NRRC Specific Regulations

Establishment and Implementation of Quality Control (QC) Program in Diagnostic Radiological Facilities

NRRC-R-01-SR03



2023



NRRC-R-01-SR03

Preamble

In accordance with the provisions of the radiation safety Regulation (NRRC-R-01), approved by the NRRC's Board of Directors in resolution No. (R/1/1/2022), dated 20 April 2022, chapter (12) section (78) article (224), this specific regulation provides detailed requirements for the quality control tests that mentioned in the radiation safety Regulation.

This specific regulation has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the and the international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments, and it has been approved by the NRRC's CEO resolution No. 1368 dated 9/7/2023.

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Chapter 1: Objective, Scope, and Definitions

Section 1: Objective

 This specific regulation sets out the specific detailed requirements for the establishment and implementation of Quality Control programs in diagnostic radiology facilities.

Section 2: Scope

- 2. This specific regulation applies to all diagnostic and interventional radiology equipment that may include but not limited to:
 - a. Conventional radiography equipment;
 - b. Fluoroscopy equipment;
 - c. Diagnostic screens
 - d. Bone densitometry equipment;
 - e. Intraoral dental radiology equipment;
 - f. Orthopantomography equipment (panoramic and cephalometric operation);
 - g. Cone Beam Computed Tomography (CBCT) equipment for dental, maxillofacial examinations;
 - h. Cone Beam Computed Tomography (CBCT) equipment and fluoroscopy equipment for use in operation rooms (O-ARMS);
 - i. Computed Tomography (CT) equipment;

- j. Conventional mammography equipment;
- k. Computed (CR) and Digital (DR) mammography equipment;
- l. Mammography screens
- m. Interventional radiology & cardiology equipment.

Section 3: Definitions

Acceptance testing

The process by which it is verified that new installed medical radiological equipment, imaging and auxiliary equipment, systems, and components used in medical exposures, operates in accordance with the associated specifications and performance criteria and can be introduced into clinical practice.

Commissioning

The process by means of which systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

Medical physicist

A Health Professional recognized by the competent authority of the Kingdom.

Quality Assurance (QA)

The function of a management system that provides confidence that specified requirements will be fulfilled.

Quality Control (QC)

Part of quality assurance (QA) program intended to verify that structures, systems and components correspond to predetermined requirements.

Quality Control equipment

The equipment (measuring devices, phantoms, test tools, etc.) used for the performance of the Quality Control (QC) tests.

Quality Control program

A written set of procedures and activities established and implemented by a facility for the performance of the required QC tests to medical radiological equipment.

Quality Control test

Testing or inspection to determine whether particular equipment or components perform within defined tolerance limits.

Tolerance limit

The limiting value above or below a measured or estimated value of a function or condition indicator must be found in order to be acceptable.

Chapter 2: Quality Control Program

Section 4: General Requirements

- 3. The authorized person shall:
 - a. Establish and implement a Quality Control program for the

- diagnostic and interventional radiology equipment clinically used in the diagnostic radiology facility.
- Ensure that the established QC program includes, the corresponding tests and criteria specified in Appendix I as a minimum.
- The authorized person shall ensure the availability of the necessary resources for the proper implementation of the established QC program.
- 5. In addition to the scheduled QC tests defined in the facility's QC program, the authorized person shall ensure that diagnostic and interventional radiology equipment undergoes QC tests, as follows:
 - a. At the time of acceptance, commissioning and relocation of the equipment, prior to their clinical use on patients, the QC tests in Appendix I that has the frequency of "During Acceptance" shall be carried out.
 - b. After any major maintenance or modification procedure that could affect the protection and safety of patients the QC tests in Appendix I that has the frequency of "Annually" shall be carried out.
 - c. After any major maintenance or modification procedure that could affect the protection and safety of patients the QC tests in Appendix I that has the frequency of "Annually" shall be carried out.

- d. After any installation of new software or modification of existing software that could affect the protection and safety of patients the QC tests in Appendix I that has the frequency of "Annually" shall be carried out.
- 6. In case the results of the QC tests show that a diagnostic or interventional radiology equipment performs out the respective tolerance limits defined in this specific regulation, the authorized person shall ensure that the equipment will not be clinically used until all the necessary corrective measures are taken, and after it has been verified that its performance is within the respective tolerance limits.

Section 5: Personnel

- 7. The authorized person shall ensure that the QC tests of the established QC program are performed by:
 - a. Medical Physicist of the facility or under the supervision of a Medical Physicist; or
 - b. The Medical Physicist may assign the performance of the QC tests to other members of the diagnostic radiology facility staff only if they have adequate training and the competence to perform the tests.
- 8. The Radiation Safety Officer of the diagnostic radiology facility shall ensure the proper implementation of the QC program.

Section 6: QC equipment

- 9. The authorized person shall ensure that:
 - Appropriate QC equipment and tools are used for the performance of the QC tests.
 - b. All the measuring equipment used for the performance of QC tests have a valid calibration certificate.

Section 7: Records

- 10. The authorized person shall keep appropriate records of the implementation of the established QC program in the radiology facility including, at least, the following:
 - Detailed description of QC tests included in the established QC program.
 - b. Periodic review of the QC program.
 - c. Non-conformities identified during the performance of the QC tests and the associated preventive and corrective actions undertaken.
 - d. Information on:
 - i. The preventive maintenance and servicing,
 - ii. Any repair(s)
 - iii. Any major component replacement(s),
 - iv. Any manufacturer's upgrade(s), and

- v. Any calibration of the diagnostic and interventional radiology equipment used in the QC tests.
- f. Records and reports of the implemented QC program.
- g. (f) Records of the results of the QC tests performed in line with the provisions of article 5.
- 11. The authorized person shall ensure that the records of the implemented QC program are available to the NRRC at all times.

Section 8: Annual reporting

- 12. The authorized person shall ensure that an annual QC report is prepared for all diagnostic and/or interventional radiology equipment of the facility, either separate for each of them or for a set of equipment which shall include, at least, the following information:
 - a. General information about the facility.
 - b. Details of the personnel performing the QC tests.
 - c. Detailed list of the QC equipment used for the performance of the QC tests.
 - d. The calibration certificates of the measuring equipment used for the performance of the QC tests and the details of the reference sources used in QC testing.
 - e. Information on the diagnostic or interventional radiology equipment tested including their type, model and serial number of the X-ray tube.

- f. Detailed list of the QC tests performed to the diagnostic or interventional radiology equipment, including:
 - i. The date of performance of each QC test,
 - ii. The data collected during each QC test, the related analysis result and the respective tolerance limit,
 - iii. A conclusion regarding the performance of the diagnostic or interventional radiology equipment (acceptable or not acceptable),
 - iv. A description of any suggested preventive and/or corrective actions, if applicable
 - v. The main findings of the QC tests and related recommendations.
- 13. In case an annual report is prepared for a set of diagnostic and/or interventional radiology equipment, the information of article 12 a-e may be provided only once, as applicable.
- 14. The Medical Physicist shall review and approve the QC reports.
- 15. The Radiation Safety Officer shall ensure that the QC reports:
 - a. Are signed by the Medical Physicist who conducted or supervised the performance of the QC tests.
 - b. Are communicated to the authorized person and the main findings and conclusions are presented in detail.

16. The authorized person shall submit to the NRRC the annual QC report for the diagnostic or interventional radiology equipment of the facility on an annual basis and within three (3) months of the specified QC dates.

Appendix I

This Appendix covers the required Quality Control (QC) tests for the diagnostic radiology equipment including their frequency and tolerance limits.

Table I: Required QC tests for conventional radiography equipment

| QC test | Frequency | Tolerance limit |
|--|--------------------------------|---|
| Adequacy of shielding | During acceptance and annually | According to the specified limits and constraints |
| Leakage radiation | During acceptance and annually | At the maximum rating specified by the manufacturer |
| Focal spot size | During acceptance and annually | ≤± 1.5 f (f: nominal value of focal spot size) |
| Focus-Image Detector Distance (FID) | During acceptance and annually | <±2cm |
| X-ray beam and light field alignment/cantering | During acceptance and annually | ±2%/±1% FID |
| X-ray beam verticality | During acceptance and annually | Deviation from 90o <1.5o |
| Grid operation | During acceptance and annually | According to the test tool specifications |
| Automatic collimation | During acceptance and annually | < ±2% of the FID |
| Half Value Layer (HVL) | During acceptance and annually | >2.9 mm Al at 80kV |
| kV accuracy | During acceptance and annually | <±5% or ±5 kV, whichever is greater |
| kV reproducibility | During acceptance and annually | < ±5% |

| Exposure time accuracy | During acceptance and annually | For exposure times >100 msec: $< \pm 10\%$ For exposure times ≤ 100 msec: $< \pm 20\%$ |
|--|--------------------------------|---|
| Exposure time reproducibility | During acceptance and annually | < ±5% |
| Radiation output | During acceptance and annually | 25-80μGy/mAs at 80 kV (and 2.5 mmAl total filitra- tion) at 100 cm from the x-ray tube focal spot |
| Linearity of radiation output | During acceptance and annually | <±15% |
| AEC system performance with the absorption thickness | During acceptance and annually | LEI $\leq 5 \mu Gy$ Acceptable max deviation: LEI $\leq 20\%$ Achievable max deviation: LEI $\leq 15\%$ |
| AEC system performance with kV | During acceptance and annually | LEI $\leq 5 \mu Gy$ Acceptable max deviation: LEI $\leq 20\%$ Achievable max deviation: LEI $\leq 15\%$ |
| AEC reproducibility | During acceptance and annually | ≤10% |
| AEC chambers | During acceptance and annually | Max deviation of mAs ≤20% |
| Typical patient dose | Annually | According to the nationally established DRLs |
| Spatial resolution | During acceptance and annually | >1.6lp/mm |
| Low contrast resolution | During acceptance and annually | According to the test tool specifications |

Table II: Required QC tests for fluoroscopy equipment

| QC test | Frequency | Tolerance limit |
|---|--------------------------------|---|
| Adequacy of shielding | During acceptance and annually | According to the specified limits and constraints |
| Leakage radiation | During acceptance and annually | At the maximum rating specified by the manufacturer |
| Half Value Layer (HVL) | During acceptance and annually | >2.9 mm Al at 80kV |
| kVp accuracy | During acceptance and annually | <±5% or ±5 kV, whichev-er is greater |
| kVp reproducibility | During acceptance and annually | < ±5% |
| Patient entrance dose rate | During acceptance and annually | ≤ 40 mGy/ min |
| Maximum patient dose rate | During acceptance and annually | ≤ 88 mGy/min for ABC standard mode ≤ 176 mGy/min for ABC high dose rate mode |
| Maximum dose rate at the entrance of the image receptor | During acceptance and annually | < 1 μGy/sec |
| Typical patient doses | Annually | Corresponding national DRLs |
| Low Contrast Detectability | During acceptance and annually | < 4 % for all the sizes field |
| High Spatial Resolution | During acceptance and annually | >0.8 lp/mm for field > 23 cm > 1 lp/mm for field \leq 23 cm |

Table III: Required QC tests for bone densitometry equipment

| QC test | Frequency | Tolerance limit |
|---|--------------------------------|---|
| Adequacy of shielding | During acceptance and annually | Pencil beam equipment: Background. Fan/cone beam equipment: <2µSv/hr at operator's position at least 2m from the examination bed. |
| Daily QC test | During | Pass/fail |
| BMD, BMC accuracy | During acceptance and annually | <± 2 % or ± 3 % |
| BMD, BMC reproducibility | During acceptance and annually | < ± 5% |
| Change of BMD and BMC values with thickness | During acceptance and annually | <± 2 % or ± 3 % |

Table IV: Required QC tests for intraoral dental radiology equipment

| QC test | Frequency | Tolerance limit |
|-------------------------------------|----------------------------------|--|
| Instantaneous dose rates | During acceptance and annually | $<\!1\mu Sv/hr$ at operator's position and $<0.5\mu Sv/hr$ at general public areas |
| Radiation field size | During acceptance and annually | < of the nominal field diameter |
| kV accuracy and reproducibility | During acceptance and annually | Accuracy $< \pm 10\%$ Reproducibility $< \pm 5\%$ |
| Half Value Layer (HVL) | During acceptance and annually | >2.5 mm Al at 70kV |
| Exposure time accuracy | During acceptance and | Accuracy < ± 10% |
| and reproducibility | annually | Reproducibility < ± 5% |
| Radiation output | During acceptance and annually | <3.7mGy for conventional equipment <1.2mGy for DR and CR equipment |
| Linearity of radiation output | During acceptance and annually | ≤ ± 20% |
| Reproducibility of radiation output | During acceptance and annually | < ±5% |
| High contrast resolution | During acceptance and annually | According to the test tool specifications |
| Typical patient doses | According to the NRRC guidelines | According to the NRRC guidelines |

Table V: Required QC tests for orthopantomography equipment (panoramic and cephalometric operation)

| QC test | Frequency | Tolerance limit |
|----------------------------|----------------------------------|--|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints |
| Radiation field size | During acceptance and annually | ≤ 10 x 150mm |
| Radiation output | During acceptance and annually | 30 - $80\mu Gy/mAs$ at $1m$ and in the clinical range of kV settings |
| Half Value Layer (HVL) | During acceptance and annually | >2.5 mm Al at 70kV |
| Symmetry | During acceptance and annually | Max measured distance <±5%. |
| High contrast resolution | During acceptance and annually | > 2.5 lp/mm |
| Low contrast detectability | During acceptance and annually | According to the test tool specifications |
| Typical patient doses | According to the NRRC guidelines | According to the NRRC guidelines |

Table VI: Required QC tests for Orthopantomography CBCT equipment for dental, maxillofacial examinations.

| QC test | Frequency | Tolerance limit |
|--|--------------------------------|---|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints |
| Leakage radiation | During acceptance and annually | <1 mSv/h @1m |
| Focal spot size | During acceptance and annually | ≤ 1.5 f (f = nominal focal spot size) |
| kV reproducibility | During acceptance and annually | ≤ ± 5 % |
| Radiation output | During acceptance and annually | ≤ ±10% of baseline |
| Radiation output reproducibility | During acceptance and annually | short-term $\leq \pm 5 \%$ long-term $\leq \pm 10 \%$ |
| Linearity of radiation output | During acceptance and annually | - |
| Half Value Layer (HVL) | During acceptance and annually | >2.5mmAl |
| Pulse duration accuracy (for pulsed equipment) | During acceptance and annually | $\leq \pm 10\%$ for pulses < 10 ms $\leq \pm 5\%$ for pulses > 10 ms |
| Exposure/examination time accuracy | During acceptance and annually | ≤ ±15% |
| CTDI accuracy | During acceptance and annually | 0.8 ≤ R ≤1.2 |
| DAP accuracy | During acceptance and annually | 0.85 ≤ R ≤1.15 |
| Typical patient doses | Annually | According to the corresponding national DRLs |
| Verification of radiation field sizes – FOV | During acceptance and annually | 0.8 ≤ R ≤1.2 |

| High Contrast Resolution (HCR) – Modulation Transfer Function (MTF) | During acceptance and annually | $MTF_{50} \ge 0.4 \text{ lp/mm}$ $MTF_{10} \ge 1.0 \text{ lp/mm}$ |
|---|--------------------------------|---|
| CBCT pixel values (PV) | During acceptance and annually | <± 20 HU |
| Image noise | During acceptance and annually | <±20% of the established baseline |
| Uniformity of the reconstructed image | During acceptance and annually | PV _{per} -PV _c should be <40PV or <±20% of the established baseline |

Table VII: Required QC tests for CBCT and fluoroscopy equipment for use in operation rooms (O-ARMS)

| QC test | Frequency | Tolerance limit |
|--|--------------------------------|--|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints |
| Leakage radiation | During acceptance and annually | <1 mSv/h @ 1 m |
| Focal spot size | During acceptance and annually | ≤ 1.5 f (f = nominal focal spot size) |
| kV accuracy (fluoroscopy) | During acceptance and annually | ≤ ± 10 % |
| kV reproducibility (fluo- roscopy) | During acceptance and annually | ≤ ± 5 % |
| Radiation output | During acceptance and annually | ≥25 µGy/mAs at 1m, ≤ ±10 % of baseline |
| Radiation output repro- ducibility | During acceptance and annually | short-term $\leq \pm 5 \%$ long-term $\leq \pm 10 \%$ |
| Half Value Layer (HVL) | During acceptance and annually | ≥ 2.5mmAl |
| Pulse duration accuracy (for pulsed equipment) | During acceptance and annually | $\leq \pm 10\%$ for pulses < 10 ms $\leq \pm 5\%$ for pulses > 10 ms |
| Patient entrance dose rate (fluoroscopy) | During acceptance and annually | >20% from the baseline in each recheck |
| Maximum patient entrance dose rate (fluoroscopy) | During acceptance and annually | >20% from the baseline in each recheck. |
| Characteristic fluoroscopy curve | During acceptance and annually | - |
| DAP accuracy | During acceptance and annually | 0.85 ≤ R ≤1.15 |

| Typical patient doses | Annually | According to the corre-sponding national DRLs |
|--|--------------------------------|--|
| Clinical low contrast de- tectability (LCD) | During acceptance and annually | < 3.9 % |
| Low contrast detectability (LCD) | During acceptance and annually | < 3.9 % |
| High Contrast Resolution (HCR) | During acceptance and annually | >30cm: ≥ 1lp/mm 24-30cm: ≥ 1.4lp/mm 18-24cm: ≥ 1.6lp/mm 15-18cm: ≥ 1.8lp/mm <15cm: ≥ 2lp/mm |
| CTDI accuracy | During acceptance and annually | 0.8 ≤ R ≤1.2 |
| Slice thickness (ST) | | <±35% |
| Reconstruction slice thickness (ST) | During acceptance and annually | For ST<2mm <50% For ST>2mm <1mm |
| High Contrast Spatial Resolution (HCSR)/MTF | During acceptance and annually | > 7 lp/cm. For MTF50 ≥ 0.4 lp/mm For MTF10 ≥ 1.0 lp/mm Deviation from the base- line $\leq \pm 20\%$ |
| CBCT pixel values (PV) | During acceptance and annually | <± 20 HU |
| Image noise | During acceptance and annually | <±20% of the established baseline |
| Uniformity of reconstructed images | During acceptance and annually | PVper-PVc should be <40PV or <±20% of the established baseline |

Table VIII: Required QC tests for diagnostic screens.

| QC test | Frequency | Tolerance limit |
|---|--|--|
| S/N and display – back- light lifetime | During acceptance and every six months | - |
| Ambient light | During acceptance and every six months | ≤ 20 lux |
| Artefacts | During acceptance and every six months | - |
| Luminance | During acceptance and every six months | Deviation between successive steps of the grayscale ≤10% |
| Luminance uniformity | During acceptance and every six months | ≤ 30% for UNL10 ≤ 10% for UNL80 |

Table IX: Required QC tests for Computed Tomography (CT) equipment.

| QC test | Frequency | Tolerance limit |
|--|---|---|
| Geometric accuracy of lasers and SPR | During acceptance and annually | ≤ ±5mm for positioning with the lasers and ≤ ±2mm for positioning with the SPR |
| Table movement accuracy | During acceptance and annually | <±2mm |
| Gantry angle accuracy | During acceptance and annually | ≤±lo |
| CT number accuracy (CT#w) & noise (SDw) | Every four months at 120kV and annually | CT# w: 0±5 HU SD ≤ ±25% |
| CT# w uniformity | Every four months at 120kV and annually | ≤ ±5 HU |
| CT number accuracy and Linearity | Annually | According to the manufacturer's limits |
| Imaged slice thickness (ST) | Annually | For ST \leq 1mm: \leq nominal $+$ 0.5mm For 1 <nominal <math="" st="">\leq2mm: \leq nominal \pm 50% For nominal ST >2mm: \leq nominal \pm 1mm</nominal> |
| Spatial Low Contrast Detectability (SLCD) | Annually | According to the manufacturer's limits |
| Spatial High Contrast Resolution (SHCR) | Annually | According to the manufacturer's limits in lp/mm |
| Accuracy of CTDI displayed indications | Annually | ≤ ±20% |
| CTDI in air | Annually | ≤ ±20% from manufac-tur- er's value |
| Typical patient doses | Annually | According to the estab-lished national DRLs |
| kV accuracy | Annually | ≤ ±5% |

Table X: Required QC tests for conventional mammography equipment.

| QC test | Frequency | Tolerance limit |
|--|---|--|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints. |
| Leakage radiation | During acceptance and annually | <1 mSv/h at 1m |
| System reproducibility | During acceptance and annually | $< \pm 5\%$ mAs or $< \pm 0.20$ OD |
| Coincidence of image receptor with the radiation field | During acceptance and annually | On all sides: the radiation field should not extend more than 5mm outside the film. On the thoracic wall: The distance between the film edge and the bucky edge should be ≤ 5mm |
| Focus – Image receptor Distance (FID) | During acceptance and annually | According to system's specifications |
| Focal spot size | In case of spatial high-res- olution degradation | According to system's specifications |
| Breast compression system force | During acceptance and annually | Maximum applicable force stable for 1min: 130-200N |
| Thickness Indication | During acceptance and annually | <±5mm |
| kV accuracy and reproducibility | During acceptance and annually | Accuracy: ≤±1kV Reproducibility: ≤±0.5kV |
| Half Value Layer (HVL) | During acceptance and annually | For Mo/Mo combination at $28kV \ge 0.3 mm$ Al. For all anode/filter combinations: $(kV/100) + 0.03 \le HVL \le (kV/100) + C$, where $C = 0.12$ for Mo/Mo, 0.19 for Mo/Rh, and 0.22 for Rh/Rh. |

| Radiation output and re- producibility of radiation output | During acceptance and annually | Mo/Mo combination, $28kV:>30\mu Gy/mAs~at~1m$ Reproducibility <±5% |
|--|---|---|
| Linearity of radiation output | During acceptance and annually | <±10% |
| Change of optical density (OD) with phantom thickness and kVp | During acceptance and annually | ≤± 0.15OD ≤± 0.5cm |
| Standard exposure time | During acceptance and annually | <2s |
| Grid uniformity | During acceptance and annually | YES/NO |
| Grid system factor | In case of a sudden increase in dose or the exposure time | <3 |
| High contrast resolution (HCR) | During acceptance and annually | >12lp/mm |
| Low contrast resolution (HCR) | During acceptance and annually | Masses: Diameter <0.7mm, Fibers: Thick-ness <0.7mm, Micro-calcifications: Di- ameter <0.3mm. Masses of diam-eter 5 - 6mm of variable contrast: <1.5% |
| Artefacts | During acceptance and annually | YES/NO |
| Entrance Surface Dose (ESD) | During acceptance and annually | According to the estab-lished national DRLs |
| Mean Glandular Dose (MGD) | During acceptance and annually | According to the estab-lished national DRLs |

Table XI: Required QC tests for Computed (CR) and Digital (DR) mammography equipment.

| QC test | Frequency | Tolerance limit |
|--|--|---|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints as in the authorization |
| Leakage radiation | During acceptance and annually | <1mSv/h at 1m |
| System reproducibility | During acceptance and annually | < ± 5% mAs |
| Coincidence of image receptor with the radiation field | During acceptance and annually1 | ≤ 5mm |
| Focus – Image receptor Distance (FID) | During acceptance and annually | According to system spec-ifications |
| Focal spot size | In case of spatial high-resolution degradation | According to system's specifications. |
| Breast compression system force | During acceptance and annually | <±20N of the measured value |
| Thickness Indication | During acceptance and annually | <±5mm |
| kV accuracy and reproducibility | During acceptance and annually | $Accuracy \leq \pm 1 kV$ $Reproducibility \leq \pm 0.5 kV$ |

| | | For Mo/Mo combination at |
|--|--------------------------------|---|
| Half Value Layer (HVL) | During acceptance and annually | For Mo/Mo combination at $28kV \ge 0.3$ mm Al. For all anode/filter combina-tions: $(kV/100) + 0.03 \le HVL \le (kV/100) + C$, where $C = 0.12$ for Mo/Mo, 0.19 for Mo/Rh, and 0.22 for Rh/Rh. |
| Radiation output and reproduci-bility of radiation output | During acceptance and annually | For Mo/Mo combination at $28kV > 30\mu Gy/mAs$ at 1m. Reproducibility $<\pm 5\%$ |
| Linearity of radiation output | During acceptance and annually | <±10% |
| Change of mAs with the darkening step | During acceptance and annually | mAs values per darkening step in the range: 5-15%. |
| Change of selected exposure pa-rameters with the phantom thickness | During acceptance and annually | PMMA(cm) CNR/CNR5cm (%) 2.0> 115 3.0> 110 4.0> 105 4.5> 103 5.0> 100 6.0> 95 7.0> 90 |
| Standard exposure time | During acceptance and annually | <2s |
| Detector response | During acceptance and annually | $R^2 > 0.99$ |

| Image uniformity | During acceptance and annually | Maximum deviation of the mean MVP value from this in the whole image <± 15%. Max SNR de- via-tion <± 15% from the mean SNR value in all the ROIs. |
|--|--------------------------------|--|
| Detector noise- Signal to Noise Ratio (SNR) | During acceptance and annually | R2 value calculated during the acceptance of the mammography system is used as the reference value. |
| Artefacts | During acceptance and annually | YES/NO |
| Detector ghosting | During acceptance and annually | GIF < 0.3 |
| High Contrast Resolution (HCR) | During acceptance and annually | > 7 lp/mm |
| Low Contrast Resolution (LCR) | During acceptance and annually | Masses: Diameter < 0.7mm, Fibers: Thickness < 0.7mm, Micro-calcifications: Diameter < 0.3mm. For masses of diameter 5 – 6mm of variable contrast: < 0.85% (Mo/Mo, 28kV). |
| Relative cassettes' response (CR equipment) | During acceptance and annually | Deviation of the SNR val-ue among different cas-settes $< \pm 15\%$. Deviation of mAs among the differ-ent cassettes: $< \pm 10\%$. Deviation of the EI value among the various cas-settes: $< \pm 10\%$. The uni-formity should be satis-factory in all images |

| Degradation of the acquired imag-es (CR equipment) | During acceptance and annually | According to reference values |
|--|--------------------------------|-------------------------------|
| Entrance Surface Dose | During acceptance and | According to the estab- |
| (ESD) | annually | lished national DRLs |
| Mean Glandular Dose | During acceptance and | According to the es- |
| (MGD) | annually | tab-lished national DRLs |

Table XII: Required QC tests for mammography screens.

| QC test | Frequency | Tolerance limit |
|--------------------------|--|---|
| Diagnostic room lighting | During acceptance and in case of problems with image quality | LCD screens ≤ 20lux CRT screens ≤ 10 lux |
| Contrast visibility | Daily | According to the phan-tom specifications |
| Resolution | Biannually | All the phantom's line patterns should be visible |
| Image distortion | Daily | YES/NO |
| Brightness range | Annually | Max _{LUM} /Min _{LUM} >250 |
| Brightness uniformity | Annually | Max deviation < 30% |

Table XIII: Requirements for QC tests for interventional radiology & cardiology equipment

| QC test | Frequency | Tolerance limit |
|---|---|---|
| Shielding adequacy | During acceptance and annually | According to the specified limits and constraints. |
| Leakage radiation | During acceptance and annually | <1 mSv/h @ 1 m |
| Spatial high contrast resolution (SHCR) | During acceptance and every six months | For new technology fluoroscopy equipment: Field size lp/mm > 30cm > 1.0 24-30cm > 1.4 18-24cm > 1.6 15-18cm > 1.8 < 15cm > 2.0 For older technology fluoroscopy equipment: Field size lp/mm > 25cm > 1.0 < 25cm > 1.2 |
| Low Contrast Detectability (LCD) | During acceptance and every six months | <3.0mm for 2% contrast and < 1.5mm for 4% con- trast. The LC thresh-old is < 4% for fluorosco-py and < 2.7% for CINE/DA |
| SDD and Table-detector distance – fluoroscopic operation (FO) | During acceptance and annually | <±2% |

| Geometric distortion (equipment with image intensifier) - FO | During acceptance and annually | GD ≤15% |
|--|--------------------------------|---|
| Patient entrance dose rate - FO | During acceptance and annually | <40mGy/min |
| Maximum patient dose rate - FO | During acceptance and annually | without grid < 88mGy/min (not for HDR modes) and <176mGy/min (for HDR modes) |
| Dose rate at the detector en-trance - FO | During acceptance and annually | Normal mode of opera-tion without grid $<1\mu Gy/s$ and with grid $<2\mu Gy/s$ |
| Typical patient doses - FO | During acceptance and annually | According to the national-ly established DRLs |
| Automatic Exposure Control (AEC) - FO | During acceptance and annually | <20% |
| Half Value Layer (HVL) - FO | During acceptance and annually | > 2.9mm Al at 80kV |
| Radiation field vs image receptor | During acceptance and annually | R < 1.15 for equipment with detector with in- ter-nal diameter > 24cm R < 1.20 for equipment with detector with in- ter-nal diameter between 18 and 24cm R < 1.25 for equipment with detector with in- ter-nal diameter < 18cm R < 1.15 for equipment with a rectangular detector |

| Patient entrance dose rate - CINE/DA/DSA | During acceptance and annually | < 2m Gy/frame (no cardio modes) for max FOV and phantom thickness of 20cm. 0.08-0.2mGy/fr for 15fr/sec, max FOV, and a phantom thickness of 20cm. Difference from reference value < 25%. |
|---|--|---|
| Dose rate at the detector en-trance - CINE/DA/DSA | During acceptance and annually | $<0.5\mu Gy/fr \ without \ grid$ or $<1\ \mu Gy/fr \ with \ grid$ (Cardiac mode) $<5\mu Gy/fr \ (DSA).$ Typical values without grid for larger FOVs: 0.1 - $0.2\mu Gy/fr$ (Cardiac mode), 0.4 - $0.8\mu Gy/fr$ (DA), and 0.8 - $2\mu Gy/fr$ (DSA) |
| Automatic Exposure Control (AEC) - CINE/DA/ | During acceptance and every six months | < 20% |
| Typical patient dose - CINE/DA/DSA | Annually | According to the national-ly established DRLs |
| Air Kerma Rate (AKR) accuracy - CINE/DA/DSA | During acceptance and annually | < ±20% (for dose>100mGy and dose rate >6mGy/min) |
| Kerma Area Product (KAP) accu-racy - CINE/ DA/DSA | During acceptance and annually | < ±35% (for KAP > 2.5Gycm ²) |

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