From Licensing to QA, How to Implement HDR Brachytherapy Into Your Clinic

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Introduction

- **Definition of HDR brachytherapy.**
- **Rationale for HDR vs. conventional LDR.**
- **HDR program:**
  - **Preparation**
  - **Shielding, licensing**
  - **Acceptance and commissioning**
  - **QA – source exchange, daily…**
  - **Logistical issues**

NRC definition of
"High dose-rate remote afterloader":

- A brachytherapy device that remotely delivers a dose rate in excess of 12 gray per hour to a point or surface where the dose is prescribed.

10 CFR 35.2

Comparison of HDR with Conventional LDR

Advantages

- Reduced exposure to staff.
- Ability to shape dose cloud – dose optimization.
- Outpatient treatments.
- More stable positioning of applicator.
- Increased distance from normal tissue.
- Ability to immediately treat patients after surgery, do not have to order sources.

Disadvantages

- Relatively complicated treatment system – more interlocks, more QA.
- Compressed time frame for treatment delivery – could result in serious consequences.
- "Predicted" radiobiological disadvantages.
- Increased need for accurate dosimetric, anatomic and geometric information.
- Potential for VERY high exposure in case of unit malfunction.

Task Group No. 59, Med Phys. 25 (4), 375 – 403 (1998).

Radionuclides that have been available as HDR Sources

Radionuclide	E_{aver} (MeV)	$T_{1/2}$	HVL_{Pb}(cm)	Specific Activity (Ci/g)
^{60}Co	1.17, 1.33	5.27 a	1.10	200
^{137}Cs	0.662	30.1 a	0.65	10
^{192}Ir*	0.38 (avg)	73.83 d	0.30	450

*Although ^{192}Ir's short half-life would seem to make it a disadvantage for use as an HDR source, this is more than compensated by its HVL and specific activity.

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HDR Program Preparation

- Meeting of the key HDR players
  - Equipment purchase
  - Room design
- NRC Licensing
- Room preparation
- Acceptance testing and commissioning
- QA program
- Logistics plan and staff training

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Equipment

- **Involved parties must discuss equipment necessary to run and sustain an HDR practice.**
  - **HDR unit**
  - **Applicators**
  - **Treatment planning computer**
  - **Ancillary equipment – i.e. digitizer, film scanner**
  - **Dummy strands**
  - **Well chamber**
  - **Survey meter**

Afterloading Units

GammaMed Plus
Varian
24 Channels
(Also available with 5 channels)

microSelectron HDR
Nucletron
18 Channels

Varisource
Varian
20 Channels

Applicators

- **Involved parties should discuss expected patient population.**
  - **Gyn applicators – cylinders, tandem & ovoids, tandem & ring**
  - **Breast applicators – Mammosite, template**
  - **Template applicators – prostate and gyn**

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Gyn Applicators

Single channel cylinder

Multi channel cylinder

Varian Medical Systems – www.varian.com

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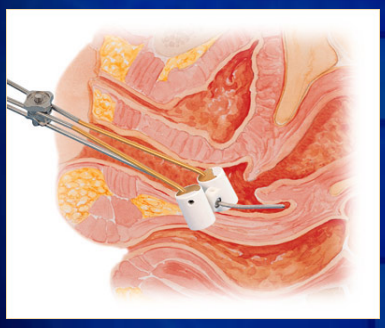
Gyn Applicators



Tandem and Ovoids

Tandem and Ring

Varian Medical Systems – www.varian.com
Nucletron – www.nucletron.com

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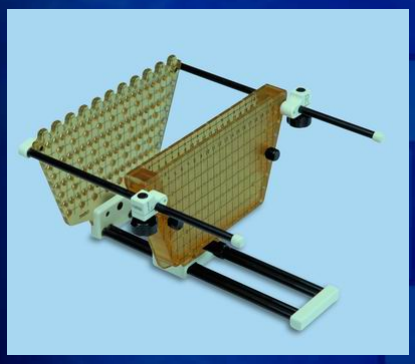
Breast Applicators



- **Kuske template.**
- **Interstitial treatment of breast.**
- **Mammosite.**
- **Used to treat lumpectomy site.**

Nucletron – www.nucletron.com
Mammosite – www.mammosite.com

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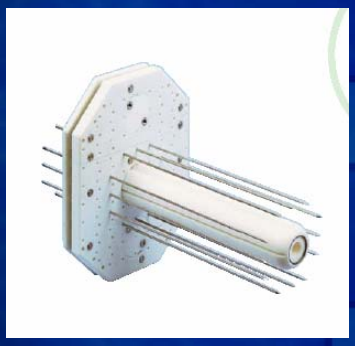
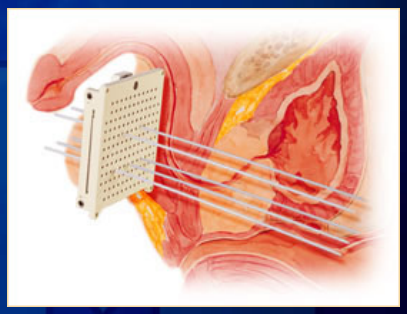
Template Applicators





- **MUPIT – Martinez Universal Perineal Interstitial Template.**
- **Used to treat vaginal and rectal cancer.**
- **Used to treat prostate cancer.**

Nucletron – www.nucletron.com

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Room Design

- **Clinic must decide where the HDR unit will reside.**
  - **Linac vault vs. dedicated suite**
  - **Decision will be dictated by expected HDR load, finances and spatial constraints.**

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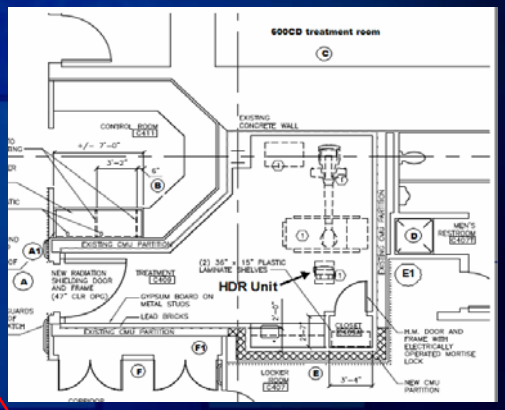
Room Shielding

$$B = \frac{Pd^2}{WT}$$

- **B – barrier transmission factor**
- **P – max permissible weekly dose**
- **d – distance from source to point of interest**
- **W – workload**
- **T – occupancy factor**

#HVL = -ln(B); #TVL = -log(B)



Dictated by the NCRP, 20 μGy/hr.

Aver # pt's per week x air kerma rate @ 1 m.

Calculation of Workload

$$W = \Gamma \times f \times A \times t$$

Γ - exposure rate constant, the exposure rate (R/hr) at a point 1 cm from a 1 mCi point source.

f - roentgen-to-rad or the exposure-to-dose conversion factor

A – activity

t – total treatment time per week

P. McGinley, Shielding Techniques for Radiation Oncology Facilities, 2nd Edition, Medical Physics Publishing, 2002.

Sample Calculation

- **Design parameters:**
  - **Maximum source activity – 15 Ci**
  - **Weekly treatment time – 10 min/fx x 25 fx/wk = 250 min/wk = 4.17 hr/wk**
- **Source parameters:**
  - **Γ_{Ir} – 0.469 R/Ci/hr @ 1 m**
  - **f – 0.971 cGy/h**

$$W = \Gamma \times f \times A \times t = 0.469 \frac{R}{Ci \cdot hr} \times 0.971 \frac{cGy}{R} \times 15Ci \times 4.17 \frac{h}{wk}$$

$$= 28.5 \frac{cGy}{wk}$$

occupancy factor (T):

Location	Occupancy Factor (*T*)
Full occupancy areas (areas occupied full-time by an individual), *e.g.*, administrative or clerical offices; treatment planning areas, treatment control rooms, nurse stations, receptionist areas, attended waiting rooms, occupied space in nearby building	1
Adjacent treatment room, patient examination room adjacent to shielded vault	1/2
Corridors, employee lounges, staff rest rooms	1/5
Treatment vault doors[b]	1/8
Public toilets, unattended vending rooms, storage areas, outdoor areas with seating, unattended waiting rooms, patient holding areas, attics, janitors' closets	1/20
Outdoor areas with only transient pedestrian or vehicular traffic, unattended parking lots, vehicular drop off areas (unattended), stairways, unattended elevators	1/40

NCRP 151

NRC Licensing

- **Types of license for medical use of byproduct material:**
  - **Specific license of limited scope**
  - **Specific license of broad scope**

"Consolidated Guidance about Materials Licenses," NUREG 1556, Vol 9, Rev 2.

Specific License of Limited Scope

- **Issued to private or group medical practices.**
- **Authorized users (AUs), authorized medical physicists (AMPs) must be specifically listed on license.**

"Consolidated Guidance about Materials Licenses," NUREG 1556, Vol 9, Rev 2.

Specific License of Broad Scope

- Issued to institutions:
  - Experienced success operation under specific license of limited scope.
  - Demonstrate compliance with regulatory agencies.
  - Engaged in medical research and routine use of byproduct materials.

"Consolidated Guidance about Materials Licenses," NUREG 1556, Vol 9, Rev 2.

NRC Licensing

- According to 10 CFR 35, the licensee must provide:
  - Facility diagram – including shielding
  - Information regarding equipment
  - Training and experience of the RSO, AUs, and AMPs.
  - Radiation safety precautions and instructions
  - Methodology for measurement of dosage
  - Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety

NUREG 1556

- **For details and examples on how to apply or amend an existing license see NUREG 1556.**

Table C.1 Applicability Table

Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.3	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Discrete Source of Ra-226 (Other than sealed sources)	Y	Y	N	N	N	Y	
8.8	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.9	Purpose(s) for Which Licensed Material Will Be Used	Y	Y	Y	Y	Y	Y	
8.10	Training and Experience	G	G	G	G	G	G	
8.11	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	L,D
8.12	Authorized User(s) (AU's)	Y	Y	Y	Y	Y	Y	D
8.13	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.14	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
8.15	Facilities and Equipment	G	G	G	G	G	G	
8.16	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.18	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.19	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.20	Other Equipment and Facilities	N	N	N	N	Y	N	
8.21	Radiation Protection Program	G	G	G	G	G	G	
8.22	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.23	Occupational Dose	P	P	P	P	P	P	M

Room Preparation

- **Before an HDR unit can be installed, one must verify:**
  - **Room shielding**
  - **Door interlocks are functional**
  - **Radiation detectors are available and functional**
  - **Sufficient number of outlets, conduits and power**
  - **Identified means in which unit, keys, TPS and room are secured**
  - **Shelves/drawers**

Acceptance Testing and Commissioning

- **HDR unit and treatment control system *(software function, source position, source calibration, safety features, indicators,…)***
- **Treatment Planning Computer (dose calculation, source decay (if applicable), standard applicators, accessories such as digitizers, film scanners…)**
- **QA equipment *(well chamber/electrometer, survey meters, QA jigs, length checkers, dummy strands,…)***
- **Applicators! *(parts inventory, assembly, condition, simulation with dummy strands pre-patient…)***

Calculation of Total Dose

- **Total dose is dependent on the position of source relative to point of interest and dwell times.**
- **TG-43 dose algorithm (review):**

$$D(r,\theta) = t \cdot S_k \cdot \Lambda \cdot \frac{G_L(r,\theta)}{G_L(r_o,\theta_o)} \cdot g_L(r) \cdot F(r,\theta)$$

$$D_{Total} = \sum_1^n D(r_n,\theta_n)$$

- **In planning system, can optimize dose based on distance or volume.**

Task Group #43, Med. Phys. 31, 633 - 674 (2004).

Monthly QA & Quarterly Source Exchange

- Source calibration (within 5% of manufacturer)
- Source position accuracy (within 1 mm)
- Safety checks (radiation detectors, interrupt/emergency buttons, battery backup, interlocks, dual x-ray operation, catheter length)
- Timer accuracy/linearity
- Applicator/transfer tube lengths and conditions

10 CFR 35.633 and Task Group No. 59, Med Phys. 25 (4), 375 – 403 (1998).

Daily QA

- Functionality of safety interlocks
- A/V system
- Emergency equipment
- All Detectors & Survey meters functional
- Camera/intercom
- Timer accuracy
- Correct date, time, decay factor
- Integrity of applicators checked

10 CFR 35.643 and Task Group No. 59, Med Phys. 25 (4), 375 – 403 (1998).

From TG-59 - Principles of an HDR brachytherapy program design:

"HDR is often hectic since the time the applicator remains in the patient must be minimized, creating an environment in which errors and miscommunications easily occur."

- **Use written documentation.**
- **Develop formal procedures.**
- **Exploit redundancy.**
- **Exploit quality improvement techniques.**

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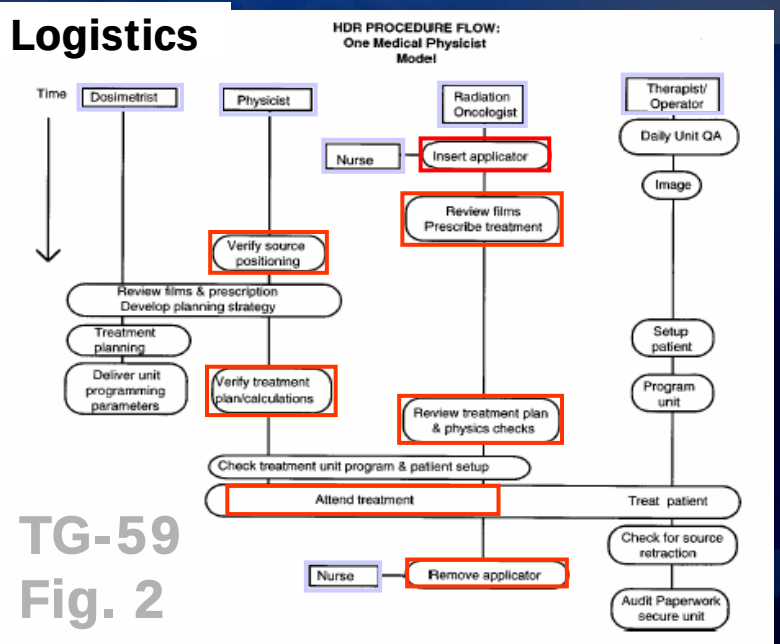
Logistics



TG-59 Fig. 2

Logistics

- **Where is equipment kept?**
- **Applicators: *sterilization, need for duplicate applicators vs. time between cases, labeling, inventory***
- **Treatment planning: *simple sim vs. CT planned, where will the TP station live?***
- **Where does patient stay between sim and treat?**
- **For subsequent fxs, how to verify applicator placement (resim or port film)**
- **Scheduling: How to time the treatments so that physicist and physician (therapist?) can all be present?**
- **What's the therapists' roll?**
- **Who is responsible for billing?**

Treatment Specific QA

- **Rx – Authorized User defines the target volume or point, selects dose and fractionation scheme and acceptable dose to normal structures. Physics/dosimetry must clarify and confirm intent, ensure that it is properly documented and develop a tx strategy.**
- **Treatment Planning – Physics/dosimetry will import patient and applicator info via CT scan, films or digitizer into TP computer, along with script info.**
- **QA of TP phase depends on difficulty of case, type of implant, type of simulation…**

Key to a successful program…

- **Teamwork**
- **Established flow**
- **Quality Assurance**
- **Documentation**
- **Experience**

Thank you!