MARYLAND DEPARTMENT OF THE ENVIRONMENT
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MDE RX 8

FLUOROSCOPIC & SPOT IMAGING

MDE Machine Number ☐☐☐☐☐/☐ Tube S.N. _____

Facility Registration Number ☐☐ - ☐☐☐☐ Facility Name _____

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

Manufacturer _____ Model _____ (Mobile? Y/N) _____

Max. kVp, mA _____/_____ Max. Spot Film mA _____ Date Manufactured_____ C-arm (Y/N) _____

Are all the components subject to Federal Certification Standards? Y/N _____

MODE: (indicate all modes available) ☐ THERAPY SIMULATOR, ☐ MANUAL, ☐ AEC,
☐ HIGH LEVEL CONTROL, ☐ CINE, ☐ DSA, ☐ PULSE ___ Max. FPS

Regulation Number	Requirements for Fluoroscopic Procedures and Equipment	Pass (P), Fail (F) or Not Applicable (N/A)
F.5	All Fluoroscopic systems must be image intensified.	☐ P ☐ F ☐ N/A
F.5(f)	Minimum source to skin distance? Measured _____ cm/inch Shall not be less than: (1) 38cm on stationary systems manufactured on/after August 1, 1974. (2) 35.5cm on stationary systems manufactured prior to August 1, 1974. (3) 30cm on all mobile/portable units. (4) 20cm for units used for specific surgical applications. (5) For all systems manufactured on/after June 10, 2006: (i) 19cm for systems with a max SID <45cm (extremity use only) (ii) 10cm for systems used for surgical applications Mobile units specifically for imaging extremities are exempt from SSD limitations.	☐ P ☐ F ☐ N/A
F.5(f)(4)(ii)	If F.5(f)(4) is true, written safety procedures are adhered to and available for reference at all times. Indicate if F.5(f)(5) is true. Indicate if F.5(f)(6) is true.	☐ P ☐ F ☐ N/A ☐ true ☐ true
F.5(a)(1)	Primary Barrier (i) Protective barrier intercepts entire cross section of useful beam at any SID? (ii) X-rays not produced unless barrier in position to intercept entire useful beam?	☐ P ☐ F ☐ N/A ☐ P ☐ F ☐ N/A
F.5(d)(1)	Exposure rate transmitted does not exceed 2 mR/hour per R/min at 10 cm?	☐ P ☐ F ☐ N/A
F.5(a)(2)(i)	For certified systems manufactured before June 10, 2006, neither length nor width of x-ray field exceeds that of the visible area by more than 3% of the SID. _____% Length Error _____% Width Error Combined Error _____% (pass if not greater than 4%)	☐ P ☐ F ☐ N/A
F.5(a)(2)(ii)	For uncertified systems manufactured before June 10, 2006 with a spot film device, the x-ray beam shall be no larger than the largest spot film size.	☐ P ☐ F ☐ N/A
F.5(a)(2)(iii)	For uncertified systems manufactured before June 10, 2006 without a spot film device, neither length nor width of x-ray field exceeds that of the visible area by more than 3% of the SID. _____% Length Error _____% Width Error Combined Error _____% (pass if not greater than 4%)	☐ P ☐ F ☐ N/A

Regulation Number	Requirements for Fluoroscopic Procedures and Equipment	Pass (P), Fail (F) or Not Applicable (N/A)
F.5(a)(2)(iv)	(a) For devices manufactured after May 22, 1979 incorporated into systems with variable SID or visible area >300 cm^2, means shall be provided to further limit field or for stepless field size adjustment.	☐ P ☐ F ☐ N/A
	(b) For fixed SID and visible area <= 300 cm^2, means shall be provided for stepless adjustment or to further limit field to <= 125 cm^2.	☐ P ☐ F ☐ N/A
	(c) For stepless, X-ray beam at greatest SID is <= 5 cm x 5 cm.	☐ P ☐ F ☐ N/A
	(d) For devices manufactured after February 25, 1978, axis of x-ray beam indicates perpendicular to plane of image receptor?	☐ P ☐ F ☐ N/A
	(e) For non-circular fields, error in alignment determined along length and width which pass through center?	☐ P ☐ F ☐ N/A
F.5(a)(2)(v)	For systems manufactured on/after June 10, 2006, max area of field on image receptor: (a) If <=34cm in any direction, at least 80% of area of field overlaps visible area of image receptor.	☐ P ☐ F ☐ N/A
	or (b) If >34cm in any direction, field along direction of greatest misalignment does not exceed more than 2cm.	☐ P ☐ F ☐ N/A
F.5(a)(3)	For systems manufactured on/after June 10, 2006 with rectangular image receptors: (i) Neither length nor width of x-ray field exceeds that of the visible area by more than 3% of the SID. Sum no greater than 4% of the SID. _____% Length Error _____% Width Error Combined Error _____% (pass if not greater than 4%)	☐ P ☐ F ☐ N/A
	(ii) Error in alignment determined along length and width which pass through center of visible area?	☐ P ☐ F ☐ N/A
F.5(a)(4)	Spot - film beam limitation: (i) Adjustment of x-ray field between source and patient?	☐ P ☐ F ☐ N/A
	(ii) Neither length nor width of x-ray field exceeds that of the image receptor by >3% of the SID. _____% Length Error _____% Width Error Combined Error _____% (pass if not greater than 4%)	☐ P ☐ F ☐ N/A
	(iii) Min. field size at greatest SID <= 5 cm x 5 cm.	☐ P ☐ F ☐ N/A
	(iv) X-ray field centered within 2% of SID.	☐ P ☐ F ☐ N/A
	(v) Axis of x-ray beam indicates perpendicular to plane of image receptor?	☐ P ☐ F ☐ N/A
F.5(a)(5)	Override of automatic field size adjustments available?	☐ P ☐ F ☐ N/A
	If yes: (i) Designed for use only in event of system failure.	☐ P ☐ F ☐ N/A
	(ii) Visible signal at fluoroscopist's position in event of override.	☐ P ☐ F ☐ N/A
	(iii) Clearly and properly labeled.	☐ P ☐ F ☐ N/A
F.5(j)	Spot Film Exposure Reproducibility: F.6(d) Coefficient of variation of exposure not to exceed 0.10 when all technique factors are held constant. Four exposures: _____, _____, _____, _____ $\bar{E} \geq 5(Emax - Emin)$ F.6(g)(1) For certified systems only, estimated coefficient of variation of radiation exposures not to exceed 0.05 for any combination of selected technique factors.	☐ P ☐ F ☐ N/A
F.5(b)	X-ray production in fluoroscopic mode is controlled by a device which requires continuous pressure?	☐ P ☐ F ☐ N/A

Regulation Number	Requirements for Fluoroscopic Procedures and Equipment	Pass (P), Fail (F) or Not Applicable (NA)
Entrance Exposure Rate Limits (All measurements must be in R/min):		
F.5(c)(1)	Entrance exposure rate measured where useful beam enters the patient within limits?	☐ P ☐ F ☐ N/A
F.5(c)(1)	Systems manufactured before May 19, 1995, determined according to F.5(c)(1)(vii): (i) with AERC (limit = 10R/min) (i)(b) with AERC and high level control (limit = 5R/min) (ii) without AERC (limit = 5R/min) (ii)(b) without AERC, with high level control (limit = 5R/min) (iii) with AERC and manual mode (limit = 10R/min) (iii)(b) with AERC and/or manual mode, with high level control (limit = 5R/min)	
F.5(c)(1)(v)	Systems manufactured between May 19, 1995 and June 9, 2006, determined according to F.5(c)(1)(vii): (limit = 10R/min) (b) With high level control (limit = 20R/min)	
F.5(c)(1)(iv)	Have AERC if greater than 5R/min?	☐ P ☐ F ☐ N/A
F.5(c)(1)(vi)	Systems manufactured on/after June 10, 2006, determined according to F.5(c)(1)(vii): (limit = 10R/min) (b) With high level control (limit = 20R/min)	
F.5(c)(1)(v)(b)	Special means of activation of High Level control available.	☐ P ☐ F ☐ N/A
F.5(c)(1)(v)(b)	Continuous audible signal indicates that High Level control is engaged?	☐ P ☐ F ☐ N/A
F.5(c)(2)(ii)	Annual and required measurements of entrance exposure rate completed and posted?	☐ P ☐ F ☐ N/A
	Annual and required measurements of maximum entrance exposure rate completed and posted?	☐ P ☐ F ☐ N/A

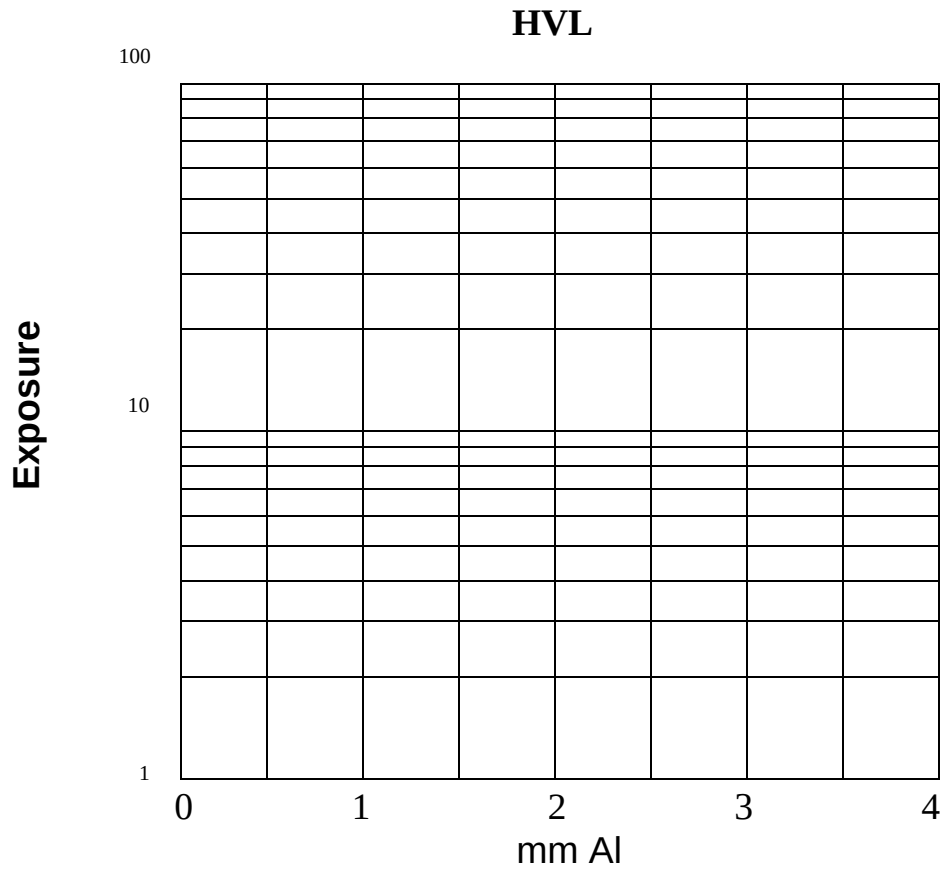
mA	kVp	kVp	kVp

mA	kVp	kVp	kVp

mA	kVp	kVp	kVp

Regulation Number	Requirements for Fluoroscopic Procedures and Equipment	Pass (P), Fail (F) or Not Applicable (NA)
F.5(e)	Tube potential (kVp) and current (mA) indicated continuously during fluoroscopy and cine?	☐ P ☐ F ☐ N/A
F.5(g)(1)	For systems manufactured before June 10, 2006: Means provided to preset cumulative on-time, not to exceed 5 minutes without resetting?	☐ P ☐ F ☐ N/A
	(i) Audible signal indicates completion of preset cumulative on-time; continue to sound until reset?	☐ P ☐ F ☐ N/A
	(ii) If no audible signal, x-rays terminate automatically?	☐ P ☐ F ☐ N/A
F.5(g)(2)	For systems manufactured on/after June 10, 2006: (i) Display at work station, functions independently of audible signal.	☐ P ☐ F ☐ N/A
	(a) Continuous display, updated at least once every 6 seconds.	☐ P ☐ F ☐ N/A
	(b) Time displayed w/in 6 seconds of terminations and remains until reset.	☐ P ☐ F ☐ N/A
	(c) Means provided to reset.	☐ P ☐ F ☐ N/A
	(ii) Audible signal for each passage of 5 minutes?	☐ P ☐ F ☐ N/A
	Audible signal until manual reset or 2 seconds for auto reset?	☐ P ☐ F ☐ N/A
F.5(h)	Mobile fluoroscope provided with image intensifier?	☐ P ☐ F ☐ N/A
F.5(i)	(1) Operator protected by at least 0.25mm lead equivalent protective apron?	☐ P ☐ F ☐ N/A
	(3) Agency sterile field exemption?	☐ P ☐ F ☐ N/A
F.5(k)	For equipment manufactured on/after June 10, 2006 shall have means to display Last-Image-Hold (LIH) following termination of exposure.	☐ P ☐ F ☐ N/A
F.5(l)	For equipment manufactured on/after June 10, 2006 AKR and cumulative air kerma to be displayed at workers console. (1) AKR in mGy/min continuously displayed, updated at least every 1 second	☐ P ☐ F ☐ N/A
	(2) Cumulative AKR displayed w/in 5 seconds of termination.	☐ P ☐ F ☐ N/A
	(3) AKR display clearly distinguishable from cumulative air kerma display	☐ P ☐ F ☐ N/A
	(4) Reference location identified and described according to F.3(a)(2)(vi)	☐ P ☐ F ☐ N/A
	(5) Means to reset display of cumulative air kerma to 0 prior to new procedure?	☐ P ☐ F ☐ N/A
	(6) Displayed AKR and cumulative air kerma not to deviate from actual values by more than +/-35% over 6mGy/min	☐ P ☐ F ☐ N/A
F.5(m)	Simulation systems exempt from F.5(a), F.5(c), F.5(d), and F.5(g) if: (1) Designed/used such that only patient is in x-ray room during exposures.	☐ P ☐ F ☐ N/A
	(2) Systems that do not meet F.5(g) indicate cumulative time of exposure.	☐ P ☐ F ☐ N/A
F.5(n)	User Qualifications (1) Energized only by licensed practitioner or radiological technologist.	☐ P ☐ F ☐ N/A
	Documentation of training available?	☐ P ☐ F ☐ N/A
	Training meets F.5(n)(2)?	☐ P ☐ F ☐ N/A
	(3) One hour of inservice training or continuing medical education available?	☐ P ☐ F ☐ N/A
	(6) Is registrant exempt from F.5(n)(1) through F.5(n)(4)? If yes, explain:	☐ Yes ☐ No

Regulation Number	Requirements for Fluoroscopic Procedures and Equipment	Pass (P), Fail (F) or Not Applicable (NA)
F.5(o)	(1) Fluoroscopic systems used as positioning tool for radiographic exams? (2) Facility demonstrated three-month in-house evaluation of fluoroscopic exposure times by procedure and licensed practitioner?	☐ Yes - F ☐ No - P ☐ P ☐ F ☐ N/A
Beam Quality:		
F.6(e)	kVp does not differ by more than 10% of indicated value? Set _____kVp Measured _____kVp Error _____%	☐ P ☐ F ☐ N/A
F.4(e)(1)	Half Value Layer: Required _____mm Al Measured _____mm Al kVp used _____ mA used _____ Max. kVp _____ Phototimer? _____(Y/N) Rate Mode? _____ _____ R/min	☐ P ☐ F ☐ N/A



EXPOSURE MEASURED				