

HIGH DOSE REMOTE AFTERLOADER INSPECTION REPORT

(All reg references proceeded by SRPAR 400-20)

Licensee: _____

Address: _____

Location of Inspection: _____

License Number: _____ Priority: _ NRC code: _____

Inspection Date: _____ Previous Inspection Date: _____

Inspection Overdue: **yes** **no**

Inspection Type: Initial . Routine ` Special

Inspection: Announced Unannounced

In Compliance: **yes** **no** Number of Violations: _____

Principal Inspector: _____

Accompanying Inspector(s): _____

Other Accompanying Personnel: _____

Licensee Participants: (list individuals, including titles)

Inspection: _____

Exit Interview: _____

Section I. Interview

1. Organization and Administration

- a. Administrator - _____
- b. Department Manager- _____
- c. RSO - _____
- d. Is RSO as listed on license? [07-.13(1)(c)] yes ` no
- e. Authorized Users (doctors) - _____

- f. Are all Authorized Users as listed on license? [07-.13(1)(b)] yes ` no
- g. Authorized Medical Physicist - _____
- h. Technicians or dosimetrists - _____

2. Radiation Safety Officer (RSO) Authority and Responsibilities [07-.17]

- a. Licensee and RSO has agreement, in writing, granting RSO authority to implement radiation protection program [07-.17(2)] yes ` no
- b. Licensee shall establish the authority, duties, and responsibilities of the RSO in writing. [07-.17(5)] yes ` no
- c. Records retained of signed RSO written agreement and duties [07-.82(2)] yes ` no
- d. Has licensee provided RSO sufficient authority, time, and resources to identify radiation safety problems, and provide and implement corrective actions as necessary. [07-.17(7)] yes ` no

3. Summary of Licensed Program (Use and Possession)

- a. Quantity and Identity of Material present at facility: _____

(1) Does a. above agree with the license? [L.C. 6,8,9,10] yes ` no
- b. Number and Type of procedures/patients per month: _____

- c. Any changes to the room or room shielding? yes ` no.

4. Training of Personnel [04-.12, 05-.56, and 07-.21] [L.C.____]

Operators of HDR Afterloader

- a. Does licensee initial training to all operators include: **yes** **no**
 ___ Radiation protection and instrumentation
 ___ Proper use of personnel dosimeters
 ___ Proper use of survey instruments
 ___ Proper use of radiation monitors
 ___ Operating and Emergency procedures
 ___ Use of device and safety system
- b. Annual refresher training **yes** **no**
- c. Training records maintained? [07-.54(1)(b)] **yes** **no**
- d. Training records required under 07-.96 contain: **yes** **no**
 ___ List of topics covered ___ Names of attendees
 ___ Date of the instruction ___ Names of individuals who provided instruction

Auxiliary Personnel Training

- e. Auxiliary Personnel (janitorial staff, etc.)
 received initial and refresher training [04-.12] **yes** **no**
- f. Training Records maintained? [L.C.____] **yes** **no**

Declared Pregnant Worker Training [05-.56] NA

- g. Are workers informed/trained as to policy? **yes** **no**
- h. Are declaration of pregnancy records maintained? [05-.135(6)] **yes** **no**

5. Written Directive Requirements [07-.21]

- a. Written procedure available for verifying patient's identity? [07-.21(1)] ... **yes** **no**
- b. Written directive procedure in accordance with 07-.21(2)? **yes** **no**
 ___ Verifying the identity of the patient
 ___ Verifying that the administration is in accordance with the written directive
 ___ Checking both manual and computer-generated dose calculations
 ___ Verifying that any computer-generated dose calculations are correctly
 transferred into the consoles of the therapeutic medical units
- c. Copy of written directive from the authorized user maintained? [07-.20(4)] **yes** **no**
- d. Written directives for HDR Afterloader therapy contain: [07-.20(2)(e)] ... **yes** **no**
 ___ Patient's name ___ Dose per fraction
 ___ Radionuclide used ___ Number of fractions
 ___ Treatment site ___ Total dose
 ___ Authorized user's signature and date [07-.20(1)]

Section II. Physical Inspection

1. Posting and Labeling [04-.11, 05-.111, & 05-.113]

- a. Are all areas posted appropriately? (CRM, CRA, CHRA) yes no
 - Door to the treatment room (CHRA)
 - Door to the storage room (CRA)
- b. Is RHS 8-3 posted? [04-.11(3)] yes no
- c. Is a notice stating where to find the license and regulations posted? yes no
- d. Is HDR labeled: [05-.113] yes no
 - CRM Activity or Quantity
 - Isotope Present Date for which the activity is estimated

2. Physical Location of HDR [L.C. ____]

- a. Is HDR located as shown on diagram in license? [application item 13] .. yes no
- b. Equipment identification:

Manufacturer's name _____	Radionuclide _____
Model number _____	Source activity _____
Serial number _____	Source serial no. _____

3. Standard Safety Precautions [07-.64, .66, .67]

- a. Before a patient is released, are surveys performed of both the patient and the HDR device to confirm that the source has been returned to the device? [07-.64(1)] yes no
- b. Records maintained of release survey above? [07-.64(2)] yes no
- c. Records required under 07-.64(2) contain: [07-.97] yes no
 - Date of survey
 - Results of survey
 - Survey instrument used
 - Name of individual who performed the survey
- d. Is the HDR, the console, the console keys and the treatment room when not in use or unattended, secured? [07-.66(1)(a)] yes no
- e. Only patient in the room during treatment? [07-.66(1)(b)] yes no
- f. Means to prevent dual operation of HDR and any other device (i.e., accelerator)? [07-.66(1)(c)] yes no
- g. Door to treatment room interlocked? [07-.67(2)] yes no
(Electrical interlock, not mechanical)
- h. After door interlock is tripped, source can only be exposed from the console? (Not just by closing the door to the room) [07-.67(2)(c)] yes no
- i. Appropriate radiation monitors available to determine a return of ambient level of radiation before any individual enters the treatment room? [07-.67(3)] yes no

(This can be a portable meter or a wall mounted detector, e.g. "Prime Alert")

- (1) If the system above is a wall mounted system: [L.C. _____]
- (i) Does the radiation monitor have a visible indication of radiation present? **yes** no
 - (ii) Is that indicator observable to anyone entering the room? **yes** no
 - (iii) Does the monitor have a back-up power supply? **yes** no
 - (iv) Is there a daily check with a check source of the monitor? **yes** no
 - (v) Records of the daily source check? **yes** no
- j. Treatment room equipped with audio and video systems? [07-.67(4)] . . . **yes** no
- k. Authorized User and Authorized Medical Physicist present during treatment? [07-.67(6)(b)] **yes** no
- l. RSO and authorized user notified as soon as possible if patient has a medical emergency? [07-.67(6)(d)] **yes** no
- m. Emergency response equipment available near treatment room? [07-.67(7)] **yes** no
- n. Sources in storage secure? (05-.100) **N/A** **yes** no

4. Emergency Procedures [07-.66]

- a. Emergency procedures available? [07-.66(1)(d) and 07-.102] **yes** no
- b. Emergency procedures include: [07-.66(1)(d)] **yes** no
 - ___ Instructions for responding to equipment failures
 - ___ The names of individuals responsible for implementing corrective actions
 - ___ The process of restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
 - ___ The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit operates abnormally
- c. Emergency procedures located at the operator's position? [07-.66(2)] . . **yes** no
- d. All operators of the HDR provided instruction on emergency procedures? **yes** no
 - ___ Initial instruction [07-.66(4)(a)]
 - ___ Annual refresher
- e. Drills of the emergency procedures performed annually? [07-.66(5)] . . . **yes** no
- f. Everyone participates in the drill of the emergency procedures? [07-.66(5)] **yes** no
 - ___ Operators
 - ___ Authorized Medical Physicists
 - ___ Authorized Users

5. Dosimetry Equipment [07-.68]

- a. Does the licensee have a calibrated dosimetry system? [07-.68(1)] **yes** no
- b. Calibration system calibrated by calibration laboratory accredited by the AAPM or published

- protocols accepted by nationally recognized bodies? [07-.68(1)(a)] **yes** **no**
- c. System calibrated within the last two years? [07-.68(1)(b)] **yes** **no**
- d. Records of calibration of the dosimetry system maintained? [07-.68(3)] **yes** **no**
- e. Calibration records include: [07-.103(2)] **yes** **no**
 - Date of calibration
 - System manufacturer name, model number and serial number
 - Correction factor determined by the calibration
 - Name of individuals who performed the calibration

6. Calibration of HDR [07-.70]

- a. HDR calibrated quarterly or after source change? [07-.70(1)(c)] **yes** **no**
- b. Records of calibration maintained? [07-.70(9)] **yes** **no**
- c. Calibration records include: [07-.104(2)] **yes** **no**
 - Date of Calibration
 - HDR manufacturer name, model number and serial number
 - Results of the calibration
 - Signature of the authorized medical physicist who performed the full calibration

7. Spot Checks [07-.73]

- a. Spot check performed daily? [07-.73(1)(a)] **yes** **no**
- b. Written spot check procedures developed by the authorized medical physicist available? [07-.73(2)] **yes** **no**
- c. Authorized medical physicist reviews the results of the spot check and reports in writing to the licensee the results of the spot check? [07-73(3)] **yes** **no**
- d. Records of spot checks maintained? [07-.73(6)] **yes** **no**
- e. Spot check records include: [07-.106(2)] **yes** **no**
 - Date of the spot check
 - HDR manufacturer name, model number, and serial number
 - An assessment of the timer accuracy
 - Notations indicating the operability of:
 - Door interlock
 - Source exposure indicator lights
 - Radiation monitors
 - Viewing and intercom systems
 - Clock and decayed source activity in the unit's computer system
 - The name of the individual who performed the spot check
 - The signature of the authorized medical physicist who reviewed record of spot check

8. Acceptance Testing of Therapy-Related Computer Systems [07-.78]

- a. Does the licensee perform or verify acceptance testing on the treatment planning system? [07-.78(1)] **yes** **no**

b. Does the licensee maintain documentation of this testing? [07-.78(1)] . . yes no

9. Facility Surveys [07-.76]

At the HDR

- a. Surveys performed to ensure radiation levels at the surface of the main source safe is within limits of the SS and D? [07-.76(1)] yes no
- b. Surveys performed at each new source installation? [07-.76(2)] yes no
- c. Records maintained of this survey? [07-.76(3)] yes no
- d. Survey record includes: [07-.109] yes no

- Date of the survey
- HDR manufacturer name, model number, and serial number
- Source identification
- Instrument used to measure radiation levels
- Each dose rate measured around the source while the unit is in the off position and the average of all measurements
- Allowable levels as stated in the SS and D registry (action limits) [07-76(1)]
- The signature of the individual who performed the survey

10. Inspector Surveys

Readings in $\mu\text{R/hr}$ or _____

Location	north wall	west wall	south wall	east wall
Room perimeter housing the HDR with source exposed MAXIMUM				
AVERAGE				
Maximum reading on surface of HDR		@		
Maximum reading outside source storage room (if applicable)		@		

Survey meter(s) used: Model _____ s/n _____ Cal date _____
 Model _____ s/n _____ Cal date _____

ROOM

HDR

Section III. Record Review

1. Personnel Exposure Records: [05-.135]

a. Supplier: _____

b. Dosimeter type: _____

c. Frequency of exchange _____ d. Badge results (in mRem): ↓

	Totals for year:		Totals for year:		Totals for year:		Totals for year:		Totals for year:	
	WB	Ring	WB	Ring	WB	Ring	WB	Ring	WB	Ring
Ave										
Max										

- e. Is every one badged? yes no
- f. Are badges returned on time? yes no
- g. Dose limits maintained? [5-.50] yes no
- h. Exposures estimated for missing badges? NA yes no
- i. All badge records present? yes no
- j. Control badge maintained in proper area? yes no
- k. Reports reviewed by (name and title) _____
- l. Attempt to obtain employee's radiation exposure from other facilities? [05-.133(1)(b)] NA yes no

2. Radiation Safety Committee [07-.17(6)] [L.C. _____]

- a. Do they have a RSC? (if required by 07-.17(6)) yes no
- b. Meetings held at least every 6 months? [07-.17(8)] yes no
- c. Do the minutes show:
 - ____ Date
 - ____ Members present
 - ____ Members absent
 - ____ Summary of discussions [07-.82(3)] ... yes no

3. Internal audits or inspections [05-.40] [L.C. _____]

- a. Audits or inspections are conducted? [05-.40] yes no
- b. Records maintained? [05-.131] yes no

4. Receipt and Disposal Records [10-.26(1)]

- a. Are sealed source receipt and disposal records maintained? yes no

5. Leak tests [07-.32] [L.C. _____]

- a. Sealed sources leak tested not greater than 6 month intervals?[07-.32(2)(a)] yes no
- b. Records maintained [07-.111(1)] yes no
- c. Dates/Sources: _____

-
- d. All Leak test results reported less than 0.005 μ Ci or <185 Bq? [07-.32(3)] **yes** **no**
 - e. Leak tests records under 07-.111(1) contain: **yes** **no**
 - ___ Model number of the source
 - ___ Serial number of the source (if one has been assigned)
 - ___ Identity of the source by radionuclide
 - ___ Estimated activity
 - ___ Results of the test
 - ___ Date of the test
 - ___ Name of the individual who performed the test

6. Survey Meter Calibration (annually) [07-.29] [L.C.____]

- a. Type & Model: _____ Last Cal Date: _____
- b. Current Calibration? [07-.29(1)] **yes** **no**
- c. Calibration date affixed to meter? [07-.29(2)(c)] **yes** **no**
- d. Calibrations performed annually? [07-.29(1)] **yes** **no**
- e. Calibration records maintained? [07-.29(4) and 07-.88] **yes** **no**
- f. Calibration records required by 07-.29(1) contain: [07-.88] **yes** **no**
 - ___ Model and serial number of the instrument
 - ___ Date of the calibration
 - ___ Results of the calibration
 - ___ Name of the individual who performed the calibration
- g. Daily operational check? **yes** **no**

7. Emergency Procedures Training

- a. Records of initial and annual refresher training on emergency procedures? [07-.66(6)] **yes** **no**
- b. Records include: ___ List of topics covered [07-.96]
 ___ date of the instruction
 ___ names of the attendees
 ___ name of individual providing the instruction . . . **yes** **no**

8. Records of Installation

- a. Does licensee have records of installation of HDR unit and subsequent source change outs? [07-.65(1)] **yes** **no**
- b. Does each record include: [07-.101]
 ___ Date of service

____ Description of service
 ____ Name(s) of individual(s) who performed the work yes no

9. Dose to Member of the Public

- a. Determination performed? [05-.60] yes no
- b. Records maintained? [05-.136] yes no

10. Misadministrations [05-.145] and Incidents [05-.141] N/A

- a. Any reportable misadministrations or incidents? yes no
(If 'yes', describe in Section IV. 2. Below)
- b. Records maintained? N/A yes no
- c. Spot check review patient records to check prescribed vs. actual dose? yes no
- d. Remind facility of the definition and reporting requirements
 for therapeutic misadministration? Yes no

Section IV. General Inspection Requirements

1. Non-Standard requirements and license conditions not addressed elsewhere N/A

2. Incidents, Overexposures, Theft or Loss, Equipment Malfunction [05-.140 & 05-.141] N/A
 (Those not described elsewhere should be reported here)

3. General Observations

4. Inspection History Violations from previous inspections:

License condition or Reg requirement	Violation	Corrective action taken (y/n)	Status

5. Exit Interview/non-compliance summary

License condition or Reg requirement	Violation	Corrective action taken (y/n)	Paragraph in which it is discussed

Records to Review

- Radiation Safety Committee Meetings (semi-annually)
- Sealed source inventory (6 months)
- HDR Calibration Records
- Emergency Procedures

- Survey instrument calibrations (annually)
- Receipt and disposal records
- Leak tests of sealed sources (6 months)
- Personnel monitoring records
- Licensee/RSO agreement and responsibilities
- Declared Pregnant Workers
- Declared Pregnant Worker Training
- Employee Training / Auxiliary Personnel Training
- Operating Procedures
- Internal/Annual Audit (annual)
- Misadministrations
- Patient Release Surveys [07-.64]
- Written Directive Procedures
- License
- State Regulations
- Operating and Emergency Procedures

Definitions:

0400-20-07-.05(14): **“Low dose-rate remote afterloader”** means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

0400-20-07-.05(19): **“Medium dose-rate remote afterloader”** means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

0400-20-07-.05(13): **“High dose-rate remote afterloader”** means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

Regulation Bibliography for High Dose Afterloader

(all reg references preceded by SRPAR 400-20-)

Chapter 4

04-.11 Posting of Notice to Employees

04-.12 Instruction to Workers

Chapter 5

05-.40 Radiation Protection Programs

05-.50 Occupational Dose Limits for Adults

- 05-.56 Dose to an Embryo/Fetus
- 05-.111 Posting Requirements
- 05-.131 Records of Radiation Protection Program
- 05-.133 Determination of Prior Occupational Dose
- 05-.135 Records of Individual Monitoring Results
- 05-.140 Reports of Theft or Loss of Licensed Material
- 05-.141 Notification of Incidents
- 05-.145 Notifications, Records and Reports of Misadministration

Chapter 7

- 07-.05 Definitions
- 07-.13 License Amendments
- 07-.17 Authority and Responsibilities for the Radiation Protection Program
- 07-.21 Procedures for Administrations Requiring a Written Directive
- 07-.29 Calibration of Survey Instruments
- 07-.32 Requirements for Possession of Sealed Sources and Brachytherapy Sources
- 07-.63 Use of a Sealed Source in a Remote Afterloader Unit
- 07-.64 Surveys of Patients Treated With a Remote Afterloader Unit
- 07-.65 Installation, Maintenance, Adjustment and Repair
- 07-.66 Safety Procedures and Instructions for Remote Afterloader Units
- 07-.67 Safety Precautions for Remote Afterloader

Units

- 07-.68 Dosimetry Equipment
- 07-.70 Full Calibration Measurements on Remote Afterloader Units
- 07-.73 Periodic Spot-Checks for Remote Afterloader Units
- 07-.76 Radiation Surveys
- 07-.78 Therapy-Related Computer Systems
- 07-.82 Records of Authority and Responsibilities for Radiation Protection Programs
- 07-.88 Records of Radiation Survey Instrument Calibration
- 07-.96 Records of Safety Instruction and Training
- 07-.101 Records of Installation, Maintenance, Adjustment and Repair of Remote Afterloader Units
- 07-.102 Records of Safety Procedures
- 07-.103 Records of Dosimetry Equipment
- 07-.104 Records of Remote Afterloader Full Calibrations
- 07-.106 Records of Periodic Spot-Checks for Remote Afterloader Units
- 07-.109 Records of Surveys of Therapeutic Treatment Units
- 07-.111 Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources

Chapter 10

- 10-.26 Records

REVISIONS

- 1 Revise misadministration section 12/6/12
- 2 Change Section I, 4., c. "L.C._____" to 07-.54(1)(b)
Add Section I, 4., d, and change under 4.: d to e, e to f, f to g, g to h.
Add Section II, 2., b 03/2013

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