

MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore Maryland 21230
 (410) 537-3193 • 1-800-633-6101 • http://www.mde.state.md.us

MDE RX 11A

MACHINE DATA
THERAPEUTIC
1 MEV OR GREATER

MDE Machine Number / Tube S.N. _____

Facility Registration Number - Facility Name _____

Begin Inspection / /
 mm dd yy Inspector License No. _____

Type of equipment _____ Year & Model _____

Maximum Output Intensity _____ Type of Use _____

Peak Energy _____

Regulation Number	Requirement for Equipment	Pass (P), Fail (F), or Not applicable (NA)
F.9(b)(1)	Leakage radiation to patient area does not exceed accepted dose.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(2)	Leakage radiation outside the patient area for new equipment does not exceed accepted dose.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(3)	Adjustable/interchangeable beam limiting device provided.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(4)(i)	Removable filters are clearly marked and documentation is available at control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(4)(iii)	(a) Irradiation is not possible until selection of filter is made.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
	(b) Interlock system provided.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
	(c) Display at control shows filter in use.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(5)	Beam quality.	
	(i) Absorbed dose shall not exceed values stated in Table III. (iii) Absorbed dose at surface shall not exceed limits stated in Table IV.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A <input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(6)	System has radiation detectors in the radiation head, and they meet the requirements of F.9(b)(6)(i)-F.9(b)(6)(iii).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(7)	Beam symmetry.	
	If difference in dose rate between two symmetrically displaced regions from the central axis exceeds 5 percent, indication is made at control panel. If the difference exceeds 10 percent, irradiation is terminated.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A <input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(8)	Selection and display of dose monitor. Meets requirements of F.9(b)(8)(i)-(iv).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(9)	Termination of irradiation by the dose monitoring system or systems during stationary beam therapy. Meets requirements of F.9(b)(9)(i)-(iv).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(10)	Interruption switches available at control panel, for use at any time during irradiation.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
	Following interruption, it is possible to restart irradiation w/o reselection.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(11)	Termination switches at control panel.	<input type="checkbox"/> Yes <input type="checkbox"/> No
F.9(b)(12)	Timer meets conformance standards in F.9(b)(12)(i)-(iv).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(13)	Selection of radiation type.	
	Interlock system meets conformance standards in F.9(b)(13)(i)-(vi).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A



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Regulation Number	Requirement for Equipment	Pass (P), Fail (F), or Not applicable (NA)
F.9(b)(14)	Selection of energy: Irradiation not possible w/o selection of energy. Interlock system provided. Selection displayed at control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(15)	Selection of stationary beam therapy or moving beam therapy: Interlock system in conformance. Mode of operation displayed at control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(16)	Absorbed dose rate can be calculated from readings. Dose monitor unit rate displayed.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(17)	Location of virtual source and beam orientation determined.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(b)(18)	Capability for all radiation safety interlocks to be checked for correct operation.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Facility and Shielding Requirements</u>		
F.9(c)(1)	Protective barriers fixed.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(c)(2)	Control panel located outside treatment room.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(c)(3)	Viewing systems to permit continuous observation in conformance (on line, not just "available").	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(c)(4)	Provision made for two-way aural communications.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(c)(5)	Warning lights near outside of all access doors to indicate when the useful beam is "on."	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(c)(6)	Entrance interlocks provided such that all entrances must be closed before treatment can begin or continue.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
D.601(d)	The controls required by D.601a. and c. do not prevent individuals from leaving a high radiation area.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Surveys</u>		
F.9(d)(1)(i)	Surveys when required made under direction of a qualified expert.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(1)(ii)	Written report of the survey shall be transmitted to the Agency within 30 days of receipt of report. Any violations should be noted.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(1)(iii)		<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Calibrations</u>		
F.9(d)(2)(i)	System calibrated at least once per year or as required.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(ii)	Calibration performed under direct supervision of a radiological physicist who is physically present at the facility during calibration.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(iii)	Calibration radiation measurements performed as required.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(iv)		<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(v)		<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(vi)	Calibration records maintained for 5 years.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(2)(vii)	A copy of the latest calibrations shall be available at the control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Spot Checks</u>		
F.9(d)(3)	Spot checks shall be performed at least once per month.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(i)	Spot check procedures shall be in writing and shall have been developed by a radiological physicist.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(ii)	If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within 15 days.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(iii)	The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(iv)	At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A



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F.9(d)(3)(v)	Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(vi)	The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(vii)	Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated as required in F.9(d)(2).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(viii)	Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for a period of 2 years after completion of the spot check measurements.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(3)(ix)	Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of F.9(d)(2)(iii) or which has been intercompared with a system meeting those requirements within the previous year.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Operating Procedures</u>		
F.9(d)(4)(i)	No individual other than the patient shall be in the treatment room during treatment of the patient.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(4)(ii)	If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
F.9(d)(4)(iii)	The system shall not be used in the administration of radiation therapy unless the requirements of F.9(d)(1), (2), and (3) have been met.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.6(a)(1)	Operator has been instructed in radiation safety and shall have demonstrated an understanding thereof.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.6(a)(2)	Operator has received copies of and instruction in Part I and the applicable requirements of Parts D and J of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.6(a)(3)	Operator has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
<u>Particle Accelerator Controls and Interlock Systems</u>		
I.8(a)	Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.8(b)	Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.8(c)	Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.8(d)	All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.8(e)	When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.8(f)	A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A



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Regulation Number		Pass (P), Fail (F), or Not applicable (NA)
	<u>Warning Devices</u>	
I.9(a)	Each location designated as a very high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.9(b)	Except in facilities designed for human exposure, each very high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such very high radiation area. Such warning device shall be clearly discernible in all very high radiation areas.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.9(c)	Barriers, temporary or otherwise, and pathways leading to very high radiation areas shall be posted in accordance with D.902 of these regulations.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
	<u>Operating Procedures</u>	
I.10(a)	Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.10(b)	The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to comply with requirements of I.10(c).	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.10(c)	All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.10(d)	Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.10(e)	If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such actions shall be: (1) authorized by the radiation safety committee and/or radiation safety officer; (2) recorded in a permanent log and a notice posted at the accelerator control console; and (3) terminated as soon as possible.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A <input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A <input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.10(f)	A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
	<u>Radiation Monitoring Requirements</u>	
I.11(b)	There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation before each use and calibrated at intervals not to exceed 1 year and after each servicing and repair.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(c)	A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(d)	Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(e)	All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(f)	Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(g)	Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(h)	All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the Agency, or the radiation safety officer.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A
I.11(i)	Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Agency.	<input type="checkbox"/> P <input type="checkbox"/> F <input type="checkbox"/> N/A

