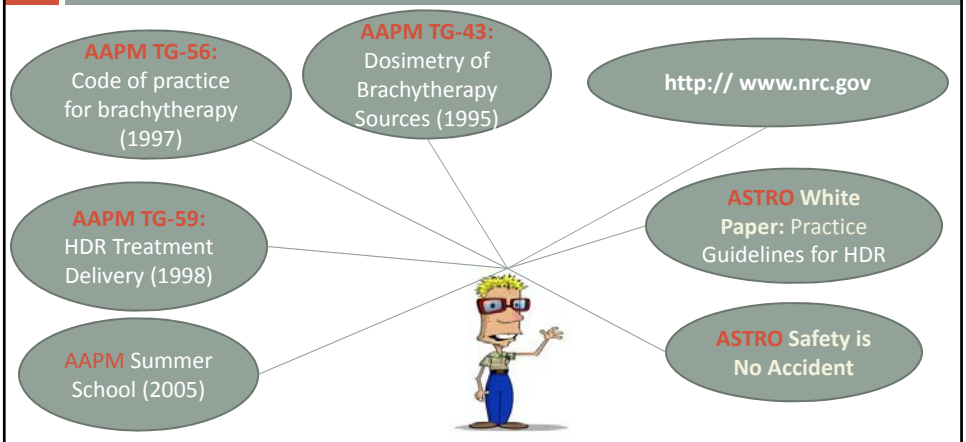


How to train a Qualified Medical Physicist?

- 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

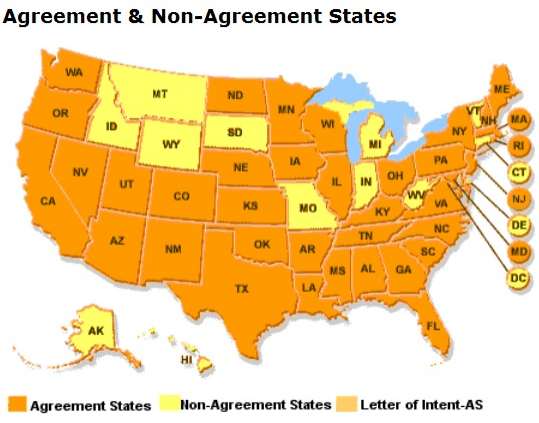
- Use written documentation
- Develop a formal procedure
- Exploit redundancy
- Exploit quality improvement techniques

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)



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

10CFR**19**: 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.

10CFR**20**:
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

10CFR**35**:
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

10CFR**35**:
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, 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), check function of:
  - Source retraction with backup battery upon power failure
  - Source transfer tubes plus applicators

10 CFR35.643: 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 (m-2015)**
2. ☐ Stopwatch available
3. ☐ TV monitor operational
4. ☐ Intercom operational
5. ☐ **Emergency procedure posted**
6. ☐ **Contact information of AU, 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 Primalert survey meter checked against dedicated check source & possesses current calibration (m-2015)**
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. ☐ Primalert 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

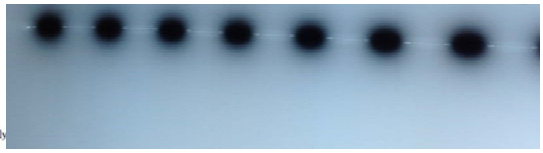
AAPM TG-56: Applicator Commissioning and QA

- "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



10CFR**35**.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

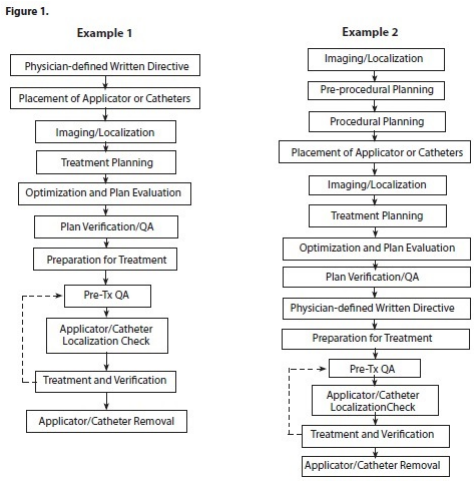
ASTRO White Paper: Responsibilities of Qualified Medical Physicist

- 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

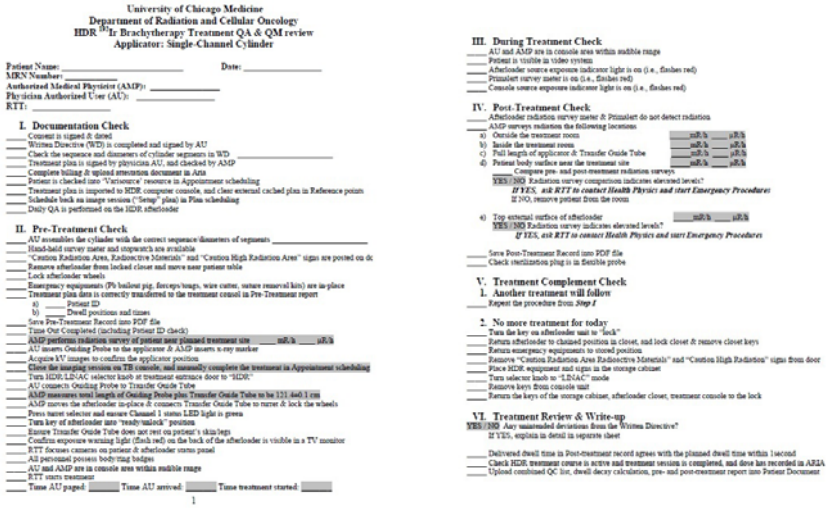
- "Extensive effort is needed by the medical physicist outside of direct patient interactions to ensure that clinical procedures are fluid and performed in an accurate and timely manner with confidence by all HDR brachytherapy team members."

Ensuring HDR Treatment Quality Control



Thomadsen et al., PRO:, 2014.

Ensuring HDR Treatment Quality: TQC Form to Parallel Workflow



University of Chicago Medicine
Department of Radiation and Cellular Oncology
HDR ^{192}Ir Brachytherapy Treatment QA & QM review
Applicator: Single-Channel Cylinder

Patient Name: _____ Date: _____
MRN Number: _____
Authorized Medical Physicist (AMP): _____
Physician Authorized User (AU): _____
RTT: _____

I. Documentation Check
___ Consent is signed & dated
___ Written Directive (WD) is completed and signed by AU
___ Check the sequence and dimensers of cylinder segments in WD _____
___ Treatment plan is signed by physician AU, and checked by AMP
___ Complete billing & upload attestation document in Aria
___ Patient is checked into 'Variosource' resource in Appointment scheduling
___ Treatment plan is imported to HDR computer console, and clear external cached plan in Reference points
___ Schedule lock ea image session ("Setup" plan) in Plan scheduling
___ Daily QA is performed on the HDR afterloader

II. Pre-Treatment Check
___ AU assembles the cylinder with the correct sequence/dimeters of segments _____
___ Hand-held survey meter and stopwatch are available
___ "Caution Radiation Area, Radioactive Materials" and "Caution High Radiation Area" signs are posted on dc
___ Remove afterloader from locked closet and move near patient table
___ Lock afterloader wheels
___ Emergency equipments (Pb bailout pig, forceps/tongs, wire cutter, suture removal kits) are in-place
___ Treatment plan data is correctly transferred to the treatment consol in Pre-Treatment report
a) ____ Patient ID
b) ____ Dwell positions and times
___ Save Pre-Treatment Record into PDF file
___ Time Out Completed (including Patient ID check)
___ AMP performs radiation survey of patient near planned treatment site ____ mR/h ____ mR/h
___ AU inserts Guiding Probe to the applicator & AMP inserts x-ray marker
___ Acquire XV images to confirm the applicator position
___ Close the imaging session on TB console, and manually complete the treatment in Appointment scheduling
___ Turn HDR-LINAC selector knob at treatment entrance door to "HDR."
___ AU connects Guiding Probe to Transfer Guide Tube
___ AMP measures total length of Guiding Probe plus Transfer Guide Tube to be 121.4±0.1 cm
___ AMP moves the afterloader in-place & connects Transfer Guide Tube to nurse & lock the wheels
___ Press turret selector and ensure Channel 1 status LED light is green
___ Turn key of afterloader into "ready/unlock" position
___ Ensure Transfer Guide Tube does not rest on patient's skin/legs
___ Confirm exposure warning light (flash red) on the back of the afterloader is visible in a TV monitor
___ RTT focuses cameras on patient & afterloader status panel
___ All personnel possess body-ring badges
___ AU and AMP are in console area within audible range
___ RTT starts treatment
___ Time AU paged: _____ Time AU arrived: _____ Time treatment started: _____

1

III. During Treatment Check
___ AU and AMP are in console area within audible range
___ Patient is visible in video system
___ Afterloader source exposure indicator light is on (i.e., flashes red)
___ Primaltert survey meter is on (i.e., flashes red)
___ Console source exposure indicator light is on (i.e., flashes red)

IV. Post-Treatment Check
___ Afterloader radiation survey meter & Primaltert do not detect radiation
___ AMP surveys radiation the following locations
a) Outside the treatment room ____ mR/h ____ mR/h
b) Inside the treatment room ____ mR/h ____ mR/h
c) Full length of applicator & Transfer Guide Tube ____ mR/h ____ mR/h
d) Patient body surface near the treatment site ____ mR/h ____ mR/h
___ Compare pre- and post-treatment radiation surveys
YES / NO Radiation survey comparison indicates elevated levels?
If YES, exit RTT to contact Health Physics and start Emergency Procedures
If NO, remove patient from the room
e) Top external surface of afterloader ____ mR/h ____ mR/h
YES / NO Radiation survey indicates elevated levels?
If YES, exit RTT to contact Health Physics and start Emergency Procedures
___ Save Post-Treatment Record into PDF file
___ Check sterilization plug is in flexible probe

V. Treatment Complement Check
1. Another treatment will follow
___ Repeat the procedure from *Step 1*

2. No more treatment for today
___ Turn the key on afterloader unit to "lock"
___ Return afterloader to chained position in closet, and lock closet & remove closet keys
___ Return emergency equipments to stored position
___ Remove "Caution Radiation Area Radioactive Materials" and "Caution High Radiation" signs from door
___ Place HDR equipment and signs in the storage cabinet
___ Turn selector knob to "LINAC" mode
___ Remove keys from console unit
___ Return the keys of the storage cabinet, afterloader closet, treatment console to the lock

VI. Treatment Review & Write-up
YES / NO Any unintended deviations from the Written Directive?
If YES, explain in detail in separate sheet

___ Delivered dwell time in Post-treatment record agrees with the planned dwell time within 1 second
___ Check HDR treatment course is active and treatment session is completed, and dose has recorded in ARIA
___ Upload combined QC list, dwell decay 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 - VariSource 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 (degs)	Beta (degs)	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 Hasan 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
✓	Confirm 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: [signature]

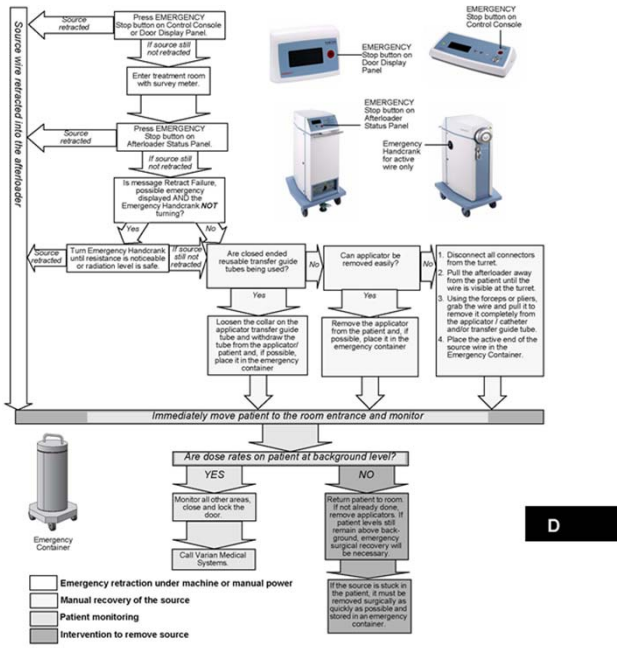


Figure D-1 Emergency Response Procedures

Qualified Medical Physicist

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