

HDR GUIDE

INFORMATION REQUIRED FOR LICENSING REMOTE AFTERLOADING DEVICES

NOTE: This document assumes that you have a medical license (of limited scope or broad scope license) and you wish to amend your license to permit the use of a remote afterloading device. Accordingly, it is not necessary to submit information about calibration of survey instruments, radiation safety committee, personnel monitoring program, leak testing and ALARA program, unless any of these prior commitments change because of this amendment request. Address these changes in your amendment request.

I. Description of the Source(s) and Device(s)

A. Source description*

1. Provide Sealed Source and Device Registry Number**:
2. Radionuclide:
3. Manufacturer's name and model number:
4. Maximum activity (please note this proposed limit may trigger Increased Controls over the security of radioactive materials):
5. Activity per source:
6. Number of sources:

B. Device description

1. Provide Sealed Source and Device Registry Number**:
2. Manufacturer's name and model number:

II. Intended Use (35.600)

The typical response is "As per the Sealed Source and Device Registry." Any other intended uses, such as "non-human use," should be described.

*If you wish to possess and use more than one radionuclide in the device, provide the information in 1-6 for each radionuclide.

**The supplier can tell you if either the device or the source(s) you propose to use within the device has not had a health and safety review by either the NRC, an Agreement State or a Licensing State (i.e., is not listed in the NRCSS "National Registry of Radioactive Sealed Sources and Devices"). If the review has not been conducted, please contact the Radiologic Health Branch for guidance.

III. Proposed Users (35.690)

If a physician is currently a 35.600 (HDR) authorized user on this license or is authorized to perform HDR procedures on another California, NRC, Agreement State or Licensing State RAM license, provide a complete copy of the license and skip this section.

A. For each proposed Authorized User (AU) submit the following:

1. The AU Physician's full name and
2. RH 313 (AU)

B. For each Authorized Medical Physicist (AMP) submit the following:

1. The AMP's full name and
2. RH 313A (AMP)

IV. Training for Individuals (35.610)

A. Confirm that the manufacturer will provide initial training to all individuals who operate the unit. Subsequent training to individuals who operate the unit may be given by the manufacturer, authorized user or medical physicist trained by the manufacturer and using manufacturer's training outline. Initial and annual training will be commensurate to the individual's assigned duties in operating procedures and emergency situations.

B. If you will be performing your own source exchange, describe additional training provided to individuals who will conduct source exchanges, including operating procedures.

C. Confirm that annual refresher training that includes drills of emergency procedures for operators, authorized medical physicists and authorized users will be performed.

D. Confirm that all training records will be documented for inspection purposes.

V. Facilities (35.610, 35.615)

A. Submit descriptive drawing(s) of each treatment room* indicating:

*If the licensee is installing the HDR afterloader unit in an existing approved linear accelerator (megavoltage) vault submit the "Authorization to Treat" letter that was provided by the branch and omit items 1-4 below.

*1. Scale,

*2. Type, density and thickness of all shielding walls, floor, ceiling,

- *3. Location of entrance, windows, conduits, etc.,
 - *4. Direction of North,
 5. Identification of room,
 6. Nature of and distance to adjacent areas,
 7. Use of adjacent areas (designate restricted areas) and name of room, and
 8. HDR operating position
- B. Describe Continuous Viewing and Audible Communication System For Each Treatment Room
1. Primary, and
 2. Backup if primary system fails, or confirm that treatments will be halted.
- C. Describe Area Security For Each Treatment Room
1. Describe Electronic Interlocks,
 2. Restricted area(s) controls (e.g., signs, locks, alarms, lights, etc.),
 3. If other radiation-producing devices are in the room, means of assuring and confirm that only one device will be in operation at a time,
 4. Means of verifying source in “safe” condition (e.g., permanently installed radiation monitor), and
 5. Confirm that, once tripped, the entry interlock must be reset before activation of device.
- D. Describe Permanently Installed Radiation Monitor
1. Confirm that the monitor is visible upon entry,
 2. Describe back-up power supply,
 3. Confirm that the monitor will be promptly replaced or repaired if needed, and
 4. Describe the operability check of the monitor including its frequency.
- E. Provide Shielding Evaluations, Calculations, Safety Measures For Each Treatment Room

*If the licensee is installing the HDR afterloader unit in an existing linear accelerator (megavoltage) vault, theoretical calculations (items 1-3 below) may

not be required. Submit proof of approval from the Department or County Health Agency regarding the approval of the linear accelerator.

1. Estimate of maximum "on-time" per hour and per week, and
2. Calculation of exposure rate in each adjacent area with most adverse source orientation(s) and source combinations.
3. For unrestricted areas, the licensee must meet the criteria below:

"Occupancy factor" is used as in NCRP Report No. 49: a factor used to correct for the degree of occupancy of the area in question while the source is in the exposed position.

- a. With "on-time" considered and an appropriate "occupancy factor":
 - i. < 2 mR in any 1 hour, AND
 - ii. < 100 mR in 1 year
4. For restricted areas, describe the following:
 - a. Physical/administrative control of access,
 - b. Signs: Location, number, wording,
 - c. Personnel monitoring, and
 - d. Surveys (state instrument type and model number) of patient

VI. Operating Procedures (35.610)

A. You need not provide a copy of procedures but at minimum, confirm the following:

1. Have implemented written operating procedures.
2. Copies shall be located at HDR unit console.
3. Procedures include:
 - a. Require securing unit, console and room when unattended.
 - b. Require that only individuals approved by the RSO or AMP be allowed with the patient in the room with device activated.
 - c. Require that the AU and AMP be physically present during the initiation of treatment.

- d. Require that the AMP and either the authorized user or a physician, under the supervision of an AU, who has been trained, provide continuing on-site supervision of the HDR operator during treatment.
 - e. Require that an individual who has been trained by the manufacturer in HDR Afterloader operations and emergency procedures provide direct supervision (physically present) over the treatment (can be trained AU, medical physicist or operator).
 - f. Require that immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of each survey shall be maintained.
4. Periodic spot checks as required by 35.643 will be performed, documented and will include checks of:
- a. Reproducibility of source positioning within catheter within +1 mm,
 - b. Verification of source position indicators (e.g., lights, alarms, room monitor),
 - c. Inspection of guide tubes for kinks and other imperfections,
 - d. Electrical interlocks,
 - e. Viewing and intercom system,
 - f. Emergency response equipment,
 - g. Timer accuracy,
 - h. Clock in units computer, and
 - i. Decayed source activity in unit's computer.
5. Full calibration as required by 35.633 will be performed, documented and will include checks of:
- a. Dose accuracy to within +/- 5 percent,
 - b. Source positioning within +/- 1 millimeter,
 - c. Source retraction in event of power failure,
 - d. Length of source transfer tubes,
 - e. Accuracy of timing device and linearity,

- f. Length of applicator, and
 - g. Function of source transfer tubes, applicators and interfaces.
 - B. Confirm that your dosimetry system will be calibrated by NIST or AAPM approved lab every 2 years.
 - C. Source Exchange (35.652)
 - 1. Confirm that the following will be performed:
 - a. Surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
 - b. Perform the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
 - D. Preventative Maintenance (35.605)
 - 1. Confirm that the manufacturer's recommended preventative maintenance schedule will be followed.
 - 2. Confirm that only the manufacturer or those individuals specifically licensed by the NRC, Agreement State or Licensing State to perform HDR preventative maintenance or repairs will be utilized and maintaining the records. Otherwise, submit the qualifications and training of the individual who will perform HDR preventive maintenance or repairs.

VII. Emergency Procedures (35.610)

- A. Confirm that emergency procedures will be located near the unit console. You do not need to submit the procedures but at a minimum, your procedures should include:
 - 1. When the procedures are to be followed,
 - 2. Step-by-step actions and by whom (including their title) these actions are to be taken,
 - 3. Minimizing patient exposure,
 - 4. Requirement to secure area; posting warning notice,
 - 5. List of names and on-duty/off-duty telephone numbers of at least 2 trained

individuals to be notified, and

6. A list of on-site emergency equipment that includes at least a lead container and forceps (wire cutters are optional).

NOTE: Manufacturers are now recommending that wire cutters not be used because of the problem with the source being cut. They now recommend putting the source while attached to the cable into the shielded container until the manufacturer rep arrives to handle the problem.

VIII. Human Use

- A. Once an amendment has been issued for physical measurements, the licensee may receive the source and perform physical measurements. Prior to human use, the licensee must submit:
 1. Physical measurements survey results,
 2. Instrument used for performing survey (ion chamber or energy-compensated GM probe),
 3. Date of last instrument calibration,
 4. Interlock check result,
 5. Alarm monitor check result, and
 6. How roof access is restricted to members of general public (if applicable).

Note: If the licensee has submitted an "Authorization to Treat" letter, is replacing an existing HDR with a new model, or is applying for service to be provided by an HDR service company that is licensed to do on site pre-licensing surveys and checks, the license may be issued for human use with a confirmation from the licensee that the above surveys and checks will be performed, confirmed satisfactory and documented for inspection prior to performing any human use treatments.

REFERENCES

1. Gammamed 12it NRC Sealed Source and Device Registry MA-1056-D-101-S.
2. Nucletron SEL 106 NRC Sealed Source and Device Registry NR-497-D-101-S.
3. Nucletron MicroSelctron HDR-Classic NRC Sealed Source and Device Registry MD-0497-D-104-S.
4. Varian Varisource HDR NRC Sealed Source and Device Registry CA-0661-D-103-S.
5. NRC FC 86-4, Rev. 1 (Draft)
6. 10 CFR 35