DEPARTMENT OF HEALTH
Republic of South Africa

REQUIREMENTS FOR LICENCE HOLDERS WITH RESPECT TO QUALITY CONTROL TESTS FOR DIAGNOSTIC X-RAY IMAGING SYSTEMS

DEPARTMENT OF HEALTH

DIRECTORATE: RADIATION CONTROL

https://sites.google.com/site/radiationcontroldoh/

Implementation date: 31 March 2009

Contents

I. GENERAL REQUIREMENTS

THE LICENCE HOLDER SHALL:

A. Display the product licence number (see list of licences from Department of Health (**DoH**)) on equipment.
- See **table 1** (row c) for which equipment this is a requirement.

B. Compile an **Individual** Equipment Record (IER) containing the information as listed in **table1 (column 2)** (see also section VI).
- IER is for example a ring binder containing all the information as prescribed in table 1 for each piece of equipment.

C. Perform the prescribed Acceptance- and Quality Control (QC) tests listed in **table 2**:

C.1. As from 31 March 2009 an Inspection Body (IB) approved by the Department of Health (DoH) **OR** an appropriately trained professional registered with the HPCSA as a medical physicist (see C.2.) must be used to perform all the acceptance tests as well as the routine tests listed in section **III.2** of **table 2.**

C.2. If a medical physicist is used to perform the tests in C.1, an Inspection Body approved by the Department of Health (DoH) must formally contract such person(s). Formally contracted means that the medical physicist is contracted by the IB (ISO/IEC 17020 and TR78-01 par 14.2a) to perform the tests.
- List of IB's available at https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Inspection Bodies

D. Acquire the relevant quality control manuals **or** compile in-house written protocols, which describe each test step by step to ensure that QC tests listed in section III.1 of **table 2 are** correctly performed.

E. Ensure that persons that perform routine tests in section III.1 of **table 2** are competent to execute the tests;

F. Ensure that the required acceptance tests are performed before the diagnostic x-ray equipment listed in **table 2** is put into clinical service when:

F.1. Acquired or

F.2. Substantially upgraded.
- Acceptance tests are the initial tests performed directly after installation and before the equipment is being put into clinical service. Acceptance tests have three purposes, namely To ensure that the unit meets stated specifications; To establish baseline parameters for the future quality control program, and To familiarize the customer with operation of the unit.

G. Ensure that all the quality control tests are performed at the prescribed frequencies as specified in **table 2**.

G.1. QC tests may be performed more frequently than specified in table 2, influenced by the age, stability, make, model, etc., of the equipment.

H. Ensure that image display monitors and reporting monitors comply with the requirements in section **V** (Table 4) of this document.

I. Establish a program to ensure that the radiation dose administered to a patient for diagnostic purposes is optimised (see page 23 for definition of optimisation). Such program must at least use the measurements under tests 37, 76 and 146 to determine whether radiation protection has been optimised.

I.1. Measurements under tests 76 and 146 must be evaluated within 13 months after the x-ray unit is put into clinical service and thereafter every 36 months. Use reference 1.2, table 3 as well as inter unit comparisons. Should the licence holder have insufficient knowledge a medical physicist must be consulted.

I.2. Measurements under tests 37 must be evaluated within 13 months after the x-ray unit is put into clinical service and thereafter every 24 months. A medical physicist must be used for these evaluations. Documents under reference 1.2 can be used for this.

J. Keep a copy of the results of the tests mentioned in section f and g of table 1 for as long as the equipment is in use and ensure that the following information is available:

J.1. The measurements (raw data), Date of test(s), Summary of the results (pass or fail), Identification of product, Details of the person(s) that performed the tests, and Details of the Inspection Body.

II. TABLE 1 INDIVIDUAL EQUIPMENT RECORD (IER)[1] – (see also section VI)

		General Radiography Equipment	Processor & Hardcopy device	CR Reader	DDR System	Film Viewer	Reporting Monitor	Fluoroscopy Equipment	Computed Tomography Equipment	Mammography Equipment
a)	Unit - make, model and system ID	X	X	X	X			X	X	X
b)	Generator – make, model and serial number	X						X	X	X
c)	Product Licence number, date of the latest licence & reference where a copy of the licence is kept	X		X				X	X	X
d)	Date of installation	X	X	X	X	X	X	X	X	X
e)	Operator's manual – (Indication that the operator's manual is available and reference where it is kept)	X	X	X	X			X	X	X
f)	Results of acceptance tests	X	X	X	X		X	X	X	X
g)	Results of routine quality control tests	X	X	X	X	X	X	X	X	X
h)	Date(s) of tube replacement(s)	X						X	X	X
i)	Details of repairs/maintenance and/or modification(s). The licence holder must ensure that all the applicable test(s) are performed that could be affected by the aforementioned	X	X	X	X	X	X	X	X	X
j)	Should any of the tests in table 2 indicate non-compliance or should any problems be detected (indicated), the licence holder must implement corrective maintenance (repairs), followed by re-testing	X	X	X	X	X	X	X	X	X
k)	Details of the IB and person(s) that performed the test(s)	X		X	X	X	X	X	X	X

- Please note: The following documents can be used as guidance documents for purchasing of test equipment, namely reference 1, 3, 4, 5, 8, 10, 14, 15 and 21 or alternatively ask your Inspection Body.
- For guidelines on what tests should be performed for an application see section VII.
- For new equipment acceptance tests is the responsibility of the company that installed the equipment.

1 The **X** in each cell for each category of equipment (column 3 to 11), indicates which information must be available in the IER.

III. TABLE 2 ACCEPTANCE AND ROUTINE QUALITY CONTROL TESTS

	Physical parameter (required test)	Frequency	Standard	References
III.1. **Routine Tests in this section are to be performed by the licence holder or person(s) appointed by the licence holder and Acceptance Tests in this section must be performed by an Inspection Body approved by Department of Health.**				
III.1.1.	**General Tests**			
1.	Indicators, mechanical and other safety checks & warm-up	On acceptance & Daily	Results must be documented at least once every 3 months	BIR section B, page 30
2.	Gonad shields, lead rubber aprons and gloves	3 monthly	Available and free from holes or cracks (Visual check and if suspect perform an x-ray test)	
3.	Appropriate technique chart displayed at x-ray unit	6 monthly	Available, applicable and compliant with ALARA principle	
III.1.2.	**X-ray Tubes and Generators**			
4.	Alignment of the centre of the X-ray field and the centre of the bucky	On acceptance & 3 monthly	Deviation must be ≤ ±1 cm @1m SID	IPEM 91 RAD03 & BIR (A2.1, A2.2)
5.	The X-ray field dimensions in the plane of the image receptor must correspond with those indicated by the beam-limiting device	On acceptance & 3 monthly	Deviation must be ≤ ±1 cm @1m SID	IPEM 91 RAD04 & BIR (A2.1, A2.2)
6.	Congruence between the X-ray field and light field	On acceptance & 3 monthly	For any one side deviation must be ≤ ±1 cm misalignment @1 m SID	IPEM 91 RAD01 & BIR (A2.1, A2.2)
7.	X-ray/light beam centring	On acceptance & 3 monthly	Deviation must be ≤ ±1 cm @1m SID	IPEM 91 RAD02 & BIR (A2.1, A2.2)
8.	Alignment and collimation to film changer / bucky	On acceptance & 6 monthly	Any side ±1 cm @1m	IPEM 91 RAD06 & BIR (A2.1, A2.2)
III.1.2.1.	**Automatic Exposure Control (AEC) Device**			
9.	Constancy (reproducibility) (test all chambers)	At 4 months intervals between annual tests	Baseline ± 20% mAs or if mAs readout not available, Baseline ± 0.3 OD (use baseline of test 86 or 87)	BIR (A4.2 or A4.1)
III.1.3.	**Processor Monitoring** Tests must be performed before diagnostic films are processed. All measurements must be plotted on graph paper (Ref 15)			
10.	Processing temperature	Daily	Baseline ± 1ºC	IPEM 91 FSP01 & BIR (D1)
11.	Base + Fog (B+F)	Daily	Variance ≤ +0.03 OD. Maximum OD < 0.3	IPEM 91 FSP02, & Ref 15
12.	Mid-density (MD) step (speed index)	Daily	Variance ≤ ± 0.15 OD	IPEM 91 FSP03 & Ref 15
13.	Density difference (DD) (contrast index)	Daily	Variance ≤ ± 0.15 OD	IPEM 91 FSP04 & Ref 15

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.1.4.	**Intensifying Screens and Darkroom**			
14.	Cleanliness of darkroom and screens	Written protocol for maintaining darkroom cleanliness, cassettes and screens clean, free from blemishes		
15.	Condition of cassettes and screens	12 monthly	Screen type, speed and date of installation Identification (cassette no.) and light tightness	IPEM 91 FSP08, BIR (B1& B3) & Ref 15
16.	Darkroom fog	Acceptance & 6 monthly & when fault reported	Density difference ≤ 0.05 for 2 minutes	Ref 15 and BIR C1 & C2
17.	Relative speed of intensifying screens	Before initial use & 24 monthly	Baseline minus 10%	IPEM 91 FSP09 & Ref 15
III.1.5.	**CR Reader (see also Ref 1.1 & KCARE (Ref 10))**			
18.	Detector dose indicator monitoring (exposure index monitoring)	On acceptance & 3 monthly	Baseline ± 20%	IPEM 91 CR01 & KCARE (Ref 10.2 (1)) & BIR (K1)
19.	Image uniformity	On acceptance & 3 monthly	Free from dots and lines	IPEM 91 CR02 & KCARE Ref 10.2 (2))
20.	Condition of cassettes and image plates	Supplier's recommendation	Free of dirt or damage	IPEM 91 CR03 & Supplier's maintenance manual
21.	Test is not required – see test 93		IPEM 91 CR04 & KCARE Ref 10.2 (3))	
22.	Test is not required – see test 95		IPEM 91 CR05 & KCARE Ref 10.2 (4))	
III.1.5.1.	**AEC Device**			
23.	Sensitivity	On acceptance & 3 monthly	Baseline ± 30%	IPEM 91 CR14 & BIR (K5)
III.1.6.	**DDR System**			
24.	Detector dose indicator monitoring	On acceptance & 3 monthly	Baseline ± 20%	IPEM 91 DDR01 & KCARE Ref 10.4 (1)
25.	Image uniformity	On acceptance & 3 monthly	Lines or rectangles not apparent	IPEM 91 DDR02 & KCARE Ref 10.4 (2)
26.	Test is not required – see test 106			IPEM 91 DDR03 & KCARE Ref 10.4 (3)

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.1.6.1.	**AEC Device**			
27.	Sensitivity	On acceptance & 3 monthly	Baseline ± 25%	IPEM 91 DDR13 & BIR (K5)
III.1.7.	**Film Viewing**			
28.	Film viewer condition	6 monthly	Perceived brightness, colours and must be clean and uniformly illuminated	IPEM 91 IDD01 & BIR (M1)
III.1.8.	**Image Display Monitor & Reporting Monitor[2]**			
29.	a) Condition of Image Display Monitor b) Condition of Reporting Monitor – Each reporting monitor must be labelled "REPORTING MONITOR"	a) At least 6 monthly. b) On acceptance & as required or at least weekly	a) Image display monitors should be clean & free from flicker b) Reporting monitors should be clean, and the perceived contrast of the test pattern should be consistent between monitors. Ensure that the 5% & 95% details superimposed on the 0% and 100% squares, respectively, are visible	IPEM 91 IDD06 & TG 18 (Use SMPTE or TG18-QC image)
30.	Test is not required – see test 119.2		IPEM 91 IDD07& TG 18	
31.	Distance and angle calibration (Comment: This test is intended for applications where measurements of distance and angle are performed using image display monitor & diagnostic workstation)	On acceptance & 3 monthly	± 5 mm ± 3° (degrees)	IPEM 91 IDD08
32.	Reporting monitors – Resolution	On acceptance & 3 monthly	Visual inspection of SMPTE or TG18-QC. Review both low contrast and high contrast resolution patterns. Check resolution at centre and periphery is consistent and similar to baseline image. Must be visible	IPEM 91 IDD09 & SMPTE or TG18
III.1.9.	**Hardcopy Device (Only applicable if prints are used for reporting (interpretation of medical images))**			
33.	Self – calibration	On acceptance & Weekly	Manufacturer's specification	IPEM 91 IDD15 & BIR (N1)
34.	Optical density consistency	On acceptance & 3 monthly	Baseline OD ± 0.20	IPEM 91 IDD16 & BIR (N2)
35.	Image quality	On acceptance & 3 monthly	Based on visual inspection	IPEM 91 IDD17 & BIR (N3)
III.1.10.	**Reject Analysis**			
36.	Reject analysis - Digital: Must use software supplied by vendor or implement effective procedure (general radiography)	3 monthly	May not increase with more than 2% from the previous determined rate and total rate should not exceed 10%	For film Screen use BIR (Ch 2), Ref 5 (4.10) & Ref 15

[2] Reporting monitors refer to primary display systems used for the interpretation of medical images – i.e. excludes systems used by general medical staff & specialists after a report has been provided as well as operators' consoles, QC workstations and monitors used with fluoroscopy units, which are all classified as Display monitors (see Chapter 7 page 49 of IPEM 91)

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.1.11. Fluoroscopy Equipment				
37.	**Fixed** fluoroscopic x-ray units sold after January 2007 must be equipped with a **Dose Area Product (DAP)** meter or a device that provide a dose read-out during fluoroscopy. Existing fixed fluoroscopic x-ray units must be equipped with a **Dose Area Product (DAP)** meter or a device that provide a dose read-out during fluoroscopy by January 2008. **DAP readings or dose read-out must be recorded in the patient record and a book/register (must include at least date, the procedure, the patient details, the operator / specialist performing the procedure and the total dose)**			
38.	Radiation warning light at entrance, excluding theatres	On acceptance & Daily	Must work when beam is activated	
39.	Dose rate reproducibility under automatic exposure control	On acceptance & 3 monthly	Baseline ± 25% (Use water container filled with water – approximately 30 cm x 30cm wide and 20cm thick)	IPEM 91 FLU01 & BIR (H3)
III.1.11.1. Fluorography (For this section use IPEM Report 77 (Ref 7))				
40.	Dose per frame reproducibility under automatic exposure control	On acceptance & 3 monthly	Baseline ± 25% (For equipment with DAP meter)	IPEM 77 & BIR (B I1.1)
41.	Resultant film density	On acceptance & 3 monthly	Baseline ±0.3 OD (Optical density)	IPEM 77 & BIR (B I1.2)
42.	Film density reproducibility	On acceptance & 3 monthly	Baseline ±0.3 OD	IPEM 77 & BIR (B I1.3)
III.1.11.2. Digital Fluorography				
43.	Test is not required – see test 137			IPEM 91 FLG01 &
44.	Test is not required – see test 138			IPEM 91 FLG02
45.	Test is not required – see test 139.1			IPEM 91 FLG03
III.1.12. Computed Tomography				
46.	Indicators, radiation warning light at entrance, mechanical and other safety checks	On acceptance & Daily	Must work properly	
47.	Image noise	On acceptance & Daily	Baseline ± 10%	IPEM 91 CT01 & BIR (B J1)
48.	CT number values	On acceptance & Daily	Water baseline ± 5 HU. Other material: baseline ± 10 HU	IPEM 91 CT02 & BIR (B J2)
49.	Scan plane localisation from alignment lights	On acceptance & 3 monthly	≤± 2 mm	IPEM 91 CT03 & IMPACT 3.5.1.1

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.1.13. Screen Film Mammography - For this section use ACR manual (Ref 2) or Reference 4 as a guideline				
50.	Image quality evaluation (phantom images)	Weekly	At a minimum, the 4 largest fibers, the 3 largest speck groups, and the 3 largest masses must be visible. The background optical density must be at least 1.4 and the density difference should be at least 0.4 for a 4-mm thick acrylic disk. Maximum allowable changes are: mAs ±15%; background density ±0.2; density difference ±0.05; fiber, speck groups or mass score decrease by 0.5. (Check manual for correct procedure)	ACR Page 167
51.	Compression	On acceptance & 6 monthly	The maximum compression force must be between 111 Newton (11.3 kg) and 200 Newton (20.4 kg)	ACR Page 199
52.	Repeat and reject analysis	3 monthly	May not increase with more than 2% from the previous determined rate and total rate shall not exceed 5%	ACR Page 202 & BIR (Chapter 2) & Reference 5 (4.10)
53.	Accuracy of stereotactic device	On acceptance & Weekly or as used	Errors of ≤ 1mm in X or Y or ≤ 3mm in Z	IPEM 91 MAM10 & IPEM Report 89 page 118
54.	Appropriate exposure technique chart (automatic and manual exposures) displayed near the control panel of the unit	6 monthly	Available and applicable	ACR page 145
55.	Analysis of fixer retention in film	6 monthly	The residual fixer retention shall be ≤ 5 micrograms per square cm	ACR page 210
III.1.14. Digital Mammography - For this section use European guidelines for quality assurance in breast cancer screening and diagnosis (Ref 4)				
56.	Repeat and reject analysis	3 monthly	May not increase with more than 2% from the previous determined rate and total rate shall not exceed 5%	ACR page 202, BIR (Chapter 2) & Reference 4 (4.10)
57.	AEC device: Long term reproducibility	On acceptance & weekly	Variation of SNR in the reference ROI and dose < ± 10%.	2b.2.1.3.4 & 0604
58.	Image receptor homogeneity	On acceptance & Weekly	Variation in mean pixel value < ± 15% (on images); Maximum deviation in SNR < ± 15% of mean SNR (on images); Maximum variation of the mean SNR between weekly images ≤± 10% (between images); Entrance surface air kerma OR tube loading (mAs) between weekly images ≤ ± 10%	2b.2.2.3. & Ref 21 (7.2.3)

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
59.	Image quality evaluation (phantom images – RMI 156)	Weekly	At a minimum, the 5 largest fibers, the 4 largest speck groups, and the 4 largest masses must be visible. The background optical density must be at least 1.4 for hard copy. Maximum allowable changes are: mAs ±10% (EI tolerances for CR see table 7 of Ref 21); fiber, speck groups or mass score decrease by 0.5 (Check manual for correct procedure) and there shall be no blotches, lines and bright or dark pixels (Ref 21 par 7.2.4.4 and 7.3.2)	ACR Page 167 & Ref 21 (7.2.4)
60.	Uncorrected defective detector elements (DR systems)	On acceptance & Weekly	Limits of the manufacturer.	2b.2.2.3.3
61.	Monitors: Geometrical distortion (CRT displays)	On acceptance & Daily	Borders should be completely visible, lines should be straight, and the active display area should be centred on the screen.	2b.4.1.2
62.	Monitors: Contrast visibility	On acceptance & Daily	All corner patches shall be visible; the 5% and 95% pixel value squares shall be clearly visible.	2b.4.1.3
63.	Monitors: Display artefacts	On acceptance & Daily	No disturbing artefacts should be visible.	2b.4.1.5
64.	Printers: Geometrical distortion	On acceptance & Daily	Borders should be completely visible, lines should be straight.	2b.4.2.1
65.	Printers: Contrast visibility	On acceptance & Daily	All corner patches should be visible; the 5% and 95% pixel value squares should be clearly visible.	2b.4.2.2
66.	Printers: Printer artefacts	Daily	No disturbing artefacts should be visible.	2b.4.2.4
III.1.15. Small Field Digital Mammography System – (Report 0705 of NHSBSP, May 2007) (Ref 13)				
67.	Image quality evaluation (phantom images – RMI 156S)	Weekly (at least) or before use	At a minimum, the 3 largest fibers, the 3 largest speck groups, and the 2.5 largest masses must be visible. The background optical density must be at least 1.4 for hard copy. Maximum allowable changes are: mAs ±10% (EI tolerances for CR see table 7 of Ref 21); background density variation if hardcopy is produced is ±0.2; fiber, speck groups or mass score decrease by 0.5 (Check manual for correct procedure).	ACR Page 167 & Ref 21 (7.2.4)
68.	Accuracy of stereotactic device	On acceptance & Weekly or as used	Errors of ≤ 1mm in X or Y or ≤ 3mm in Z	IPEM 91 MAM10 & IPEM Report 89 page 118

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.1.16. Additional tests for mobile Mammography Systems – IPEM Report 89 (Ref 9)				
69.	Must ensure that all freely moveable objects/equipment are firmly locked or strapped down	Before moving		Report 89 par 5.5.1
70.	Perform visual check of breast support and associated equipment for possible damage	After moving		Report 89 par 5.5.2
71.	Compression device	After moving	Mechanical function and safety aspects must be checked	
72.	Alignment of x-ray beam to image receptor	After moving	For screen film see tests 149, 150 & 151 of this document; For digital see test 166 of this document	
73.	AEC system	After moving	For screen film see tests 153 & 154 of this document; For digital see test 57 and 173 of this document	
74.	Image quality	After moving	For screen film see test 50 of this document; For digital see test 59 of this document	

Table 2 continued

III.2. Acceptance tests and Routine tests listed in this section must be performed by an Inspection Body approved by the Department of Health				
	Physical parameter (required test)	**Frequency**	**Acceptance Standard**	**References**
III.2.1.	**General Tests**			
75.	Safety of premises	On acceptance & and when the workload increase or technique factors change that may jeopardise premises safety	Controlled areas ≤ 5mSv/year, for uncontrolled areas ≤ 1mSv/year	NCRP 147 & Ref 19
76.	Entrance Surface Exposure (ESE) in air without backscatter for Chest, Lumbar Spine, Abdomen, Skull and Foot	12 months from clinical use and then every 36 months	ESE shall be evaluated in accordance with the guideline Inspection Body must submit ESE measurements	Ref 14
III.2.2.	**X-ray Tubes and Generators**			
77.	Accuracy of the source (focal spot)-to-image distance (SID) indicators	On acceptance & 12 monthly	The difference between the indicated focus to film distance (FFD) and the actual FFD must be ≤ 2%	IPEM 91 RAD05 & Reference 5 par 3.4
78.	Brightness of the light field, which defines the x-ray field.	On acceptance & 12 monthly	Average illuminance must be ≥ 100 lux at 100 centimetres or at the maximum FFD, whichever is less	Reference 5 par 2.11
79.	Radiation output: repeatability	On acceptance & 12 monthly	Mean ± 10%	IPEM 91 RAD09
80.	Radiation output: reproducibility	On acceptance & 12 monthly	Baseline ± 20%	IPEM 91 RAD10
81.	The accuracy of the timer for different settings	On acceptance & 12 monthly	Manufacturers' specifications for specific model or if not available ≤ 10%	IPEM 91 RAD11
82.	The accuracy of the kV for different settings	On acceptance & 12 monthly	Manufacturers' specifications for specific model or if not available ≤ 10%	IPEM 91 RAD12
83.	Beam quality (half value layer (HVL))	On acceptance & Only to be tested when the x-ray tube or collimator is replaced	See section IV table 3	Reference 5 par 2.3
84.	Leakage radiation from the diagnostic source assembly (x-ray tube)	At acceptance and after intervention on the tube housing.	< 1 mGy in 1 hour at 1 m from the focus	Ref 18

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.2.2.1.	**Automatic Exposure Control (AEC) Device**			
85.	Consistency between chambers	On acceptance & 12 monthly	Mean ± 0.3 OD	IPEM 91 FSP 14
86.	Repeatability (post-exposure mAs readout available, if not perform 87) (86 or 87)	On acceptance & 12 monthly	Mean ± 20%	IPEM 91 FSP15
87.	Repeatability	On acceptance & 12 monthly	Mean ± 0.2 OD	IPEM 91 FSP16
88.	Reproducibility (test all chambers) (as FSP13 but for different technique values – more extensive)	On acceptance & 12 monthly	Baseline ± 0.3 OD	IPEM 91 FSP17
89.	Image receptor dose	On acceptance & 12 monthly	Baseline ± 30%	IPEM 91 FSP18
III.2.3.	**CR Reader (see also Ref 1.1 & KCARE (Ref 10))**			
90.	Detector dose indicator repeatability	On acceptance & 12 monthly	Baseline ± 10%	IPEM 91 CR06
91.	Detector dose indicator reproducibility	On acceptance & 12 monthly	Baseline ± 20%	IPEM 91 CR07
92.	Measured uniformity	On acceptance & 12 monthly	Mean ± 10%	IPEM 91 CR08
93.	Threshold contrast detailed detectability	On acceptance & 12 monthly	See comments CR09	IPEM 91 CR09
94.	Erasure cycle efficiency	On acceptance & 12 monthly	Blocker not visible in second image	IPEM 91 CR10
95.	Limiting spatial resolution	On acceptance & 12 monthly	Baseline minus 25%	IPEM 91 CR11
96.	Scaling errors	On acceptance & 12 monthly	≤ 2%	IPEM 91 CR12
97.	Dark Noise	On acceptance & 12 monthly	Baseline + 50%	IPEM 91 CR13
III.2.3.1.	**AEC Device**			
98.	Consistency between chambers (Sensitivity / reproducibility)	On acceptance & 12 monthly	Baseline ± 30% Mean ± 20%	IPEM 91 CR16
99.	Repeatability	On acceptance & 12 monthly	Mean ± 20%	IPEM 91 CR17
100.	Reproducibility	On acceptance & 12 monthly	Baseline ± 30%	IPEM 91 CR18
101.	Image receptor dose	On acceptance & 12 monthly	Baseline ± 30%	IPEM 91 CR19

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.2.4.	**DDR System (see also KCARE (Ref 10))**			
102.	Test not required - see 107			IPEM 91 DDR04
103.	Detector dose indicator repeatability	On acceptance & 12 monthly	Baseline ± 10%	IPEM 91 DDR05
104.	Detector dose indicator reproducibility	On acceptance & 12 monthly	Baseline ± 20%	IPEM 91 DDR06
105.	Measured uniformity	On acceptance & 12 monthly	Mean ± 5%	IPEM 91 DDR07
106.	Threshold contrast detail detectability	On acceptance & 12 monthly	See comments in report 91	IPEM 91 DDR08
107.	Limiting spatial resolution	On acceptance & 12 monthly	Baseline minus 25%	IPEM 91 DDR09
108.	Uniformity of resolution	On acceptance & 12 monthly	No increase in blurring from baseline	IPEM 91 DDR10
109.	Scaling errors	On acceptance & 12 monthly	≤2%	IPEM 91 DDR11
110.	Dark noise	On acceptance & 12 monthly	Baseline ± 50%	IPEM 91 DDR12
III.2.4.1.	**AEC Device**			
111.	Consistency between chambers (sensitivity reproducibility)	On acceptance & 12 monthly	Baseline ± 30% Mean ± 20%	IPEM 91 DDR15
112.	Repeatability	On acceptance & 12 monthly	Mean ± 20%	IPEM 91 DDR16
113.	Reproducibility	On acceptance & 12 monthly	Baseline ± 30%	IPEM 91 DDR17
114.	Image receptor dose	On acceptance & 12 monthly	Baseline ± 30%	IPEM 91 DDR18
III.2.5.	**Film Viewing (Viewing boxes used for Reporting/Interpretation of medical images - see Chapter 7 of IPEM 91) & Film processing**			
115.	Film viewer luminance	On acceptance & 12 monthly	≥1500 cd/m^2 for general radiography	IPEM 91 IDD02
116.	Film viewer uniformity	On acceptance & 12 monthly	≤ 20%	IPEM 91 IDD03
117.	Film viewer variation	On acceptance & 12 monthly	≤ 20% difference from the mean value in bank	IPEM 91 IDD04
118.	Room illumination	On acceptance & 12 monthly	≤100 lux for general radiography	IPEM 91 IDD05
118.1.	Film processing evaluation - STEP	12 monthly	Processing speed between 80% to 120%	Reference 23

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.2.6.	**Reporting Monitor[3]**			
119.	DICOM greyscale calibration	On acceptance & 12 monthly	GSDF ±10%	IPEM 91 IDD11
119.1.	Minimum requirements for monitors	On acceptance & 12 monthly	Comply with table 4 see also table 1 & 2 of reference 23	Ref 23
119.2.	Reporting monitors – Greyscale (luminance response)	On acceptance & 12 monthly	Ratio white to black ≥250	IDD07& TG 18
120.	Luminance uniformity	On acceptance & 12 monthly	Maximum variation ≤ 30%	IPEM 91 IDD12
121.	Variation between monitors	On acceptance & 12 monthly	≤ 30%	IPEM 91IDD13
122.	Room illumination	On acceptance & 12 monthly	≤ 15 lux	IPEM 91IDD14
III.2.7.	**Fluoroscopy Equipment**			
123.	Display monitor set–up	On acceptance & 12 monthly	All steps visible and black/white circles	IPEM 91 FLU02
124.	Minimum requirements for monitors	On acceptance & 12 monthly	Comply with table 4	Ref 22
125.	Test is not required – see test 130		IPEM 91 FLU04 & BIR (B, H2)	
126.	Field limitation requirement. X-Ray field/Image intensifier	On acceptance & 12 monthly	The ratio of the areas ≤ 1.15.	IPEM 91 FLU05
127.	Dose rate at entrance surface of phantom	On acceptance & 12 monthly	≤ 50 mGy/min (entrance air kerma) and baseline ± 25%	IPEM 91 FLU06
128.	Entrance exposure rate to image intensifier	On acceptance & 12 monthly	Baseline ± 25%	IPEM 91 FLU07
129.	Limiting spatial resolution	On acceptance & 12 monthly	36-40 cm: ≥ 0.7 line pairs mm^{-1}; 30-35 cm: ≥ 0.8 line pairs mm^{-1} 25-29 cm: ≥ 0.9 line pairs mm^{-1}; 20-24 cm: ≥ 1.0 line pairs mm^{-1} 15-18 cm ≥ 1.25 line pairs mm^{-1}.	IPEM 91 FLU09
130.	Threshold contrast	On acceptance & 12 monthly	See comments Flu10	IPEM 91 FLU10
131.	Image resolution uniformity	On acceptance & 12 monthly	See Comments FLU11	IPEM 91 FLU11
132.	Calibration of Dose area product meter (DAP/KAP meter) or the device that provides a dose read-out during fluoroscopy (total dose)	On acceptance & 12 monthly	Calibration of DAP/KAP meter or dose read out device according to manufacturer's specifications	Ref 20 (Page 336 – 340 of TRS 457)
III.2.7.1.	**Fluorography (For this section use IPEM Report 77 (Ref 7))**			
133.	Overall Image quality	On acceptance & 12 monthly	Manufacturer's specifications for a specific model	BIR (B I1.4)

[3] Reporting monitors – see page 8 of this doc and Chapter 7 page 49 of IPEM 91

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
134.	Resultant film density	On acceptance & 12 monthly	Baseline ±0.3 OD	BIR (B I1.3)
135.	Dose per frame at the input face of the image intensifier under automatic exposure control	On acceptance & 12 monthly	Baseline ± 25% or ≤ 1 μGy per frame (Largest field)	BIR (B I1.1)
136.	Image quality: limiting spatial resolution	On acceptance & 12 monthly	1.6 line-pairs/mm for 30-35 cm systems; 2.5 line-pairs/mm for 23-25 cm systems, and 3 line-pairs/mm for 15-18 cm systems.	IPEM 77 & BIR (B I1.4)
III.2.7.2.	**Digital Fluorography**			
137.	Dose per image at the input face of the image receptor under automatic exposure control	On acceptance & 12 monthly	Baseline ± 25 %	IPEM 91 FLG04
138.	Limiting spatial resolution	On acceptance & 12 monthly	Baseline reduced by 2 groups	IPEM 91 FLG05
139.	Dynamic range	On acceptance & 12 monthly	See Comments FLG07	IPEM 91 FLG07
139.1.	Threshold contrast	On acceptance & 12 monthly	Baseline ± 2 discs	IPEM 91 FLG06
III.2.8.	**Computed Tomography**			
140.	Image noise	On acceptance & 12 monthly	Baseline ± 10% Inter –slice variation; Mean ± 10%	IPEM 91 CT06
141.	CT number values	On acceptance & 12 monthly	Water baseline ± 5 HU Other materials: baseline ± 10HU	IPEM 91 CT07
142.	CT number uniformity	On acceptance & 12 monthly	Head phantom: ≤±10HU Body phantom: ≤±20HU	IPEM 91 CT08
143.	High contrast spatial resolution	On acceptance & 12 monthly	Baseline ±20%	IPEM 91 CT09
144.	Computed tomography dose index (CTDI)	On acceptance & 12 monthly	Baseline ±15%	IPEM 91 CT10
145.	Image slice thickness	On acceptance & 12 monthly	Baseline ±20% or ± 1mm, whichever is greater	IPEM 91 CT13
146.	$CTDI_{vol}$ for single slice or rotation	On acceptance & 3 yearly	≤ Reference dose - table 3 of reference 1.2	IPEM 91 CT11
III.2.9.	**Screen Film Mammography - For this section use ACR manual (Ref 2) as a guideline**			
147.	Screen-film systems – Image receptors	On acceptance & 12 monthly	Must have image receptors of 18x24 cm and 24x30 cm with matching moving grids	
148.	Assessment of locks, detents, angulation indicators, and mechanical support devices for X-ray tube and image receptor holder assembly	On acceptance & 12 monthly	Must function properly	Page 231

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
149.	Collimation assessment: Deviation between X-ray field and light field	On acceptance & 12 monthly	The sum of left plus right edge deviations or anterior plus chest edge deviations must be ≤ 2% of SID	Page 233
150.	Collimation assessment: Deviation between X-ray field and edges of the image receptor	On acceptance & 12 monthly	The X-ray field may not exceed the image receptor at any side by more than 2% of SID and the X-ray field may not fall within the image receptor on the chest wall side	Page 233
151.	Collimation assessment: Alignment of chest-wall edges of compression paddle and film	On acceptance & 12 monthly	The chest-wall edge of the compression paddle may not fall within the image receptor or project beyond the chest-wall edge of the image receptor by more than 1% of SID	Page 233
152.	Evaluation of system resolution	On acceptance & 12 monthly	The resolution with the bars parallel to the anode-cathode axis must be ≥ 13 line–pairs/mm or with the bars perpendicular to the anode-cathode axis must be ≥ 11 line–pairs/mm	Page 238
	Automatic exposure control (AEC) system performance:			Page 241
153.	Automatic exposure control (AEC) system performance: Thickness tracking, kVp tracking and image mode tracking	On acceptance & 12 monthly	Equipment sold prior to 01/01/2003: The AEC system must maintain the film optical density within ±0.3 of the mean when the thickness of the phantom is varied over 2-6 cm and the kVp is varied over the range of those used clinically for these thickness. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thickness and compositions that must be used so that optical densities within ±0.3 of the average can be produced under photo timed conditions. Equipment sold after 01/01/2003: The AEC system must maintain the film optical density within ±0.15 of the mean when the thickness of the phantom is varied over 2-6 cm and the kVp is varied over the range of those used clinically for these thickness.	Page 241
154.	Automatic exposure control (AEC) system performance: Density control	On acceptance & 12 monthly	Each step (density setting) shall result in a 12-15% change in mAs, or approximately a 0.15 change in film optical density	Page 241
155.	Uniformity of screen speed (for all cassette sizes)	On acceptance & 12 monthly	The standard deviation for the control cassette densities must be less than 0.05 and density range for all cassettes (of the same size) must be ≤0.30	Page 246
156.	Image quality evaluation	On acceptance & 12 monthly	At a minimum, the 4 largest fibers, the 3 largest speck groups, and the 3 largest masses must be visible. The background optical density must be at least 1.4 and the density difference should be at least 0.4 for a 4-mm thick acrylic disk.	Page 258

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
157.	Artefact evaluation	On acceptance & 12 monthly	No significant artefacts must be visible	Page 249
158.	kVp accuracy and reproducibility	On acceptance & 12 monthly	The mean kVp may not differ from the nominal kVp (set value) with more than ±5%, or the coefficient of variation may not exceed 0.02	Page 271
159.	Beam quality (HVL) measurement	On acceptance & 12 monthly	The measured HVL must be ≥ kVp/100 (mm Al) (Please note 0.03 must be added when filtration is performed with compression paddle (see page 275) of 1999 addition, ACR)	Page 273
160.	AEC reproducibility	On acceptance & 12 monthly	The coefficient of variation for R (exposure) or mAs must be ≤ 0.05	Page 277
161.	Average glandular dose	On acceptance & 12 monthly	The dose must be ≤ 300 mRad (3 mGy) for 4.2 cm effective breast thickness	Page 277
162.	Radiation output rate	On acceptance & 12 monthly	The output must be ≥ 800 mR/s (7.0 mGy/s) at maximum SID [4]	Page 277
163.	View box luminance, room illuminance and masking	On acceptance & 12 monthly	Luminance of the view box shall be ≥ 3000 cd/m^2 and iluminance of the room shall be ≤ 50 lux Viewboxes must be masked to the exposed area of the film	Page 286
III.2.10. Digital Mammography - For this section use European guidelines for quality assurance in breast cancer screening and diagnosis (Ref 4)				
164.	Assessment of locks, detents, angulation indicators, and mechanical support devices for X-ray tube and image receptor holder assembly	On acceptance & 12 monthly	Comply to par 8.2.1 of Ref 21	Ref 21 (8.2.1)
165.	X-ray source: Source-to-image distance – Only if adjustable	On acceptance & 12 monthly	Manufacturers specification, typical 600-650 mm.	2b.2.1.1.2
166.	X-ray source: Alignment of X-ray field/image receptor	On acceptance & 12 monthly	All sides: X-rays must cover the film by no more than 5 mm outside the film. On chest wall edge: distance between film edge and edge of the bucky must be ≤ 5 mm.	2b.2.1.1.3
167.	X-ray source: Radiation leakage	On acceptance and after intervention on the tube housing.	≤ 1 mGy in 1 hour at 1 m from the focus	2b.2.1.1.4
168.	X-ray source: Tube output	On acceptance & 12 monthly	> 30 µGy/mAs at 1 metre and > 70% of value at acceptance	2b.2.1.1.5
169.	Tube voltage reproducibility and accuracy	On acceptance & 12 monthly	Accuracy for the range of clinically used tube voltages: < ± 1 kV Reproducibility < ± 0.5 kV	2b.2.1.2.1
170.	Half Value Layer (HVL)	On acceptance and after intervention on the tube housing.	For 28 kV Mo/Mo the HVL must be over 0.30 mm Al equivalent	2b.2.1.2.2

[4] Units manufactured after 01-01-2003. Units manufactured prior to 01-01-2003 and that does not comply may not be resold.

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
171.	AEC-system: Optical density control setting: central value and difference per step (if applicable)	On acceptance & 12 monthly	5 - 15% increase in exposure per step	2b.2.1.3.1
172.	AEC-system: Short term reproducibility	On acceptance & 12 monthly	< ± 5%	2b.2.1.3.3
173.	AEC-system: Object thickness and tube voltage compensation	On acceptance & 12 monthly	Thickness indicator < ± 0.5 cm and density < ± 0.15 OD.	2b.2.1.3.5
174.	Compression force	On acceptance & 12 monthly	130 - 200 N (13-20 kg) maintained unchanged for at least 1 minute and indicated compression force should be within ± 20 N of the measured value	2b.2.1.4
175.	Compression plate alignment	On acceptance & 12 monthly	≤ 5 mm	2b.2.1.4 & Ref 21 (8.9)
176.	Grid system factor (if present)	On acceptance	Manufacturer's specification, typical value < 3.	2b.2.1.5.1
177.	Grid imaging	On acceptance & 12 monthly	No significant non uniformity	2b.2.1.5.2
178.	Image receptor response function	On acceptance & 12 monthly	R^2 > 0.99, results at acceptance are used as reference.	2b.2.2.1.1
179.	Image receptor Noise evaluation	On acceptance & 12 monthly	Results at acceptance are used as reference	2b.2.2.1.2
180.	Missed tissue at chest wall side	On acceptance	Width of missed tissue at chest wall side ≤ 5 mm	2b.2.2.2 4 & Ref 21 (8.9)
181.	Image receptor homogeneity and Image receptor detector element failure (DR systems)	On acceptance & 12 monthly	Variation in mean pixel value < ± 15% (on images); Maximum deviation in SNR < ± 15% of mean SNR (on images); Maximum variation of the mean SNR between weekly images ≤± 10% (between images); Entrance surface air kerma OR tube loading (mAs) between annual images ≤ ± 10% Limits of the manufacturer.	2b.2.2.3.1 and 2b.2.2.3.2
182.	Inter plate sensitivity variations (CR systems)	On acceptance & 12 monthly	SNR variation ≤ ± 15%. Variation in entrance surface air kerma OR tube loading (mAs)≤± 10%,	2b.2.2.4
183.	Influence of other sources of radiation (CR)	On acceptance	The coins should not be visible.	2b.2.2.5
184.	Fading of latent image (CR)	On acceptance	Results at acceptance are used as reference.	2b.2.2.6
185.	Dosimetry	On acceptance & 12 monthly	< 2.5 mGy for 4.5 cm PMMA - see 2a.2.5.1 for rest of values	2b.2.3
186.	Threshold contrast visibility	On acceptance & 12 monthly	See table in 2b.2.4.1 for limiting values	2b.2.4.1

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
187.	Exposure time	On acceptance & 12 monthly	< 2 s	2b.2.4.3
188.	Geometric distortion and artefact evaluation	On acceptance & 12 monthly	No disturbing artefacts, no visible distortion.	2b.2.4.4
189.	Ghost image/erasure thoroughness	On acceptance & 12 monthly	"Ghost image"-factor < 0.3	2b.2.4.5
190.	Monitors : Ambient light	On acceptance & 12 monthly	< 10 lux	2b.4.1.1
191.	Monitors: Resolution	On acceptance & 12 monthly	All line patterns should be discernible.	2b.4.1.4
192.	Monitors: Luminance range: Maximum to minimum luminance ratio	On acceptance & 12 monthly	Primary display devices ≥ 250 Secondary display devices ≥ 100; Displays belonging to one displaying station should not exceed 5% of the lowest.	2b.4.1.6
193.	Monitors: Greyscale Display Function	On acceptance & 12 monthly	<± 10% of the GSDF for primary class displays and <± 20% of the GSDF for secondary class displays	2b.4.1.7
194.	Monitors: Luminance uniformity	On acceptance & 12 monthly	Maximum luminance deviation of a display device should be less than 30% for CRT displays and LCD displays ((Lmax-Lmin)/Lcentre < 0.3).	2b.4.1.8
195.	Monitors: Resolution	On acceptance	All line patterns should be discernible	2b.4.2.3
196.	Monitors: Greyscale Display Function	On acceptance & 12 monthly	The calculated contrast response should fall within ± 10% of the GSDF contrast response.	2b.4.2.6
197.	Monitors: Density uniformity	On acceptance & 12 monthly	Maximum optical density deviation should be less than 10% ((Dmax-Dmin)/Dcentre < 0.1)	2b.4.2.7
198.	Image quality evaluation (phantom images – RMI 156)	On acceptance & 12 monthly	At a minimum, the 5 largest fibers, the 4 largest speck groups, and the 4 largest masses must be visible. The background optical density must be at least 1.4 for hard copy. Maximum allowable changes are: mAs ±10% (EI tolerances for CR see table 7 of Ref 21); fiber, speck groups or mass score decrease by 0.5 and there shall be no blotches, lines and bright or dark pixels (Ref 21 par 7.2.4.4 and 7.3.2)	ACR Page 167 & Ref 21
199.	Viewing boxes	On acceptance & 12 monthly	If mammograms are read on printed images, use the method and limiting values described in section 2a.2.4.1	2b.4.3

Table 2 continued

	Physical parameter (required test)	Frequency	Acceptance Standard	References
III.2.11. Small Field Digital Mammography System – (Report 0705 of NHSBSP, May 2007) (Ref 13)				
200.	For dedicated small field digital imaging systems the applicable quality control tests specified in section III.2.10 and III.1.14 must be included. For image quality use RMI 156S phantom			
201.	Beam alignment: Alignment of the light field to the x-ray field	On acceptance & 12 monthly	± 10 mm on all sides	3.1
202.	Beam alignment: Alignment of the x-ray field to the imaged field	On acceptance & 12 monthly	0 to + 10 mm on all sides	3.1.1
203.	Size of image field	On acceptance	Each dimension should be within 5% of specified value	3.1.2
204.	X-ray field non-uniformity	On acceptance & 12 monthly	Variation in *pixel value* ≤10% from the value measured in the centre of the image	3.2
205.	Automatic exposure control: Overall repeatability	On acceptance & 12 monthly	Maximum deviation in mAs ≤ 5% from the mean	3.3.1
206.	Constancy with change in phantom thickness	On acceptance & 12 monthly	Maximum deviation in *pixel values* ≤ 10% of the mean	3.3.2
207.	Constancy with change in tube voltage	On acceptance & 12 monthly	Maximum deviation in *pixel values* should not exceed 10% of the mean	3.3.3
208.	Display devices: Greyscale	On acceptance & 12 monthly	Monitor – 5% steps from 0% and 100% grey levels equally visible Hardcopy – baseline greyscale step ±0.15 OD (±0.05 OD for minimum density step)	3.4.1
209.	Display devices: Resolution	On acceptance & 12 monthly	Frequency high contrast resolution pattern resolved	3.4.1
210.	Hardcopy printer: Greyscale	On acceptance & 12 monthly	Greyscale must match the image display monitor and the greyscale steps selected shall be within the following tolerances: Step 1: ± 0.05; Step 2: ± 0.15; Step 3: ± 0.15	3.4.2
211.	Hardcopy printer: Resolution	On acceptance & 12 monthly	Maximum frequency in the high contrast patterns should be resolved	3.4.2
212.	Image quality: Limiting spatial resolution	On acceptance & 12 monthly	Should be at least 70% of the Nyquist frequency of the detector. Should be at least 75% of the value determined at commissioning	3.5.1
213.	Image quality evaluation (phantom images – RMI 156S)	On acceptance & 12 monthly	≥ 3 largest fibers, ≥ 3 largest speck groups, and ≥ 2.5 largest masses be visible. The background optical density ≥ 1.4 for hard copy. Maximum allowable changes are: mAs ±15%; fiber, speck groups or mass score decrease by 0.5.	ACR Page 167
214.	Measurement of dose: Dose to the standard breast at the clinical setting	On acceptance & 12 monthly	Variation within ± 25% of value determined at commissioning and the dose must be ≤ 3 mGy for 4.2 cm effective breast thickness	3.6.1

IV. TABLE 3 – HVL values

X-ray tube voltage (kilovolt peak)	71	80	90	100	110	120	130	140	150	> 150
Minimum HVL (mm of Al)	2.1	2.3	2.5	2.7	3.0	3.2	3.5	3.8	4.1	See note 2
Minimum HVL (mm of Al), manufactured after June 2006	2.5	2.9	3.2	3.6	3.9	4.3	4.7	5.0	5.4	

1. HALF-VALUE LAYERS for intermediate selected voltages are to be obtained by linear interpolation. 2. Linear extrapolation is to be used.

V. Table 4 - MINIMUM REQUIREMENTS FOR MONITORS (Reference 22 table 1)

Band	Description and application	Monitors purchased on or after 1 March 2012		Monitors purchased before 1 March 2012		
		Licensed with Department of Health as a medical device for import	Minimum resolution	CE medical device	Minimum resolution	To perform an optimum diagnostic examination and to reduce the occurrence/chance of any misdiagnosis:
A+	Highest end reporting monitor used in mammography	**Yes**	**5 Megapixel**	**Yes**	**3 Megapixel**	5 Megapixel is strongly recommended
A	High quality reporting monitor used in conventional radiology	**Yes**	**3 Megapixel**	**Yes**	**2 Megapixel**	3 Megapixel is strongly recommended
B	Reporting monitor for lower contrast or resolution modalities or highly supportive review applications, i.e. immediate feedback to clinical activity. Examples – CT, cardiology, etc. Image display monitor for Community Health or for Occupational Health where reporting is done off-site	**Yes**	**2 Megapixel**	**Yes**	**1.3 Megapixel**	2 Megapixel is strongly recommended
C	Image display monitor not to be used for diagnosis but images viewed only in conjunction with the report – ward, clinic, theatre, etc; Workstations, and Image review monitors (not used for immediate feedback to clinical activity)	**No**	**1 - 2 Megapixel**	**No**	**1 - 2 Megapixel**	

1. **Optimisation in diagnostic radiology means that equipment and methods must be selected to ensure that radiation administered to a patient for diagnostic purposes, is sufficient to enable the procedure to provide the required information; and not greater than is necessary to provide that information.**
2. **All diagnostic image interpretation shall be performed by making use of the application software which includes, zoom, pan, magnification and windowing tools to optimise spatial and contrast resolution.**

VI. EXAMPLE OF A FORM THAT SHOULD BE INCLUDED IN IER

A	UNIT PARTICULARS								
DoH ref. no.:		**Date of latest DoH document**			**Copy is available at:**				
Product Licence no.:		**Appointed person responsible for QC tests:**							
Inspection Body[5] :									
X = Indicate Applicability	**General Radiography**	**Processor & Hardcopy device**	**CR System**	**DDR System**	**Reporting Monitor**	**Fluoroscopy Equipment**	**CT**	**Mammo**	
Date of installation		Operator's manual(s) is available & where is it kept?				Results of acceptance tests is available &date			
Date(s) of replacement(s) / upgrading									

B	COMPONENT PARTICULARS		
	Make	**Model**	**ID number /Serial number**
Unit - make, model and system ID			
Generator			
X-ray Tube(s)			
Comments			

[5] An Inspection Body is an Organisation that is accredited by SANAS (www.sanas.co.za) and approved by the Department of Health

C	TESTS APPLICABLE ON MACHINE	DoH Licence no.

Table 2 Section III.1	The licence holder must perform Routine Tests. An Inspection Body must perform acceptance tests.		Table 2 Section III.2	An Inspection Body must perform acceptance tests and Routine tests[6].	
Ref. No.	**Physical parameter to be tested**	**X = Indicate Applicability**	**Ref. No.**	**Physical parameter to be tested**	**X = Indicate Applicability**
III.1.1	General Tests		III.2.1	General Tests	
III.1.2	X-Ray Tubes and Generators		III.2.2	X-Ray Tubes and Generators	
III.1.2.1	Automatic Exposure Control (AEC) Device		III.2.2.1	Automatic Exposure Control (AEC) Device	
III.1.3	Processor Monitoring				
III.1.4	Intensifying Screens and Darkroom				
III.1.5	CR Reader		III.2.3	CR Reader	
III.1.5.1	AEC Device		III.2.3.1	AEC Device	
III.1.6	DDR System		III.2.4	DDR System	
III.1.6.1	AEC Device		III.2.4.1	AEC Device	
III.1.7	Film Viewing		III.2.5	Film Viewing	
III.1.8	Image Display Monitor		III.2.6	Image Display Monitor	
III.1.9	Hardcopy Device				
III.1.10	Repeat and Reject Analysis				
III.1.11	Fluoroscopy Equipment		III.2.7	Fluoroscopy Equipment	
III.1.11.1	Fluorography		III.2.7.1	Fluorography	
III.1.11.2	Digital Fluorography		III.2.7.2	Digital Fluorography	
III.1.12	Computed Tomography		III.2.8	Computed Tomography	
III.1.13	Screen Film Mammography		III.2.9	Screen Film Mammography	
III.1.14	Digital Mammography		III.2.10	Digital Mammography	
III.1.15	Small Field Digital Mammography System		III.2.11	Small Field Digital Mammography System	
III.1.16	Additional Tests for mobile Mammography Systems				

[6] An Inspection Body is an Organisation that is accredited by SANAS (www.sanas.co.za) and approved by the Department of Health

VII. TEST GUIDELINES

- X-Ray Tubes and Generators – Conventional film systems; (tests 1-17, 28, 33-36, 75-89, 115-118.1);
- Computerised Radiography Reader (tests 18-20, 23, 29-35, 90-101, 119-122);
- Direct Digital Radiography System, (tests 1-8, 24-25, 27, 29-36, 75-84,102-114,119-122);
- Fixed Fluoroscopy Equipment (tests 1-3, 37-42, 75, 79-84, 123-139.1);
- Mobile Fluoroscopy and X-Ray Tubes and Generators (tests 1-3, 39, 79-84, 123-131, 137-139.1)
- Computed Tomography (tests 1-3, 29-32, 36, 46-49, 75, 119-122, 140-146)
- Screen film Mammography (tests 1,10-17, 28, 50-55, 69-75, 116-117, 118.1, 147-163)
- Digital Mammography (tests 1, 56-75, 119-122, 164-214)

VIII. REFERENCES

- References listed below can/should be used as guidelines. Purchasing of these documents is not a requirement. Other sources could be consulted in obtaining the relevant information.

1. AAPM (American Association of Physicists in Medicine), Instrumentation Requirements of Diagnostic Radiological Physicists, Report no. 60 www.aapm.org

   1.1. Report no 93, Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems, www.aapm.org

   1.2. Reference Values for Diagnostic Radiology: Application and Impact; Gray, JE, Archer, BR, Butler, PF, et al. *Radiology* 2005; 235: 354-358. Report of AAPM Task Group No. 7 (Reference Values for Diagnostic X-Ray Examinations) of the Radiation Protection Committee, www.aapm.org or https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Diagnostic Reference Levels ➔ 354_full

2. ACR (American College of Radiology), Mammography Quality Control Manual (1999) www.arc.org ➔ ACR Store ➔ Quality and Safety ➔ Quality Control Manuals
3. BIR (British Institute of Radiology), Assurance of Quality in the Diagnostic Imaging Department 2nd Edition, 2001, http://www.bir.org.uk ➔ Publications ➔ Bookshop
4. European guidelines for quality assurance in breast cancer screening and diagnosis – fourth edition, European Communities, 2006, www.google.co.za ➔ search for ➔ ISBN 92-79-01258-4
5. IMAGING QUALITY ASSURANCE MANUAL Published by the Radiation Safety Office for the University of Rochester Medical Center, Revision 1, Dated 3/05, http://extranet.urmc.rochester.edu/radiationSafety/ ➔ Forms, Manuals & Posters ➔ Radiology QA Manual
6. IMPACT, CT Scanner Acceptance Testing, www.impactscan.org ➔ Reports & info ➔ acceptance testing of CT
7. IPEM (Institute of Physics and Engineering in Medicine) 1997, Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems, Report no. 77, www.IPEM.org.uk
8. IPEM (Institute of Physics and Engineering in Medicine) 2005, Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems, Report no. 91, www.IPEM.org.uk
9. IPEM (Institute of Physics and Engineering in Medicine), Report 89, The Commissioning and Routine Testing of Mammographic X-Ray Systems, www.IPEM.org.uk
10. KCARE; Protocols for QA of CR System – Routine and Annual; Protocols for QA of DDR Systems – Routine and Annual, http://www.kcare.co.uk ➔ Education ➔ Protocols

10.1. CR system: Commissioning & Annual tests;

10.2. CR system: Routine QA tests;

10.3. DDR system: Commissioning & Annual tests, and

10.4. DDR system: Routine QA tests.

11. NCRP (National Council on Radiation Protection and Measurements) 2004, Structural Shielding Design for Medical X-Ray Imaging Facilities, NCRP Report No.147, http://www.ncrponline.org

12. NHSBSP Equipment Report 0604, June 2006, Commissioning and Routine testing of full field digital mammography systems, www.cancerscreening.nhs.uk ➔ Search this site for ➔ *Report 0604*

13. NHSBSP Equipment Report 0705, May 2007, Commissioning and Routine testing of small field digital mammography systems, www.cancerscreening.nhs.uk ➔ Search this site for ➔ *Report 0705*

13.1. Quality Assurance Guidelines for Mammography Including Radiographic Quality Control, Publication No 63, www.cancerscreening.nhs.uk ➔ Search this site for ➔ *Quality Assurance Guidelines for Mammography Including Radiographic*

14. Patient Dose Measurements in Diagnostic Radiology https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines

15. Test procedures for film processing and intensifying screens, https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines

16. TG18 by AAPM (American Association of Physicists in Medicine), Task Group 18, http://deckard.mc.duke.edu/~samei/tg18 OR www.aapm.org ➔ Publications ➔ Reports ➔ OR-03

17. Measurement of the Performance Characteristics of Diagnostic X-Ray Systems: Digital Imaging Systems, www.IPEM.org.uk

18. Tube leakage, https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines

19. Shielding, https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines

20. www-pub.iaea.org/MTCD/publications/PDF/TRS457_web.pdf OR http://www.radcal.com/PDC.html

21. Quality Assurance for Digital Mammography Programme, www.iaea.org/books ➔ look under Human Health Series

22. Display considerations for hospital-wide viewing of soft copy images, DS Brettle, BJR, 80 (2007), 503-507, https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines

23. Sensitometric Technique for Evaluation of Processing (STEP), https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Guidelines