South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

29 August 2022

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

The South African Health Products Authority (SAHPRA) is the regulatory authority of South Africa responsible for the regulation of health products intended for human and animal use; amongst others, radiation emitting devices and radioactive nuclides.

This guideline sets out requirements with respect to quality control tests for radiation safety associated with the use of medical diagnostic x-ray equipment to promulgate the Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973).

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and published for implementation	April 2015
1	- Content structured on the new SAHPRA Guideline Template - A unique document number SAHPGL-RDN-XR-01 allocated to this Guideline	September 2022

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
AAPM	American Association of Physicists in Medicine
AEC	Automatic Exposure Control
ALARA	As low as reasonably achievable
BIR	British Institute of Radiology
CR	Computed Radiographs
CT	Computed Tomography
DAP	Dose area Product
DDR	Direct Digital Radiograph
DOH	Department of Health
DRL	Diagnostic reference levels
HVL	Half Value Layer
IB	Inspection Body
IER	Individual Equipment Record
IPEM	Institute Of Physics and Engineering in Medicine
NCRP	National Council on Radiation Protection and measurement
QA	Quality Assurance
QC	Quality Control
SAHPRA	South African Health Products Regulatory Authority
SANAS	South African National Accreditation Standards

1. INTRODUCTION

The goal of quality assurance is to improve patient care. quality control (QC) refers to the specific test required to ensure effective and safe equipment performance. QC tests check the performance of the equipment under routine clinical conditions, following established protocols for facilities, equipment, and procedures.

It is important to properly perform acceptance tests for image quality and safety purposes right after the installation and during routine operation of a diagnostic x-ray device. Having a quality control (QC) program for facilities operating medical X-Ray diagnostic device will ensure that patients are not receiving excessive radiation during their examination.

1.1 Purpose

The purpose of this diagnostic quality control requirements document is to set the general requirements and type of tests to be performed on acceptance and routinely on the various devices.

1.2 Scope

The guideline is reference document for licenced Inspection bodies who performs the quality control tests on a regular basis as per their scope and for licence holders who performs certain test as stipulated below.

2. LEGAL PROVISION

The Regulations R1332 of the hazardous substances act 15 of 1973; requires that a joint product and premises licence be obtained for X-ray equipment before it may be installed and commissioned.

a) Licences are not transferable and are issued: To a specific person or institution; For specific equipment and its application, and

b) For a specific premise.

It is the responsibility of the prospective user of an x-ray unit to be in possession of a licence from the regulator prior to installation of the unit. Practitioners may be assisted by the supplier of the equipment in this process.

3. GENERAL REQUIREMENTS

3.1 The Licence Holder shall:

3.1.1 Display the product licence number (see list of licences from Department of Health (DoH)) on equipment.

3.1.1.1 See table 1 (row c) for which equipment this is a requirement.

3.1.2 Compile an Individual Equipment Record (IER) containing the information as listed in table1 (column 2) (see also section 7.1).

3.1.3 Perform the prescribed Acceptance- and Quality Control (QC) tests listed in table 2 by:[30 31]

3.1.3.1 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 3.2.) must be used to perform all the acceptance tests as well as the routine tests listed in section III.2 of table 2.

3.1.3.2 If a medical physicist is used to perform the tests in 3.1, 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) to perform the tests.

3.1.4 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.

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

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

3.1.6.1 Acquired or

3.1.6.2 Substantially upgraded.

- Acceptance tests are the initial tests performed directly after installation and before the equipment is being put into clinical service.

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

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

3.1.8 Ensure that image display monitors and reporting monitors comply with the requirements in section V (Table 4, page 27) of this document.

3.1.9 Establish a program to ensure that the radiation dose administered to a patient for diagnostic purposes is optimised (see bottom of table 4, page 27 for definition of optimisation). Such program must at least use the measurements under tests 37, 76, 146, 161 and 185 to determine whether radiation protection has been optimised.

3.1.9.1 Measurements (test results) for tests 37, 76, 146, 161 and 185 must be evaluated at the

prescribed frequencies. The following documents can be used as guidance documents for establishment of Diagnostic Reference Levels (DRLs) and for comparisons [3] [27] [28] [29] Inter unit comparisons must also be performed.

3.1.9.2 A medical physicist must be appointed in writing to establish and implement an optimisation program for Interventional Radiology procedures listed in section III.2.15.4.1. This optimisation program must amongst other include the establishment of Diagnostic Reference Levels (DRLs). The appointed medical physicist must audit and review the optimisation program on a **twelve-monthly** cycle.

3.1.9.2.1 The tasks of the appointed medical physicist shall at least include the following but not limited to:

3.1.9.2.1.1 Implementation of procedures in establishment and use of DRLs;

3.1.9.2.1.2 Investigate and review the program when DRLs are consistently exceeded and ensure that corrective action is taken where appropriate.

3.1.9.2.1.3 Provide suitable training to theatre staff to achieve optimisation and such training must be documented.

3.1.9.2.1.4 Assist with the investigations of over exposure to theatre staff.

3.1.9.2.1.5 Developing a local clinical protocol for each type of interventional procedure and each x-ray unit, and this protocol must at least [38] include the following:

3.1.9.2.1.5.1 A statement on the 'expected' radiographic images including:

3.1.9.2.1.5.1.1 Projections; and technique factors, and

3.1.9.2.1.5.2 The 'nominal' values for:

3.1.9.2.1.5.2.1 Fluoroscopy times and DAP readings / or dose; and air kerma rates; and resulting cumulative dose at each skin site exposed, and

3.1.9.2.1.6 Any other tasks that could be included under optimisation and protection of staff against unnecessary exposure to ionising radiation.

3.1.10 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:

3.1.10.1 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.

3.1.11 Report to the Director: Radiation Control if any one or more of the following conditions (trigger values or trigger events) are observed:

3.1.11.1 Kerma-Air Product is greater than 500 Gy.cm2 per patient

3.1.11.2 Cumulative Dose at interventional reference point Ka,r is greater than 5 Gy per patient

3.1.11.3 A radiation injury is observed.

3.1.11.4 An unprescribed or erroneously prescribed procedure is performed, and

3.1.11.5 The patient is pregnant, and the pregnancy is unknown at the time of the procedure.

3.2 If the licence holder can provide sufficient proof that all QC tests as listed in Table 2 were performed on general diagnostic imaging equipment under his control for the last two years, such licence holder may apply to the Directorate; Radiation Control that the12 month QC test cycle be extended to a 24-month cycle (Equipment excluded is: Mammography, Fluoroscopy, Computed Tomography, and x-ray units installed in vehicles). This provision will be cancelled with immediate effect if full compliance with the requirements in this document is not maintained.

4. TABLE 1 INDIVIDUAL EQUIPMENT RECORD (IER) - (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

- The following documents can be used as guidance documents for purchasing of test quipment or[1, 5, 6, 7, 10, 12, 16, 17 & 23] or alternatively ask the IB.
- 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.

5. TABLE 2 ACCEPTANCE AND ROUTINE QUALITY CONTROL TESTS 37

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 SAHPRA: Radiation Control.				
	Physical parameter (required test)	**Frequency**	**Standard**	**Reference**
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	page 30 [5]
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	RAD03 [10] & (A2.1, A2.2) [5]
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	RAD04 [10] & (A2.1, A2.2) [5]
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	RAD01 [10] & (A2.1, A2.2) [5]
7.	X-ray/light beam centring	On acceptance & 3 monthly	Deviation must be ≤ ±1 cm @1m SID	RAD02 [10] & (A2.1, A2.2) [5]
8.	Alignment and collimation to film changer / bucky	On acceptance & 6 monthly	Any side ±1 cm @1m	RAD06 [10] & (A2.1, A2.2) [5]
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)	(A4.2 or A4.1) [5]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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	IFSP01 [10] & (D1) [5]
11.	Base + Fog (B+F)	Daily	Variance +0.03 OD. Maximum OD 0.3	FSP02 [10] & [17]
12.	Mid-density (MD) step (speed index)	Daily	Variance ± 0.15 OD	FSP03 [10] & [17]
13.	Density difference (DD) (contrast index)	Daily	Variance ± 0.15 OD	FSP04 [10] & [17]
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	FSP08 [10] (B1& B3) [5] & [17] ,
16.	Darkroom fog	Acceptance & 6 monthly & when fault reported	Density difference 0.05 for 2 minutes	(C1 & C2) [5] & [17]
17.	Relative speed of intensifying screens	Before initial use & 24 monthly	Baseline minus 10%	FSP09 [10] & [17]
III.1.5.	**CR Reader** [2] & [12]			
18.	Detector dose indicator monitoring (exposure index monitoring)	On acceptance & 3 monthly	Baseline ± 20%	CR01 [10] [5] [12.2] . (K1) & (1)
19.	Image uniformity	On acceptance & 3 monthly	Free from dots and lines	CR02 [10] & (2) [12.2]
20.	Condition of cassettes and image plates	Supplier's recommendation	Free of dirt or damage	CR03 [10] & Supplier's maintenance manual
21.	Test is not required – see test 93		[10] [12.2] CR04 & (3)	
22.	Test is not required – see test 95		CR05 [10] [12.2] & (4)	

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
III.1.5.1.	**AEC Device**			
23.	Sensitivity	On acceptance & 3 monthly	Baseline ± 30%	CR14 [10] & (K5) [5]
III.1.6.	**DDR System**			
24.	Detector dose indicator monitoring	On acceptance & 3 monthly	Baseline ± 20%	DDR01 [10] & (1) [12.4]
25.	Image uniformity	On acceptance & 3 monthly	Lines or rectangles **not** apparent	DDR02 [10] & (2) [12.4]
26.	Test is not required – see test 106			DDR03 [10] & (3) [12.4]
III.1.6.1.	**AEC Device**			
27.	Sensitivity	On acceptance & 3 monthly	Baseline ± 25%	DDR13 [10] & (K5) [5]
III.1.7.	**Film Viewing**			
28.	Film viewer condition	6 monthly	Perceived brightness, colours and must be clean and uniformly illuminated	DD01 [10] & (M1) [5]
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‖	) At least 6 monthly.) On acceptance & as required or at least weekly	) Image display monitors should be clean & free from flicker) Reporting monitors should be clean, and the perceived contrast of the test pattern should be	IDD06 [10] & Use SMPTE or TG18 [18]
30.	Test is not required – see test 119.2		IPEM 91 IDD07& TG 18	

[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 (page 49 [10])

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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)	IDD08 [10]
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	IDD09 [10] & SMPTE or TG18 [18]
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	IDD15 [10] & (N1) [5]
34.	Optical density consistency	On acceptance & 3 monthly	Baseline OD ± 0.20	IDD16 [10] & (N2) [5]
35.	Image quality	On acceptance & 3 monthly	Based on visual inspection	IDD17 [10] & (N3) [5]
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 (Ch 2) [5] (4.10) [7] & [17]
III.1.11. Fluoroscopy Equipment				
37.	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. **DAP readings or dose read-out must be recorded in a book/register. The book/register must include the procedure, date of procedure, patient details, operator, specialist performing the procedure, the total dose (DAP reading/or dose) and the total fluoroscopy time. For each procedure in section III.2.15.4 the average DAP reading / average dose and average time must be calculated for a 12 month cycle by the licence holder and be recorded (see also test 216).**			
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)	FLU01 [10] & (H3) [5]
III.1.11.1. Fluorography (For this section use IPEM Report 77)				
40.	Dose per frame reproducibility under automatic exposure control	On acceptance & 3 monthly	Baseline 25% (For equipment with DAP meter)	[9] & (B I1.1) [5]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
41.	Resultant film density	On acceptance & 3 monthly	Baseline 0.3 OD (Optical density)	[9] & (B I1.2) [5]
42.	Film density reproducibility	On acceptance & 3 monthly	Baseline 0.3 OD	[9] & (B I1.3) [5]
III.1.11.2.	**Digital Fluorography**			
43.	Test is not required – see test 137			FLG01 [10]
44.	Test is not required – see test 138			FLG02 [10]
45.	Test is not required – see test 139.1			FLG03 [10]
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%	CT01 [10] & (B J1) [5]
48.	CT number values	On acceptance & Daily	Water baseline ± 5 HU. Other material: baseline ± 10 HU	CT02 [10] & (B J2) [5]
49.	Scan plane localisation from alignment lights	On acceptance & 3 monthly	± 2 mm	CT03 [10] & (3.5.1) [18]
III.1.13. Screen Film Mammography - For this section use ACR manual [4] OR [6] Or 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)	Page 167 [4]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
51.	Compression	On acceptance & 6 monthly	The maximum compression force must be between 111 Newton (11.3 kg) and 200 Newton (20.4 kg)	page 199 [4]
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%	page 202 [4], (Chapter 2) [5] & (4.10) [7]
53.	Accuracy of stereotactic device	On acceptance & Weekly or as used	Errors of 1mm in X or Y or 3mm in Z	MAM10 [10] & page 118 [11]
54.	Appropriate exposure technique chart (automatic and manual exposures) displayed near the control panel of the unit	6 monthly	Available and applicable	page 145 [4]
55.	Analysis of fixer retention in film	6 monthly	The residual fixer retention shall be 5 micrograms per square cm	page 210 [4]
III.1.14. Digital Mammography - For this section use European guidelines for quality assurance in breast cancer screening and diagnosis [6 & 35]				
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%	(Chapter 2) [5] page 202 [4] & (4.10) [6]
57.	AEC device: Long term reproducibility	On acceptance & weekly	Variation of SNR in the reference ROI and dose < ± 10%.	2b.2.1.3.4 [6] & 0604 [14]
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. [6] & (7.2.3) [23]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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	page 167 [4] & (7.2.4) [23]
60.	Uncorrected defective detector elements (DR systems)	On acceptance & Weekly	Limits of the manufacturer.	2b.2.2.3.3 [6]
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	2b.4.1.2 [6]
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 [6]
63.	Monitors: Display artefacts	On acceptance & Daily	No disturbing artefacts should be visible.	2b.4.1.5 [6]
64.	Printers: Geometrical distortion	On acceptance & Daily	Borders should be completely visible, lines should be straight.	2b.4.2.1 [6]
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 [6]
66.	Printers: Printer artefacts	Daily	No disturbing artefacts should be visible.	2b.4.2.4 [6]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
III.1.15. Small Field Digital Mammography System [15]				
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).	page 167 [4] & (7.2.4) [23]
68.	Accuracy of stereotactic device	On acceptance & Weekly or as used	Errors of 1mm in X or Y or 3mm in Z	MAM10 [10] & page 118 [11]
III.1.16. Additional tests for mobile Mammography Systems [11]				
69.	Must ensure that all freely moveable objects/equipment are firmly locked or strapped down	Before moving		par 5.5.1 [11]
70.	Perform visual check of breast support and associated equipment for possible damage	After moving		par 5.5.2 [11]
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 (IB) approved by the Department of Health			
	Physical parameter (required test)	**Frequency**	**Acceptance Standard**	**Reference**
III.2.1. General Tests				
75.	Safety of premises – On acceptance, when the workload increase or technique factors change that may jeopardise premises safety	On acceptance & changes that jeopardise safety	Controlled areas 5mSv/year, for uncontrolled areas 1mSv/year	NCRP 147 [13] [21] &
76.	Entrance Surface Exposure (ESE) in air without backscatter for Chest, Lumbar Spine, Abdomen, Skull and Foot (ANSI phantom) For Paediatric – Perform measurements without phantom and on manual setting (technique factors used by radiographer) See section III.2.15.1 page 28	First set of ESE results must be reported after 12 months & thereafter every 24 months	ESE shall be evaluated in accordance with the guideline For Paediatric measurements the detector must be positioned at table to detector distance (TDD) – See section III.2.15.1 page 28 (IB report results on Electronic Submission)	Patient Dose Measurements [16] i Paediatric, Table 19, Page 97 [36]
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%	RAD05 [10] & par 3.4 [7]
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	par 2.11 [7]
79.	Radiation output: repeatability	On acceptance & 12 monthly	Mean ± 10%	RAD09 [10]
80.	Radiation output: reproducibility	On acceptance & 12 monthly	Baseline ± 20%	RAD10 [10]
81.	The accuracy of the timer for different settings	On acceptance & 12 monthly	Manufacturers' specifications for specific model or if not available 10%	RAD11 [10]
82.	The accuracy of the kV for different settings	On acceptance & 12 monthly	Manufacturers' specifications for specific model or if not available 10%	RAD12 [10]
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	par 2.3 [7]
84.	Leakage radiation from the diagnostic source assembly (x-ray tube)	Acceptance, tube replacement or after intervention of tube housing.	< 1 mGy in 1 hour at 1 m from the focus	Tube leakage [20]

Table 2 Continued

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

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
100.	Reproducibility	On acceptance & 12 monthly	Baseline ± 30%	CR18 [10]
101.	Image receptor dose	On acceptance & 12 monthly	Baseline ± 30%	CR19 [10]
III.2.4. DDR System (KCARE [10])				
102.	Test not required - see 107			DDR04 [10]
103.	Detector dose indicator repeatability	On acceptance & 12 monthly	Baseline ± 10%	DDR05 [10]
104.	Detector dose indicator reproducibility	On acceptance & 12 monthly	Baseline ± 20%	DDR06 [10]
105.	Measured uniformity	On acceptance & 12 monthly	Mean ± 5%	DDR07 [10]
106.	Threshold contrast detail detectability	On acceptance & 12 monthly	See comments in report 91	DDR08 [10]
107.	Limiting spatial resolution	On acceptance & 12 monthly	Baseline minus 25%	DDR09 [10]
108.	Uniformity of resolution	On acceptance & 12 monthly	**No** increase in blurring from baseline	DDR10 [10]
109.	Scaling errors	On acceptance & 12 monthly	2%	DDR11 [10]
110.	Dark noise	On acceptance & 12 monthly	Baseline ± 50%	DDR12 [10]
III.2.4.1. AEC Device				
111.	Consistency between chambers (sensitivity reproducibility)	On acceptance & 12 monthly	Baseline ± 30% Mean ± 20%	DDR15 [10]
112.	Repeatability	On acceptance & 12 monthly	Mean ± 20%	DDR16 [10]
113.	Reproducibility	On acceptance & 12 monthly	Baseline ± 30%	DDR17 [10]

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
114.	Image receptor dose	On acceptance & 12 monthly	Baseline ± 30%	DDR18 10
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	IDD02 [10]
116.	Film viewer uniformity	On acceptance & 12 monthly	20%	IDD03 [10]
117.	Film viewer variation	On acceptance & 12 monthly	20% difference from the mean value in bank	IDD04 [10]
118.	Room illumination	On acceptance & 12 monthly	100 lux for general radiography	IDD05 [10]
~~**118.1.**~~	~~Film processing evaluation – STEP~~	~~12 monthly~~	~~Processing speed between 80% to 120%~~	STEP [25]
III.2.6. Reporting Monitor				
119.	DICOM greyscale calibration	On acceptance & 12 monthly	GSDF ±10%	IDD11 [10]
119.1.	Minimum requirements for monitors	On acceptance & 12 monthly	Comply with table 4	table 1 & 2 [24]
119.2.	Reporting monitors – Greyscale (luminance response)	On acceptance & 12 monthly	Ratio white to black 250	IDD07 [10] [18]
120.	Luminance uniformity	On acceptance & 12 monthly	Maximum variation 30%	IDD12 [10]
121.	Variation between monitors	On acceptance & 12 monthly	30%	IDD13 [10]
122.	Room illumination	On acceptance & 12 monthly	15 lux for CRT displays & < 20 lux for LCD displays	IDD14 [10] + test 190
III.2.7. Fluoroscopy Equipment				
123.	Display monitor set–up	On acceptance & 12 monthly	All steps visible and black/white circles	FLU02 [10]
124.	Minimum requirements for monitors	On acceptance & 12 monthly	Comply with table 4	24
125.	Test is not required – see test 130		IPEM 91 FLU04 & BIR (B, H2)	

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
126.	Field limitation requirement. X-Ray field/Image intensifier	On acceptance & 12 monthly	The ratio of the areas 1.15.	FLU05 [10]
127.	Dose rate at entrance surface of phantom	On acceptance & 12 monthly	50 mGy/min (entrance air kerma) and baseline 25%	FLU06 [10]
128.	Entrance exposure rate to image intensifier	On acceptance & 12 monthly	Baseline 25%	FLU07 [10]
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}.	FLU09 [10]
130.	Threshold contrast	On acceptance & 12 monthly	See comments Flu10	FLU10 [10]
131.	Image resolution uniformity	On acceptance & 12 monthly	See Comments FLU11	FLU11 [10]
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	(Page 336 – 340) [22]
III.2.7.1.	**Fluorography**			
133.	Overall Image quality	On acceptance & 12 monthly	Manufacturer's specifications for a specific model	(B I1.4) [5]
134.	Resultant film density	On acceptance & 12 monthly	Baseline 0.3 OD	(B I1.3) [5]
135.	Dose per frame at the input face of the image intensifier under automatic exposure control	On acceptance & 12 monthly	Baseline 25% or 1 Gy per frame (Largest field)	(B I1.1) [5]
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.	(B I1.4) [5] & [9]
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 %	FLG04 [10]
138.	Limiting spatial resolution	On acceptance & 12 monthly	Baseline reduced by 2 groups	FLG05 [10]
139.	Dynamic range	On acceptance & 12 monthly	See Comments FLG07	FLG07 [10]
139.1.	Threshold contrast	On acceptance & 12 monthly	Baseline ± 2 discs	FLG06 [10]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
III.2.8. Computed Tomography				
140.	Image noise	On acceptance & 12 monthly	Baseline ± 10% Inter –slice variation; Mean ± 10%	CT06 [10]
141.	CT number values	On acceptance & 12 monthly	Water baseline ± 5 HU Other materials: baseline ± 10HU	CT07 [10]
142.	CT number uniformity	On acceptance & 12 monthly	Head phantom: ±10HU Body phantom: ±20HU	CT08 [10]
143.	High contrast spatial resolution	On acceptance & 12 monthly	Baseline ±20%	CT09 [10]
144.	Computed tomography dose index (CTDI)	On acceptance & 12 monthly	Baseline ±15%	CT10 [10]
145.	Image slice thickness	On acceptance & 12 monthly	Baseline ±20% or ± 1mm, whichever is greater	CT13 [10]
146.	$CTDI_{vol}$ for technique factors used for groups specified in section III.2.15.3 page 28	On acceptance & 12 monthly	Reference dose - table 3 of reference 1.2 and reference 24 (IB report results on Electronic Submission)	CT11 [10]
III.2.9. Screen Film Mammography [4]				
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 [4]
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 [4]
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 [4]
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 [4]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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 [4]
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 [4]
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 [4]
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 [4]
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 [4]
157.	Artefact evaluation	On acceptance & 12 monthly	No significant artefacts must be visible	Page 249 [4]
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 [4]
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 [4]

Table 2 Continued

	Physical parameter (required test)	Frequency	A cceptance Standard	Refe
160.	AEC reproducibility	On acceptance & 12 monthly	The coefficient of variation for R (exposure) or mAs must be 0.05	Page 2 77 4
161.	Average glandular dose	On acceptance & 12 monthly	The dose must be 300 mRad (3 mGy) for 4.2 cm effective breast thickness (IB report results on Electronic Submission)	Page 2 77 4
162.	Radiation output rate	On acceptance & 12 monthly	The output must be 800 mR/s (7.0 mGy/s) at maximum SID [3]	Page 2 77 4
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 2 86 4
III.2.10. DDR & CR Mammography [6&35] (Reference 35 must be consulted)				
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	(8.2.1) 23
~~165.~~	~~X-ray source: Source-to-image distance – Only if adjustable~~	~~On acceptance & 12 monthly~~	~~Manufacturers specificatio n, typical 600-650 mm.~~	2b.2.1.1.2 6
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 6
~~167.~~	~~X-ray source: Radiation leakage~~ ~~On acceptance and afte housing.~~	~~r intervention on the tube~~	~~≤ 1 mGy in 1 hour at 1 m from the focus~~	2b.2.1.1.4 6
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 6
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 6
170.	Half Value Layer (HVL) On acceptance and afte housing.	r intervention on the tube	4th edition supplement stand ard.	2b.2.1.2.2 35

[3] Test 168 - Units manufactured after 01-01-2003. Units manufactured prior to 01-01-2003 and that do not comply may not be resold.

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
171.	AEC-system: Optical density control setting: central value and difference per step (if applicable)	On acceptance & 12 monthly	Measure increase in exposure per step and inform user - must be displayed at technique chart	2b.2.1.3.1 [6]
172.	AEC-system: Short term reproducibility	On acceptance & 12 monthly	< ± 5%	2b.2.1.3.3 [6]
173.	AEC-system: Object thickness and tube voltage compensation	On acceptance & 12 monthly	Thickness indicator < ± 0.5 cm and 4th edition supplement standard.	2b.2.1.3.5, [6, 35]
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 [6]
175.	Compression plate alignment	On acceptance & 12 monthly	≤ 5 mm	2b.2.1.4 [6] & (8.9) [23]
176.	Local dense area (only DR systems)	On acceptance & 12 monthly	The SNR of each image should be within 20% of the average SNR	2b.2.1.3.6 [35]
~~**177.**~~	~~Grid imaging~~	~~On acceptance & 12 monthly~~	~~No significant non uniformity~~	2b.2.1.5.2 [6]
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 [6]
179.	Image receptor Noise evaluation	On acceptance & 12 monthly	Results at acceptance are used as reference	2b.2.2.1.2 [6]
180.	Missed tissue at chest wall side	On acceptance	Width of missed tissue at chest wall side ≤ 5 mm	2b.2.2.2 4 [6] & (8.9) [23]
181.	Image receptor homogeneity and Image receptor detector element failure (DR systems)	On acceptance & 12 monthly	Variation in mean pixel value < ± 30% (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 [35] & 2b.2.2.3.2 [6]
182.	Inter plate sensitivity variations (CR systems)	On acceptance & 12 monthly	SNR variation ≤ ± 10%. Variation in entrance surface air kerma OR tube loading (mAs)≤± 10%,	2b.2.2.4 [6, 35]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
~~**183.**~~	~~Influence of other sources of radiation (CR)~~	~~On acceptance~~	~~The coins should not be visible.~~	2b.2.2.5 ~~6~~
~~**184.**~~	~~Fading of latent image (CR)~~	~~On acceptance~~	~~Results at acceptance are used as reference.~~	2b.2.2.6 ~~6~~
185.	Dosimetry	On acceptance & 12 monthly	< 2.5 mGy for 4.5 cm PMMA - see 2a.2.5.1 for rest of values (IB report results on Electronic Submission)	2b.2.3 6
186.	Threshold contrast visibility	On acceptance & 12 monthly	See table in 2b.2.4.1 for limiting values	2b.2.4.1 6
187.	Exposure time	On acceptance & 12 monthly	< 2 s	2b.2.4.3 6
188.	Geometric distortion and artefact evaluation	On acceptance & 12 monthly	No disturbing artefacts, no visible distortion.	2b.2.4.4 6
189.	Ghost image/erasure thoroughness	On acceptance & 12 monthly	—Ghost image‖-factor < 0.3	2b.2.4.5 6
190.	Monitors : Ambient light	On acceptance & 12 monthly	< 10 lux for CRT displays & < 20 lux for LCD displays	2b.4.1.1 6 +35
191.	Monitors: Resolution	On acceptance & 12 monthly	All line patterns should be discernible.	2b.4.1.4 6
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 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 6
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 6
195.	Printers: Resolution	On acceptance	All line patterns should be discernible	2b.4.2.3 6
196.	Printers: Greyscale Display Function	On acceptance & 12 monthly	The calculated contrast response should fall within ± 10% of the GSDF contrast response.	2b.4.2.6 6
197.	Printers: Density uniformity	On acceptance & 12 monthly	Maximum optical density deviation should be less than 10% ((Dmax-Dmin)/Dcentre < 0.1)	2b.4.2.7 6

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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)	Page 167 [4] & 23
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 [6]
III.2.11. Small Field Digital Mammography System [15]				
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 [15]
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 [15]
203.	Size of image field	On acceptance	Each dimension should be within 5% of specified value	3.1.2 [15]
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 [15]
205.	Automatic exposure control: Overall repeatability	On acceptance & 12 monthly	Maximum deviation in mAs ≤ 5% from the mean	3.3.1 [15]
206.	Constancy with change in phantom thickness	On acceptance & 12 monthly	Maximum deviation in *pixel values* ≤ 10% of the mean	3.3.2 [15]
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 [15]
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 [15]
209.	Display devices: Resolution	On acceptance & 12 monthly	Frequency high contrast resolution pattern resolved	3.4.1 [15]

Table 2 Continued

	Physical parameter (required test)	Frequency	Acceptance Standard	Reference
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 [15]
211.	Hardcopy printer: Resolution	On acceptance & 12 monthly	Maximum frequency in the high contrast patterns should be resolved	3.4.2 [15]
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 [15]
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.	Page 167 [4]
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 [15]
III.2.12. DRLs				
215.	A Medical physicist is appointed in writing and an optimisation program is implemented	12 monthly	Comply with requirements in paragraph I.A.9.1.1	
216.	For each procedure in section III.2.15.4 the average DAP reading / average dose and average time was calculated by licence holder, documented and reported by IB	12 monthly	The Inspection Body must report these results on the Electronic Submission	Fluoroscopy 27, 28 & 29

6. Table 3 & Table 4 (HVL values and Minimum requirements for monitors)

III.2.13. 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.										

III.2.14. Table 4 - MINIMUM REQUIREMENTS FOR MONITORS [24]			
Description and application	**Monitors purchased on or after 1 March 2012**		
	Licensed with Department of Health as a medical device for	**Minimum**	**CE medical**
01. Diagnostic (reporting) monitor used in mammography	**Yes**	**5 Megapixel**	**Yes**
02. Diagnostic (reporting) monitor used in conventional radiology	**Yes**	**3 Megapixel**	**Yes**
03. Diagnostic (reporting) monitor used in Computed Tomography	**Yes**	**1.3 Megapixel**	**Yes**
04. All monitors not covered under 01, 02 and 03 (e.g. Image display monitor not to be used for diagnosis but images viewed only in conjunction with the report – ward, clinic, theatre, etc; Workstations; Image review monitors (not used for immediate feedback to clinical activity); Fluoroscopy (production of dynamic x-ray images which are	**No**	**1 Megapixel**	**Yes**

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.**

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.

7. TABLE 1 DIAGNOSTIC REFERENCE LEVELS

III.2.15.1.	**GENERAL RADIOGRAPHY**								
Report ESD per radiograph (mGy) as determined with test 76									
250	Chest (PA) Grid	251	Abdomen (AP) Grid	252	Lumbar Spine (AP) Grid	253	Skull (Lateral) Grid	254	Foot - Non-grid
255	Chest 1 year (TDD 13 cm)	256	Abdomen 1 year (TDD 13 cm	257	Chest 5 year (TDD 15 cm)	258	Abdomen 5 year (TDD 15 cm)		
259	Chest (PA) 10 year (TDD 16.8 cm)	260	Abdomen 10 year (TDD 16.8 cm)						
III.2.15.2.	**MAMMOGRAPHY**								
Report ESD per radiograph (mGy) as determined with test 161 & 185 – Dose values for a 4.5 cm phantom must be reported									
261	Mammography Average glandular dose								
III.2.15.3.	**COMPUTED TOMOGRAPHY**								
Report average $CTDI_{vol}$ per examination (mGy) as determined with test 146 Paediatric is between 1 to 5 years.									
262	Adult head	263	Adult chest	264	Adult abdomen-pelvis	265	IVP	266	Paediatric abdomen	267	Paediatric head

III.2.15.4. FLUOROSCOPIC EXAMINATIONS

Report average DAP value per examination **(Gy.cm^2)** and average fluoroscopy time per examination as determined with test 37 for **each** fixed fluoroscopic unit. Pediatric is between 1 to 5 years. The correction factor as determined with test 132 must be used to correct all average values for reporting

282	Barium (or water soluble) swallow	283	Barium meal	284	Barium follow through	285	Barium (or water soluble) enema
286	Small bowel enema	287	MCU	288	MCU - Pediatric		

III.2.15.4.1. INTERVENTIONAL EXAMINATIONS

	Procedure Name	Also known as		Procedure Name	Also known as
289	Coronary Angiography	CA (Coronary Angiogram) / Cardiac Catheterization	290	Cerebral Angiography	Cerebral Angiogram / Neuro-Angiogram
291	Cerebral Angiography + Interventions	Neuro-Angiogram + Interventions	292	Renal Angiography	Renal Angiogram / Renal Arteriography
293	Peripheral Angiography	Peripheral Angiogram / Peripheral Anteriogram	294	CA + EPS	Coronary angiogram + Electro Physiology Study
295	Ablation	Catheter Ablation - Radio Frequency / Cardiac RF ablation / Radio Frequency ablation	296	CA + LV function	CA + LV function; Left Ventriculography
297	EPS	Electrophysiology Study	298	Pacemaker (Bi Vent)	Biventricular Pacemaker / CRT (Cardiac Resynchronization Therapy)
299	CA + EPS + Ablation	CA + EPS + Catheter ablations	300	TAVI	Valve placement; Transcatheter Aortic Valve Implantation
301	Pacemaker (Permanent)	Pacemaker/ PPM	302	Pediatric Diagnostic heart caths	Pediatric Diagnostic left & right heart catheters
303	EVAR	Endovascular Anuerysm Repair / Endovascular Aortic Repair	304	Femoral angiogram	
305	Uterine Artery Embolisation (UAE) Percutaneous transhepatic		306	ERCP (Endoscopic retrograde cholangiopancreatography)	

8. 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[4] :								
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								

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[5].**	
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				

[33] An Inspection Body is an organization that is accredited by SANAS (www.sanas.co.za) and approved by the SAHPRA RADIATION CONTROL

9. TEST GUIDELINES

- X-Ray Tubes and Generators – Conventional film systems; (tests 1-17, 28, 33-36, 75-89, 115-118 ~~118.1~~);
- Computerized 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, 215, 216);
- 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)

10. 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.

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

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

6.3 **AAPM** ,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

6.4 **ACR** (American College of Radiology), Mammography Quality Control Manual (1999) www.arc.org ACR Store Quality and Safety Quality Control Manuals

6.5 **BIR** (British Institute of Radiology), Assurance of Quality in the Diagnostic Imaging Department 2nd Edition, 2001, http://www.bir.org.uk Publications Bookshop

6.6 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

6.7 Imaging Quality Assurance Manual Published by the Radiation Safety Office for the University of Rochester Medical Center, Revision 15 Dated 7/03/2014, http://extranet.urmc.rochester.edu/radiationsafety/documents/QA_Manual.pdf

6.8 **IMPACT,** CT Scanner Acceptance Testing, www.impactscan.org Reports & info acceptance testing of CT

6.9 **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

6.10 **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

6.11 **IPEM** (Institute of Physics and Engineering in Medicine), **Report 89**, The Commissioning and Routine Testing of Mammographic X-Ray Systems, www.IPEM.org.uk

6.12 **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

6.12.1 CR system: Commissioning & Annual tests;

6.12.2 CR system: Routine QA tests;

6.12.3 DDR system: Commissioning & Annual tests, and

6.12.4 DDR system: Routine QA tests.

6.13 **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

6.14 **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*

6.15 **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*

6.15.1 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*

6.16 Patient Dose Measurements in Diagnostic Radiology https://sites.google.com/site/radiationcontroldoh/ **lectronic devices – Use lectronic devices - ionising radiation uidelines**

6.17 Test procedures for film processing and intensifying screens, https://sites.google.com/site/radiationcontroldoh/ **lectronic devices – Use lectronic devices - ionising radiation uidelines**

6.18 **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**

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

6.20 Tube leakage, https://sites.google.com/site/radiationcontroldoh/ lectronic devices – Use lectronic devices - ionising radiation Guidelines

6.21 Shielding, https://sites.google.com/site/radiationcontroldoh/ lectronic devices – Use lectronic devices - ionising radiation Guidelines

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

6.23 Quality Assurance for Digital Mammography Programme, www.iaea.org/books ook under Human Health Series

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

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

6.26 DRLs for adult and pediatric patients, https://sites.google.com/site/radiationcontroldoh/ lectronic devices – Use lectronic devices - ionising radiation iagnostic Reference Levels DRLs tables;

6.27 IPEM 2004, Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-Ray Examinations, Report no. 88, www.IPEM.org.uk

6.28 NCRP Report no. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States

6.29 ARPANSA - Diagnostic Reference Level Fact Sheet, https://sites.google.com/site/radiationcontroldoh/ lectronic devices – Use lectronic devices - ionising radiation iagnostic Reference Levels;

6.30 TR 78-03, Technical requirements for the application of SANS/ISO/IEC 17020: 2012 for testing of Diagnostic X-ray Imaging Systems by Inspection Bodies, www.Sanas.co.za;

6.31 ISO/IEC 17020: 2012, Conformity assessment — Requirements for the operation of various types of bodies performing inspection.

6.32 Navy Diagnostic Imaging Equipment Performance Survey Manual, Navy and Marine Corps Public Health Center Technical Manual NMCPHC TM-6470.1, http://www.med.navy.mil/sites/nmcphc/Documents/oem/Navy-Diagnostic-Imaging-Equipment-Performace-Survey-Manual.pdf

6.33 The Royal Australian and New Zealand College of Radiologists, Guidelines for Quality Control Testing for Digital (CR DR) Mammography http://www.ranzcr.edu.au/quality-a-safety/radiology/practice- quality-activities

6.34 Heggie *et al,* ACPSEM Position Paper, Recommendations for a Digital Mammography Quality Assurance Program v3.0

6.35 European guidelines for quality assurance in breast cancer screening and diagnosis – fourth edition - Supplements, European Communities, 2013, www.google.co.za Search for ISBN 978-92-79- 32970-8

6.36 Dosimetry in Diagnostic Radiology for Paediatric Patients, Pub1609, IAEA

6.37 Diagnostic Radiology Physics: A Handbook for Teachers and Students, IAEA http://www-naweb.iaea.org/nahu/dmrp/publication.asp

6.38 Radiation Protection in Diagnostic and Interventional Radiology, Publication No. 14.1, ARPANSA, page 19, http://www.arpansa.gov.au/

6.39 Test phantoms, http://www.leedstestobjects.com

11 VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Diagnostic QC, revised April 2015. It will be reviewed on this timeframe or as and when required.