Developing and Maintaining a Safe HDR Brachytherapy Practice

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HDR versus 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**

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

- Lessons learned
  - NUREG-1480
  - IAEA Safety Reports Series No. 17
- Developing an HDR program (TG 56):
  - Preparation
  - Shielding, licensing
  - Acceptance and commissioning
- Developing an HDR QA program
  - 10 CFR 35
  - AAPM TG recommendations
- Logistical issues (TG 56)
• “Loss of an Ir-192 Source and Therapy Misadministration…”
  • Nov ‘92 during HDR interstitial treatment, source became detached from wire
  • Alarming area monitor disregarded
  • Patient released to nursing home w/o survey
  • Within 5 days, the patient expired
    – Planned total dose 1800 cGy (in 3 fx), delivered dose 
      \(~1.6 \times 10^6\) cGy – overdose \(~3\) orders of magnitude
  • Over the course of 17 days, 94 individuals were exposed to radiation
Summary of issues

1. Weakness of safety culture at clinic
   - Area monitor previously alarmed during/following EBRT txmt, staff believed device malfunctioning
     • Patient was not surveyed before being released
   - Med phys not present during txmt (contract/temp employee, HDR support not written into contract)
   - RadOnc physician not continuously present at HDR console
Summary of issues

1. Weakness of safety culture at clinic
2. Weakness in rad safety program
   - Regular rad safety training not provided to staff, no one knew who was responsible for training
   - Neither physician nor RTTs were familiar w/ RSO
   - RTTs not familiar w/ how to operate portable survey meter
Summary of issues

1. Weakness of safety culture at clinic

2. Weakness in rad safety program

3. Weakness in design and testing of source wire
   - Vendor did not test scenarios that would result in source becoming dislodged from wire
   - Afterloader failed to detect loss of part of source wire
   - Error messages did not indicate severity of situation
     - “wire path constriction detected”
   - Written documentation from vendor did not address error messages
Summary of issues

1. Weakness of safety culture at clinic
2. Weakness in rad safety program
3. Weakness in design and testing of source wire
4. Weak regulatory oversight
   - 10 CFR 35 did not specifically cover HDR brachytherapy
   - No specific guidance on QC program
   - Some inspectors and licensees believed post implant survey could be accomplished w/ area monitor
Lessons Learned

• Immediately following the 1992 misadministration, the NRC published bulletins 92-03 and 92-84 (12/92)

  1. Surveys MUST be performed upon completion of txmt w/ an “appropriate” meter (portable survey meter for HDR)

  2. Written emergency procedure must be available

  3. Staff must be trained to use equipment for normal and emergency procedures

  4. Initial and semiannual rad safety training and drills necessary (current requirements – initial and annual training)

  5. Staff and equipment MUST be available in event of emergency
“Quality Management in Remote Afterloading Brachytherapy”

- In 1994, more extensive changes to NRC regulations were published based on the lessons learned from NUREG 1480.
In 2000, the IAEA published a report on “Lessons Learned from Accidental Exposures in Radiotherapy”

Event No 82: “Delivery of [dose] to the wrong site because of a defective catheter”

- Kink in catheter resulted in delivery of full dose 26 cm from target location.

Contributing factors

- No QC of catheter
- No radiographic verification of source position (film w/ dummy wire)
• Event No 83: “Using a HDR prescription for wrong patient”
  – Incorrect patient chart selected resulting in wrong patient information entered into treatment console

• Contributing factors
  – No verification of patient identity
  – No independent check of treatment information
• Up until 2002, Title 10 of the Code of Federal Regulations Part 35.600 focused on regulations for Teletherapy units.

• In 2003, an update to 10CFR35.600 extended to Photon Emitting Remote Afterloader and Gamma Stereotactic Radiosurgery units.
Summary of Lessons Learned

- Failure analysis
  - Inadequate training and/or documentation
  - Inadequate supervision
  - Poor communication among txmt team
  - Poorly designed txmt planning or delivery system
  - Excessive time pressure

- What can we do to prevent or minimize likelihood of errors?
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
Afterloading Units

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

**microSelectron HDR**
Nucletron
18 Channels
(Also available with 30 channels)

**Varisource**
Varian
20 Channels
Applicators

- Involved parties should discuss expected patient population.
  - Gyn applicators – cylinders, tandem & ovoids, tandem & ring
  - Breast applicators – intracavity applicators
  - Interstitial templates – prostate, breast, and gyn
  - Surface applicators
NRC Licensing

- Types of license for medical use of byproduct material:
  - Specific license of limited scope
  - Specific license of broad scope
According to 10 CFR 35, the licensee must provide:

- Facility diagram – including shielding information.
- Information regarding equipment
- Training and experience qualifications of the RSO, authorized user(s), and authorized medical physicist(s).
- Radiation safety precautions and instructions
- Methodology for measurement of dosages or doses to be administered to patients or human research subjects
- Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety
For details and examples on how to apply or amend an existing license see NUREG 1556.

### Table C.1 Applicability Table

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<th>Section</th>
<th>Topic</th>
<th>35.100/200</th>
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</table>
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.
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
Room Shielding

\[ B = \frac{P d^2}{WT} \]

- **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)

Controlled 0.1 mSv/wk; Uncontrolled 0.02 mSv/wk

Aver # pt’s per week x air kerma rate @ 1 m.
Acceptance Testing and Commissioning

- HDR unit and treatment control system (10 CFR 35.615 & 633)
  - Software function
  - Source position - ± 1 mm
  - Source calibration - ± 5%
  - Safety features
    - Backup battery
    - Timer accuracy and linearity
  - Functionality of interlocks
  - Indicators
Acceptance Testing and Commissioning

- HDR unit and treatment control system
- Treatment Planning Computer (10 CFR 35.657)
  - Verify source-specific input parameters required by the dose calculation algorithm.
  - Verify the accuracy of dose, dwell time, and treatment time calculations at representative points;
  - Verify the accuracy of isodose plots and graphic displays;
  - Verify the accuracy of the software used to determine sealed source positions from radiographic images;
  - Verify the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
Acceptance Testing and Commissioning

- HDR unit and treatment control system
- Treatment Planning Computer
- QA equipment
  - Well chamber/electrometer
  - Survey meters - ± 20% (10 CFR 35.61)
  - QA jigs
  - Length checkers
  - Dummy strands
Acceptance Testing and Commissioning

- HDR unit and treatment control system
- Treatment Planning Computer
- QA equipment
- Applicators
  - Parts inventory
  - Assembly
  - Condition
  - Verify length of transfer tubes and applicators (10 CFR 35.633)
  - Function of transfer tube and applicators (10 CFR 35.633)
  - Simulation with dummy strands pre-patient
Additional Recommendations

- TG 40
  - Applicator QA – radiograph/autoradiograph
  - Procedure specific QA
    - Rx verification
    - Plan accuracy and consistency with Rx
    - Post implant survey
    - Post implant review and audit
<table>
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<tr>
<th>Frequency</th>
<th>Test</th>
<th>Tolerance</th>
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<tbody>
<tr>
<td>Daily</td>
<td>Door interlocks, lights and alarms</td>
<td>Functional</td>
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<tr>
<td></td>
<td>Console functions, switches, printer</td>
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<td>Inspection of transfer tubes</td>
<td>Free of kinks and firmly attached</td>
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<td>Accuracy of source/dummy</td>
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<tr>
<td></td>
<td>Source positioning</td>
<td>1mm</td>
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<tr>
<td>Frequency</td>
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<td>Tolerance</td>
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<td>Source exchange/quarterly</td>
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<td></td>
<td>Timer accuracy</td>
<td>1%</td>
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<tr>
<td></td>
<td>Length of transfer tubes</td>
<td>1mm</td>
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<td></td>
<td>Integrity of applicators</td>
<td>Functional</td>
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<tr>
<td>Annual</td>
<td>Dose calc algorithm</td>
<td>3%, 1mm</td>
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<td></td>
<td>Simulate emergency conditions</td>
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<tr>
<td></td>
<td>Verify source inventory</td>
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</table>
Additional Recommendations

- TG 41 – “Remote Afterloading Technology”
  - Acceptance testing
    - Afterloader
    - Facility/Txmt room
    - Transfer tubes and applicators
    - Source
    - Txmt planning system
  - Quality assurance
Additional Recommendations

- TG 56 – “Code of Practice for Brachytherapy Physics”
  - Patient safety QA
    - Functionality of error recognition
    - Functionality of interlocks
    - Trmt status indicators
    - Functionality of area and portable monitors
    - Functionality of A/V system
TG 56 (Cont.)

- Source calibration - ± 5%
- Internal dimensions
- Positional accuracy - ± 1mm
- Temporal accuracy - ± 2%
- Txmt planning QA
- Dose delivery accuracy
  - Verify date, time and source strength
  - Double check dwell times
Additional Recommendations

• TG 59 – “HDR brachytherapy treatment delivery”
  – Program design
  – Staffing and training
  – Txmt specific QA
  – Emergency procedures
“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.
Logistics Examples

- **Where is equipment kept?** (applicators, qa jigs, survey meters, well chamber, source transfer tubes…)

- **Applicator sterilization** (duplicate applicators vs. time between cases, labeling, inventory)

- **Treatment planning:** Which cases are simple sim vs. CT planned, and where will the TP station live?

- **Where does patient stay** between sim/CT and treat while treatment planning is happening?

- **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?**
QA Program – Monthly QA & Quarterly Source Exchange

- Source calibration (calibration should be within 5% of manufacturer)
- Source position calibration (with trusted qa jigs or special chamber insert, within 1 mm)
- Safety checks (radiation detectors, interrupt/emergency buttons, battery backup, interlocks: door, key, dual x-ray operation, catheter length)
- Timer accuracy/linearity
- Applicator/transfer tube lengths and conditions
- Survey of unit

Radiation Oncology 10 CFR 35, AAPM TG 40, AAPM TG 41, AAPM TG 56, and AAPM TG 59
QA Program – Daily QA

- Correct date, time, decay factor
- Emergency equipment
- Safety Interlocks (door, interrupt, beam on and ready indicators…)
- All Detectors & Survey meters functional
- Camera/intercom
- Timer accuracy
- Integrity of applicators checked
- Applicator specific QA

10 CFR 35, AAPM TG 40, AAPM TG 41, AAPM TG 56, and AAPM TG 59
QA Procedures – Treatment Specific QA

• Rx – AU defines 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.
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.
• Additional checks should be performed based on the type of applicator utilized.
  – QA will be related to complexity of implant
• Final Checks:

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<tr>
<th>Treatment date</th>
<th>Attach transfer tubes</th>
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<tr>
<td>Simulator films/CT scan</td>
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<td>Isodose Plan</td>
<td>Check patient set up on camera</td>
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<td>Physician sign on written directive</td>
<td>Treat patient</td>
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<td>Check Daily QA sheet</td>
<td>Post-tx survey: patient &amp; applicators</td>
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<td>Time Out (verify patient ID via name and DOB)</td>
<td>TCS post-tx printout checked and signed</td>
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<tr>
<td>Correct patient plan on TCS</td>
<td>Complete Appointment - Billing</td>
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<tr>
<td>Check dwell times vs plan and TCS hardcopy</td>
<td>Add tx to Implant list &amp; Close Course in Vision (last fx)</td>
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<td>Survey meter and serial number</td>
<td>Physicist signature</td>
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<td>Pre-tx patient survey</td>
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Radiation Oncology
Treatment Delivery

• Who must be present?
  – Initiation of txmt - An AU and an AMP MUST be physically present
  – Duration of txmt - An AMP and either an AU or a physician, under the supervision of an AU, with appropriate training, MUST be physically present
Key to a successful program...

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

- NUREG 1480
- IAEA Safety Reports Series No. 17
- NUREG/CNR-6276
- Title 10 of the Code of Federal Regulations, Part 35
- AAPM TG Reports 40, 41, 43, 56, and 59
- NCRP 151