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Regulation for Photon Emitting *High dose-rate Remote afterloader* Units (HDR) 高劑量率遙控後荷式治療機

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Varian HDR Remote Afterloader

Nucletron HDR Remote Afterloader

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Definition of HDR

Defined as a brachytherapy (device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

This device, (or any device used to treatment patient) must be FDA approved device.

FDA-Food and Drug Administration

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Use of a sealed source in a remote afterloader unit

A licensee shall use sealed sources in photon emitting remote afterloader units, for therapeutic medical uses:

- (a) As approved in the Sealed Source and Device Registry; or
- (b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

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Surveys of patients after treatment

Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

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Installation, maintenance, adjustment, and repair

(1) Only a person specifically licensed by the Commission shall install, maintain, adjust, or repair a remote afterloader unit, that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(2) Only a person specifically licensed by the Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units.

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Safety procedures and instructions

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position with controls from outside the treatment room.

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Safety procedures and instructions

(5) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties,

(6) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

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Safety Precautions

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will prevent start of treatment unless door is closed and couse source to retract if door is open.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

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Safety Precautions

(4) A licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) A licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

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Safety Precautions

(6) An authorized user and an authorized medical physicist must be physically present during the initiation of all patient treatments involving the unit; and

(7) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, must be physically present during continuation of all patient treatments involving the unit.

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Safety Precautions

(8) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(i) Remaining in the unshielded position; or

(ii) Lodged within the patient following completion of the treatment.

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Dosimetry equipment

A licensee shall have a calibrated dosimetry system available for use.

The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration;

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Full calibration measurements

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate;

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Full calibration measurements

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

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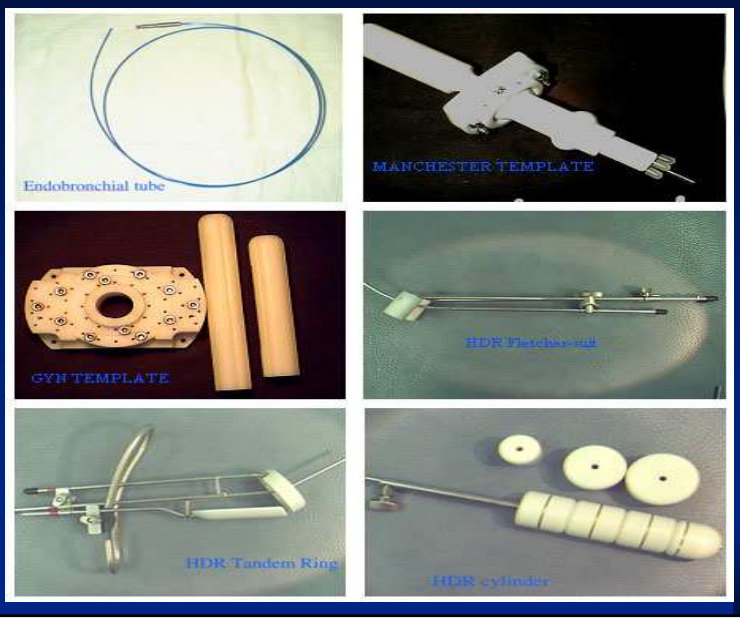

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Full calibration measurements

(c) A licensee shall use the dosimetry system to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) A licensee shall mathematically correct the outputs determined for physical decay at intervals consistent with 1 percent physical decay.

(g) Full calibration measurements must be performed by the authorized medical physicist.

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Periodic spot-checks

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit—

(1) Before the first use of a high dose-rate unit on a given day;

(2) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

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Periodic spot-checks

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of—

(1) Electrical interlocks at each remote afterloader unit room entrance;
(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(3) Viewing and intercom systems in each high dose-rate remote afterloader facility;
(4) Emergency response equipment;
(5) Radiation monitors used to indicate the source position;
(6) Timer accuracy;
(7) Clock (date and time) in the unit's computer; and
(8) Decayed source(s) activity in the unit's computer.

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Periodic spot-checks

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check.

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Mobile remote afterloader units

(a) A licensee providing mobile remote afterloader service shall—

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

Mobile remote afterloader units

(b) In addition to the periodic spot-checks required, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of—

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

Mobile remote afterloader units

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check.

Radiation surveys

(a) A licensee shall make 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. (normally less than 1mR/hr)

(b) The licensee shall make 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).

(c) A licensee shall retain a record of the radiation surveys.

Therapy-related computer systems

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

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Training for use of HDR

Training requirement for Authorized User—Radiation Oncologist

Training requirement for Authorized Medical Physicist

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NRC FORM 313A (AMP)

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

http://www.nrc.gov/materials/miau/med-use-toolkit.html

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