South African Health Products
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REQUIREMENTS FOR LICENCE HOLDERS WITH RESPECT TO QUALITY CONTROL TESTS FOR DENTAL 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.

The legislative mandates of SAHPRA are derived from the Constitution; the National Health Act, 2003 (Act No. 61 of 2003); the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (hereinafter referred to as "the Medicines Act"); and other relevant legislation, regulations and policies.

Further, SAHPRA's mandate has expanded to include the regulation and control of radiation emitting devices and radioactive nuclides under the Medicines Act and the Hazardous Substances Act, 1973 (Act No. 15 of 1973). The Hazardous Substances Act does not allow any person to use radiation equipment unless he/she holds a licence under the Act for that purpose.

Document History

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Contents

Document History 1

Glossary 3

1. INTRODUCTION 4

1.1 Purpose 4

1.2 Scope 4

2. LEGAL PROVISION 4

3. GENERAL REQUIREMENTS 4

3.1 License Holder Shall: 4

3.2 TABLE 1 Individual Equipment Record (IER) -See Also Section VI 7

3.3 TABLE 2: Acceptance and Routine Quality Control Tests 8

3.4 TABLE 3 Half value layers (HVL-values) and Table 4 Minimum Requirements for Monitors 22

3.5 TEST GUIDELINES 23

4. REFERENCES 23

5. VALIDITY 25

Glossary

Abbreviation/ Term	Meaning
Al	Aluminum
CR	Computed Radiography
CT	Computed Tomography
DAP	Dose Area Product
DICOM	Digital Imaging and Communications in Medicine
DDR	Direct Digital Radiography
HVL	Halve Value Layer
HPCSA	Health Professions Council of South Africa
IER	Individual Equipment Record
kV	Kilovolt
mGy	milligray
QC	Quality Control
Acceptance Tests	The initial tests performed directly after installation and before the equipment is being put into clinical service
Extraoral Radiography	X-rays taken when the image detector and the X-ray machine are placed outside the patient's mouth.
Intraoral Radiography	X-rays taken with image receptor/film placed within the oral cavity/mouth
Inspection Body	An organization accredited by SANAS and approved by SAHPRA Radiation Control
SAHPRA	South African Products Regulatory Authority
SANAS	South African National Accreditation System
Cephalometric Radiography **Panoramic Radiography**	A specialized radiographic technique concerned with imaging the side of your head, exposing teeth, jaw, and surrounding structures. When two components rotate simultaneously around the patient to produce an image.

1. INTRODUCTION

Licensed dentists play an important role in maintaining radiation exposures of patients and staff as low as reasonably achievable (ALARA). Greater numbers of intra-oral radiographs are being requested and a wide range of other dental radiographic examinations (panoramic, cephalometric) are being performed on a routine basis with the addition of advanced imaging modalities. Individuals who operate dental X-ray equipment must have a basic knowledge of the inherent health risks associated with radiation and must have demonstrated familiarity with basic rules of radiation safety as explained in this study guide.

1.1 Purpose

To ensure that license holders and users of diagnostic dental imaging devices establish an optimum quality assurance program to protect patients, radiation workers, the public and the environment against over-exposure to ionizing radiation, without limiting its beneficial use. To guard against incorrect diagnosis by way of reducing apparatus and operator faults.

1.2 Scope

The license holder must ensure that all applicable requirements are implemented as stipulated in this guideline. The license holder shall ensure that only an Inspection Body accredited by SANAS and approved by SAHPRA is used to perform all the prescribed acceptance tests as well as the routine tests.

2. LEGAL PROVISION

This guideline is implemented in promulgated the Hazardous Substances Act 15, 1973 and the Regulations R.1332

3. GENERAL REQUIREMENTS

3.1 License Holder Shall:

A. Display the product licence number (see list of licences from SAHPRA 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).**

- 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. An Inspection Body (IB) approved by SAHPRA **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 SAHPRA must formally contract such person(s). Formally contracted means that the medical physicist is contracted by the IB (ISO/IEC 17020 and TR78 (latest edition)) to perform the tests.

- List of IB's available on SAHPRA website

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 sectionII.1 of table 2 are correctly performed.

E. Ensure that persons that perform routine tests in section II.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 14 for definition of optimisation).Such program must at least use the measurements under tests 44, 46 and 64 to determine whether radiation protection has been optimised.

I.1. Measurements under test 64 must be evaluated after the x-ray unit is put into clinical service and thereafter every 12 months.

I.2. Measurements under tests 44 and 46 must be evaluated after the x-ray unit is put into clinical service and thereafter every 36 months.

- Use reference 4.

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.

3.2 TABLE 1 Individual Equipment Record (IER) -See Also Section VI

		X-Ray Equipment	Processor & Hardcopy device	CR Reader	Digital detectors	Film Viewer	Reporting Monitor
a)	**Unit -** make, model and **system ID**	X	X	X	X		
b)	**Generator –** make, model and serial number	X					
c)	Product Licence number, date of the latest licence & reference where a copy of the licence is kept	X		X			
d)	Date of installation	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		
f)	Results of acceptance tests	X	X	X	X		X
g)	Results of routine quality control tests	X	X	X	X	X	X
h)	Date(s) of tube replacement(s)	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
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
k)	Details of the IB and person(s) that performed the test(s)	X		X	X	X	X

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

3.3 TABLE 2: Acceptance and Routine Quality Control Tests

II.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.				
	Physical parameter (required test)	**Frequency**	**Standard**	**References**
II.1.1.	**General**			
1.	Lead rubber aprons	3 monthly	Free from holes or cracks	Ref 2 procedure 11
II.1.2.	**Extra-oral X-ray tubes with intra-oral image receptors, panoramic radiography and cephalometric radiography**			
2.	Indicators, mechanical and other safety checks & warm-up	On acceptance & 3 monthly	Results must be documented at least once every 3 months	Ref 2 procedure 5
3.	Tube Head stability (intraoral x-ray unit)	On acceptance & 3 monthly	The tube does not drift out of position or oscillate	Ref 2 procedure 7
4.	Appropriate technique chart displayed at x-ray unit	6 monthly	Available, applicable and compliant with ALARA principle	
5.	Condition of digital detectors	On acceptance & monthly	No damage to cable or detector or phosphor plate	IPEM 91 DEN07
6.	Evaluation of total image chain (**Image quality)** (film and digital) Images shall be preserved for a period of 36 months. IB must compare results for last 36 months **Note:** The IB must verify that the licence holder possesses the applicable phantom. If a phantom is not available the test must be reported as **FAIL**	On acceptance & monthly IB every 3 years	No visible deterioration compared with reference image **Film & digital** - Intra-oral - Use *To UniDENT* phantom orsimilar **Film** - Intra-oral ,Panoramic & Cephalometric radiography - Use *TOR DEN conventional* phantom orsimilar **Digital** - Intra-oral ,Panoramic & Cephalometric radiography - Use *TOR DEN digital* phantom or similar	Ref 25
7.	Panoramic radiography reproducibility and uniformity	On acceptance & 3 monthly	No significant visible difference to baseline (professional judgement required)	IPEM 91 DEN10
8.	Panoramic radiography beam alignment and synchronisation of exposure with tube motion	On acceptance & 3 monthly	Edge of beam must be visible on film and detector	IPEM 91 DEN11, Ref 2 procedure 12 & Ref 7 p 6
9.				

10.	Cephalometric radiography - X-ray beam alignment	On acceptance & 3 monthly	Edge of beam must be visible on film and detector	IPEM 91 DEN11, Ref 2 procedure 12 & Ref 7 p 7
	Physical parameter (required test)	**Frequency**	**Acceptance Standard**	**References**
II.1.3.	**Dental Film Processing**			
11.	Developer temperature	Every time processing solutions are used	Baseline ± 2ºC - The temp must be ≥ 18ºC and ≤ 40ºC and comply with recommendations of manufacturer.	IPEM 91 DEN01, BIR (D1) & Ref 6
12.	Condition of processing solutions Development time Chemistry changes Cleaning	Every time processing isused or as specified by manufacturer	As recommended by manufacturer. Time-temperature chart must be displayed at the processor	Ref 2 procedure 3, IPEM 91 DEN02 & Ref 6
15.	Cleanliness of darkroom, daylight processor (intra-oral daylight processor) and screens	Written protocol for maintaining darkroom cleanliness, intra-oral daylight processor, cassettes and screens clean, free from blemishes		Ref 2 procedure 3
16.	Darkroom fog and light tightness of intra-oral daylight processor	Acceptance & 12 monthly & when fault reported	No visible fogging in 2 minutes	IPEM 91 DEN05; Ref 2 procedure 10A & 10B, Ref 5 and BIR C1 & C2
II.1.4.	**Film Viewing**			
17.	Film viewer condition	Acceptance & 6 monthly	Perceived brightness, colours and must be clean and uniformly illuminated	IPEM 91 IDD01 & BIR (M1)

II.1.5.	**Image Display Monitor & Reporting Monitor[2]**			
18.	Condition of Image Display Monitor	At least 6 monthly.	Image display monitors should be clean & free from flicker	Ref 23
~~**19.**~~				
20.	**Reporting Monitor** - Resolution, Brightness and contrast, GreySteps & Alphanumerics and Geometric Distortion	On acceptance & 3 monthly	Requirements of Ref 23 During acceptance install SMPTE or TG18-QC test pattern for user and demonstrate use	Ref 23 & IPEM 91 IDD06 & TG 18 (Use SMPTE or TG18-QC image IPEM 91 IDD09, IDD10
II.1.6.	**Hardcopy Device (Only applicable if prints are used for reporting (interpretation of medical images))**			
21.	Self – calibration	On acceptance & Weekly	Manufacturer's specification	IPEM 91 IDD15 & BIR (N1)
22.	Optical density consistency	On acceptance & 3 monthly	Baseline OD ± 0.20	IPEM 91 IDD16 & BIR (N2)
23.	Image quality	On acceptance & 3 monthly	Based on visual inspection	IPEM 91 IDD17 & BIR (N3)

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)

	Physical parameter (required test)	Frequency	Acceptance Standard	References
II.1.7.	**Dental Cone Beam CT**			
24.	Indicators, mechanical and other safety checks	On acceptance & Daily	Must work properly	
~~**25.**~~				
~~**26.**~~				
~~**27.**~~				
28.	Image display monitor condition	On acceptance & Monthly	See Explanatory paragraph under DCB04	Ref 4 DCB04 & IPEM 91IDD06
29.	Image display monitor distance calibration	On acceptance & 3 Monthly	± 5 mm	Ref 4 DCB05 & IPEM 91IDD08
30.	Image display monitor resolution	On acceptance & 3 Monthly	See Explanatory paragraph under DCB06	Ref 4 DCB06 & IPEM 91IDD09
II.1.8.	**CR Reader (see also Ref 1.1 & KCARE (Ref 10))**			
~~**31.**~~				
32.	Image uniformity	On acceptance & 3 Monthly	Free from dots and lines	IPEM 91 CR02 & KCARERef 10.2 (2))
33.	Condition of cassettes and image plates	On acceptance & 3 Monthly	Free of dirt or damag	IPEM 91 CR03 & Supplier's maintenance manual

	Physical parameter (required test)	Frequency	Acceptance Standard	References
II.1.9.	**DDR System**			
~~**35.**~~				
36.	Image uniformity	On acceptance & 3 Monthly	Lines or rectangles **not** apparent	IPEM 91 DDR02 & KCARE Ref 10.4 (2)
II.1.10.	**Repeat and Reject Analysis**			
38.	**Repeat and reject analysis** – (Comment for Digital: Must usesoftware supplied by vendor or implement effective procedure)	3 monthly	May not increase with more than 2% from the previous determined rate and total rate should not exceed 10% IB must check that software/procedure is in place	For film Screen use BIR (Ch 2), Ref 2 procedure 6 & Ref 26 page 95

II.2. Acceptance 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**
39.	Safety of premises	On acceptance & when the workload increase or technique factors change that may jeopardise premises safety	Controlled areas 5mSv/year, for uncontrolled areas 1mSv/year	NCRP 145 & Ref 19

II.2.1.	Extra-oral X-ray tubes with intra-oral image receptors, panoramic radiography and cephalometric radiography			
40.	Tube voltage (measured 100 ms from initiation of exposure + stability of line voltage must be checked if failed)	On acceptance & 3 years	±10% of intended and for fix kV units if deviates more ±10% the correct kV must be indicated on unit. Intra-oral ≥ 50kV and only units with a tube voltage ≥ 60 kV maybe sold	IPEM 91 DEN12 and ref 1 page 20 & Ref 7 page 2 & 8
41.	Exposure time	On acceptance & 3 years	±20% from baseline	IPEM 91 DEN13
42.	Intra-oral radiography – Beam size collimation. **IB must report in comment field if Pointer Cone is used**	On acceptance & 3 years	Circular: ≤ 60 mm diameter at the open end of collimator(Equipment with pointer collimator may not be sold) OR Rectangular: ≤ 40x50 mm at the open of collimator	IPEM 91 DEN14 & Ref 24 page 21
42.1.	Intra-oral radiography – Minimum focus to skin distance – IB must report Focus to Skin Distance in ES	On acceptance & 3 years	Focus to skin distance of at least 200 mm (Less than 200 mm onlypermitted for existing units, however may not be sold)	IEC 60601-2-65 (203.9)
43.	Intra-oral digital systems: Imaging spatial resolution	On acceptance & 3 years	Baseline ≤ minus 25%	IPEM 91 DEN15
44.	Intra-oral radiography:	On acceptance & 3 years	Measured values below must be reported in mGy (dose) and mGy cm^2 (DAP) on Electronic Submission (See test 6)	IPEM 91 DEN16 and ref 29
44.1.	Dose at collimator (cone) tip for **average adult** mandibularmolar radiograph	On acceptance & 3 years	Must be below SA reference level (when established)	
44.2.	**DAP** value at collimator (cone) tip for **average adult** mandibular molar radiograph	On acceptance & 3 years	Must be below SA reference level (when established) – If displayed should be within ± 15%, if not add correction factor	

44.3.	Dose at collimator (cone) tip for **child** mandibular molarradiograph	On acceptance & 3 years	Must be below SA reference level (when established)	
44.4.	**DAP** value at collimator (cone) tip for **child** mandibularmolar radiograph	On acceptance & 3 years	Must be below SA reference level (when established) – If displayed should be within ± 15%, if not add correction factor	

	Physical parameter (required test)	Frequency	Acceptance Standard	References
45.	Panoramic radiography: beam size/collimation	On acceptance & 3 years	Must comply with the specifications by equipment manufacturer, and the useful beam must not exceed receptor height	IEC 61223-3-4, par 7.5.2
46.	Panoramic & cephalometric radiography: DAP Values	On acceptance & 3 years	The measured values must be recorded in mGy cm^2 on Electronic Submission – If displayed should be within ± 30%, if not add correction factor ≤ ≤	IPEM 91 DEN18 and Ref 27
46.1.	Panoramic radiography for average adult	On acceptance & 3 years	Should be less than 92 mGy cm^2 – Baseline ± 15%	
46.2.	Panoramic radiography for child	On acceptance & 3 years	Must be below SA reference level (when established)	
46.3.	Cephalometric radiography for average adult	On acceptance & 3 years	Must be below SA reference level (when established)	
46.4.	Cephalometric radiography for child	On acceptance & 3 years	Must be below SA reference level (when established)	
~~47.~~				
48.	Max dimensions of x-ray field for cephalometric radiography	On acceptance & 3 years	Must comply with the specifications by equipment manufacturer and shall be smaller than the receptor. All edges of x-ray field visible.	IEC 61223-3-4, par 7.5.2
49.	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
50.	Radiation output repeatability	On acceptance & 3 years	Mean ± 10%	IPEM 91 RAD09

51.	Radiation output reproducibility	On acceptance & 3 years	Baseline ± 10%	IPEM 91 RAD10
52.	Leakage radiation from the diagnostic source assembly (x-ray tube) Also applicable on Cone Beam CT	At acceptance and after intervention on the tube housing.	≤1 mGy in 1 hour at 1 m from the focus and ≤ 0.25 mGy for apparatus used with intra-oral image receptors. If certificate of x- ray tube manufacturer for tube leakage is available, this can be used without testing.	Ref 18 and Ref 7
II.2.2.	**Dental Cone Beam CT**			
53.	Reconstructed Image measurement	On acceptance & 12 monthly	± 0.5 mm	IPEM 91 DDR11 & Ref 4 DCB07
54.	Image noise	On acceptance & 12 monthly	Must meet manufacturer's specs or Baseline or inter slice variation mean ± 10%	IPEM 91 CT06 &Ref 4 DCB08
55.	Image density values	On acceptance & 12 monthly	Must meet manufacturer's specs or Baseline ± 10%	IPEM 91 CT07 &Ref 4 DCB09

	Physical parameter (required test)	Frequency	Acceptance Standard	References
56.	Image uniformity	On acceptance & 12 monthly	Must meet manufacturer's specs or Baseline ± 10%	IPEM 91 CT08 &Ref 4 DCB10
57.	High contrast spatial resolution	On acceptance & 12 monthly	Must meet manufacturer's specs or Baseline ± 20%	IPEM 91 CT09 &Ref 4 DCB11
~~**58.**~~				
~~**59.**~~				
60.	Radiation field size	On acceptance & 12 monthly	≤ 10 mm or 10% of expected field size (whichever is smaller)	Ref 4 DCB14
61.	Radiation output repeatability	On acceptance & 12 monthly	Mean ± 10%	IPEM 91 RAD09 & Ref 4 DCB15
62.	Radiation output reproducibility	On acceptance & 12 monthly	Baseline ± 10%	IPEM 91 RAD10 & Ref 4 DCB16
63.	Operating potential	On acceptance & 12 monthly	≤ ±5% of intended or ± 5 kV (whichever is smaller) and ≥ 60 kV	IPEM 91 RAD12 & Ref 4 DCB17
63.1.	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	Ref 4 page 45

64.	Dental cone beam CT: DAP	On acceptance & 24 monthly	Measured values below must be reported in mGy cm^2 (DAP) on Electronic Submission. If displayed should be within ± 15%, if not add correction factor	Ref 4 DCB18 &
64.1.	The adult measurement shall be made using the clinical protocol for the placement of an upper first molar implant in a standard male	On acceptance & 24 monthly	Must be below SA reference level (when established)	
64.2.	The child measurement shall be made using the clinical protocol to image a single impacted maxillary canine of a 12 year old male	On acceptance & 24 monthly	Must be below SA reference level (when established)	
65.	High Contrast material	On acceptance & 12 monthly	Explanatory paragraph on page 24 Ref 4	Ref 4 page 46
	Physical parameter (required test)	**Frequency**	**Acceptance Standard**	**References**
II.2.3.	**Film Viewing (Viewing boxes used for Reporting/Interpretation of medical images - see Chapter 7 of IPEM 91) & Film processing**			
66.	Film viewer luminance	On acceptance & 3 years	1500 cd/m^2 for general radiography	IPEM 91 IDD02
67.	Film viewer uniformity	On acceptance & 3 years	20%	IPEM 91 IDD03
68.	Film viewer variation	On acceptance & 3 years	20% difference from the mean value in bank	IPEM 91 IDD04
69.	Room illumination	On acceptance & 3 years	100 lux for general radiography	IPEM 91 IDD05
II.2.4.	**Reporting Monitor[3]**			
72.	General image quality and artefacts; Geometric distortion; Luminance, reflection, noise, and glare & Resolution	On acceptance & 3 years	Use TG18-QC image	Ref 23 & Ref 16 IPEM 91 IDD09

73.	DICOM greyscale calibration	On acceptance & 3 years	GSDF ±10%	IPEM 91 IDD11
74.	Minimum resolution	On acceptance & 3 years	Comply with table 4	Ref 21 & 22
75.	Reporting monitors – Greyscale (luminance response)	On acceptance & 3 years	For Cone Beam CT: Ratio white to black ≥ 250; For intra-oral, panoramic and cephalometric radiography: Ratio white to black 100	IDD07& TG 18
76.	Luminance uniformity	On acceptance & 3 years	Maximum variation 30%	IPEM 91 IDD12
~~**77.**~~				
78.	Room illumination	On acceptance & 3 years	20 lux Images produced with intra-oral image receptors 100 lux A hood can be placed over the monitor to achieve the above orinstall dimmer lights, etc.	IPEM 91IDD14 Ref 22 p 53

[3] Reporting monitors – see page 14 of this doc and Chapter 7 page 49 of IPEM 91

	Physical parameter (required test)	Frequency	Acceptance Standard	References
II.2.5.	**CR Reader (see also Ref 1.1 & KCARE (Ref 10))**			
~~**79.**~~				
~~**80.**~~				
81.	Measured uniformity	On acceptance & 3 years	Mean ± 10%	IPEM 91 CR08
82.	Threshold contrast detailed detectability	On acceptance & 3 years	See comments CR09	IPEM 91 CR09
83.	Erasure cycle efficiency	On acceptance & 3 years	Blocker **not** visible in second image	IPEM 91 CR10
84.	Limiting spatial resolution	On acceptance & 3 years	Baseline minus 25%	IPEM 91 CR11
85.	Scaling errors	On acceptance & 3 years	2%	IPEM 91 CR12
86.	Dark Noise	On acceptance & 3 years	Baseline + 50%	IPEM 91 CR13
87.	AEC device available	On acceptance & 3 years	IB must report YES or NO on ES	
II.2.6.	**DDR System (see also KCARE (Ref 10))**			
~~**91.**~~				
~~**92.**~~				
~~**93.**~~				

94.	Threshold contrast detail detectability	On acceptance & 3 years	See comments in report 91	IPEM 91 DDR08
95.	Limiting spatial resolution	On acceptance & 3 years	Baseline minus 25%	IPEM 91 DDR09
96.	Uniformity of resolution	On acceptance & 3 years	**No** increase in blurring from baseline	IPEM 91 DDR10
97.	Scaling errors	On acceptance & 3 years	2%	IPEM 91 DDR11
98.	Dark noise	On acceptance & 3 years	Baseline ± 50%	IPEM 91 DDR12
99.	AEC device available	On acceptance & 3 years	IB must report YES or NO on ES	

3.4 TABLE 1 Half value layers (HVL-values) and Table 4 Minimum Requirements for Monitors

III. TABLE 3 – HVL values										
Intra-oral kV	50	60	70	71	80	90				
Minimum HVL (mm of Al)	1.5	1.5	1.5	2.1	2.3	2.5				
Other dental equipment; X-ray tube voltage (kilovolt peak)				70	80	90	100	110	120	130
Minimum HVL (mm of Al)				2.1	2.3	2.5	2.7	3.0	3.2	3.5
Minimum HVL (mm of Al), manufactured after June 2006				2.5	2.9	3.2	3.6	3.9	4.3	4.7

- CFR - Code of Federal Regulations Title 21, volume 8, 1 April 2013

IV. Table 4 - MINIMUM REQUIREMENTS FOR MONITORS			
Description and application	Monitors purchased on or after 1 January 2014		
	Licensed with Department of Healthas a medical device for import	**Minimum resolution**	
Reporting monitor for Cone Beam CT	Yes	1.3 Megapixel	**To perform an optimum diagnostic examination andto reduce the occurrence/chance of any misdiagnosis**
Reporting monitor for images produced with intra-oral image receptors, cephalometric and panoramic radiography.	No	1.3 Megapixel High-Definition Monochrome monitor with display format of at least 1920 x 1080 and aspect ratio of 16:9 is **recommended**	

1. Optimisation in diagnostic radiology means that equipment and methods must be selected to ensure that radiation administered to a patient for diagnostic purposes, issufficient 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 optimize spatial and contrast resolution

3.5 TEST GUIDELINES

- Dental X-ray equipment (tests 2-10, 11-16, 17, 38, 39, 40-52, 66-69)
- Digital Dental X-ray equipment (tests 2-10, 18-23, 31-36, 38, 39, 40-52, 72-87, 91- 99)
- Cone Beam CT (tests 18-20, 21-23, 24-30, 39, 49, 52, 53-65, 72-78)

4. REFERENCES

The following related documents are referenced:

4.1 Radiation Protection in Dentistry Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005), RPS no 10, http://www.arpansa.gov.au/publications/codes/rps.cfm

4.2 Quality Control Recommendations for Diagnostic Radiography, Volume 1, Dental Facilities, http://www.crcpd.org/Pubs/default.aspx or at https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Dental

4.3 Doses to Patients from Radiographic Procedures in the UK – HPA-CRCE-34, https://www.gov.uk/.../radiation-hpa-crce-scientific-and-technical-report-series ;

4.4 Guidance on the Safe Use of Dental Cone Beam CT (Computed Tomography) Equipment, HPA-CRCE-010, https://www.gov.uk/government/.../dental-cone-beam-computed-tomography-safe-us

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

4.6 Kodak QA in Dental radiography, https://sites.google.com/site/radiationcontroldoh/ ➔ Electronic devices – Use ➔ Electronic devices - ionising radiation ➔ Dental;

4.7 Radiation Guideline 6 dentistry, www.epa.nsw.gov.au/resources/**radiation**/test_protocols.pdf

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

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

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

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5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline on the Requirements for Licence Holders with Respect to Quality Control Tests for Dental Diagnostic X-Ray Imaging Systems, revised March 2017. It will be reviewed on this timeframe or as and when required.