

Belgian Protocol

for

Annual Quality control

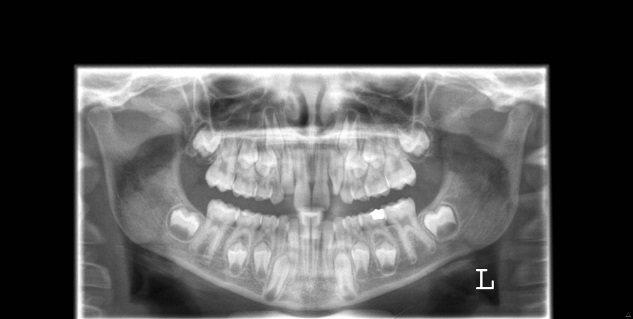
of

X-Ray Equipment :

Systems for fluoroscopy



Belgian Hospital Physicist Association



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# Belgian Protocol for Annual Quality Control of X-Ray Equipment: Part Fluoroscopy Systems

## Introduction

Fluoroscopic systems are not only used in the radiology department but also outside radiology, for example in the operating theater. The systems can be simple and used for limited purposes but can also be very complex for angiography examinations or cardiac catheterization. Especially in complex interventional procedures the state and the clinical settings of the unit play a major role. Interventional radiology and cardiology procedures are so sophisticated or ambitious that they are often, especially in obese patients, characterized by long exposure times which implies a real chance of deterministic radiation effects at the level of the skin. Recently, an increased attention was asked regarding the eye lens dose because more radiation effects were seen then previously assumed. This increases the need to examine the pre-programmed procedures in detail. Justification of these examinations implies that not only the device but also the adjustments of the device meet the standards. The link between the dose to the patient and the radiation exposure to the operator is an extra motivation for a careful assessment of fluoroscopic systems.

Each fluoroscopy system needs to be tested for its intended use. A good interaction with the staff in the examination rooms has to ensure that it is known how the system is used. The list of clinical programs for further evaluation of present protocol shall be established in consultation with the staff.

Fluoroscopy devices can be classified according to function and geometry:

**• According to function**

1. Radiography / Fluoroscopy systems with movable table for barium studies, iodine contrast studies, classical recordings in which positioning is done using fluoroscopy.

2. Mobile image intensifier or flat panel image receptor with C-arm used for example during surgery

3. C-arm for vascular diagnostic and therapeutic studies.

4. Angiography systems for cardiac applications (C-arc sometimes equipped with Bi-plane image receptor and RX tube).

5. Systems for specific applications, such as lithotripsy, urology, etc.

**• According to geometry**

1. C-arm.
2. Under couch configuration (X-ray tube below table, detector above).
3. Over couch configuration (X-ray tube above table, detector below).

Some systems do not permit manual changes of beam quality or dose level at the image receptor. Some creativity is required in order to be able to image certain test objects with the beam qualities suggested in the protocol.

The tests in this protocol should, where possible and appropriate, be performed in radiography mode (ex. the accuracy of the tube voltage). A typical set-up for the measurement of tube output or tube voltage is the lateral direction: with this configuration there is no table in the radiation beam while the table can be used to mount the test objects.

The intention of this document is to be a standalone text that can be applied to compare a fluoroscopy system with the applicable standards. This text is not a manual for optimizing a system, although this is a very important task of a medical physics expert (MPE).

A system for fluoroscopy must at least comply with the following requirements:

* The system must include either an image intensifier or any other digital image receptor. Direct fluoroscopy is prohibited.
* Each system must have a dose indicator as prescribed in the FANC decree of 28 September 2011.
* Each system must produce an acoustic signal every 5 minutes of fluoroscopy.
* Each system must have an automatic exposure control, except for very specific applications.
* Systems purchased after 2016 may not be pre-programmed with continuous fluoroscopy for clinical use.
* Systems purchased after 2016 should have Last Image Hold.
* Systems purchased after 2016 should be provided with virtual collimation: it must be possible to collimate on the Last Image Hold.
* Systems purchased after 2016 must have the latest DICOM standards of structured dose reports.
* Some systems don’t include the time in between X-ray pulses in the measure of accumulated fluoroscopy time. This is not acceptable.

MPEs have an increasing advisory role in the purchase of new systems. Aspects that have to be considered are:

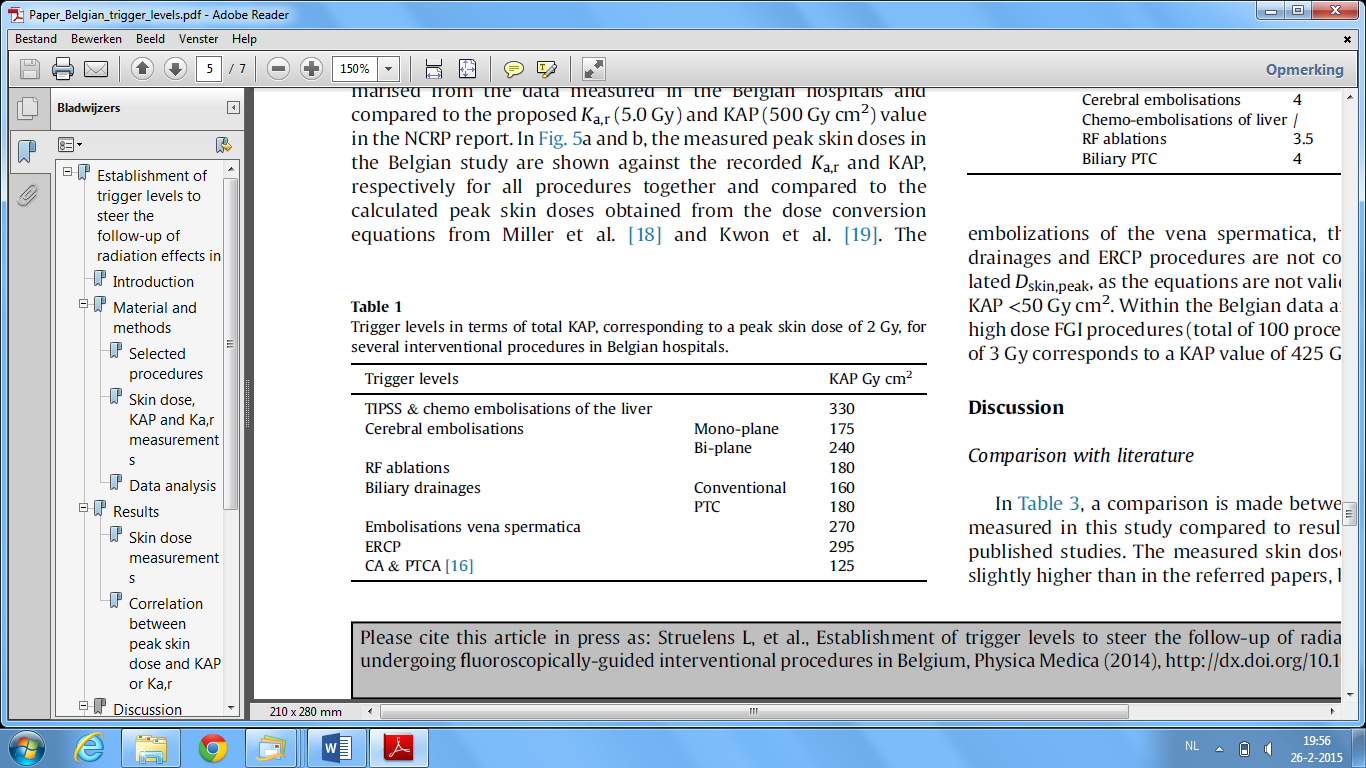
* Removable grid; an obligation in case of pediatric applications.
* Customized filtration; an obligation for angiography / cardiac examinations.
* Possibility of different pulse rates and dose levels.
* Application specific pre-programming possible.

We urge the manufacturers to provide the "physics mode”, in accordance with the proposals of MITA. This mode should include the possibility of manually selecting the exposure settings, the access to raw (for processing) data, automatically stored dose data, easy access to these data and the opportunity to save a calibration factor for dosimetric applications.

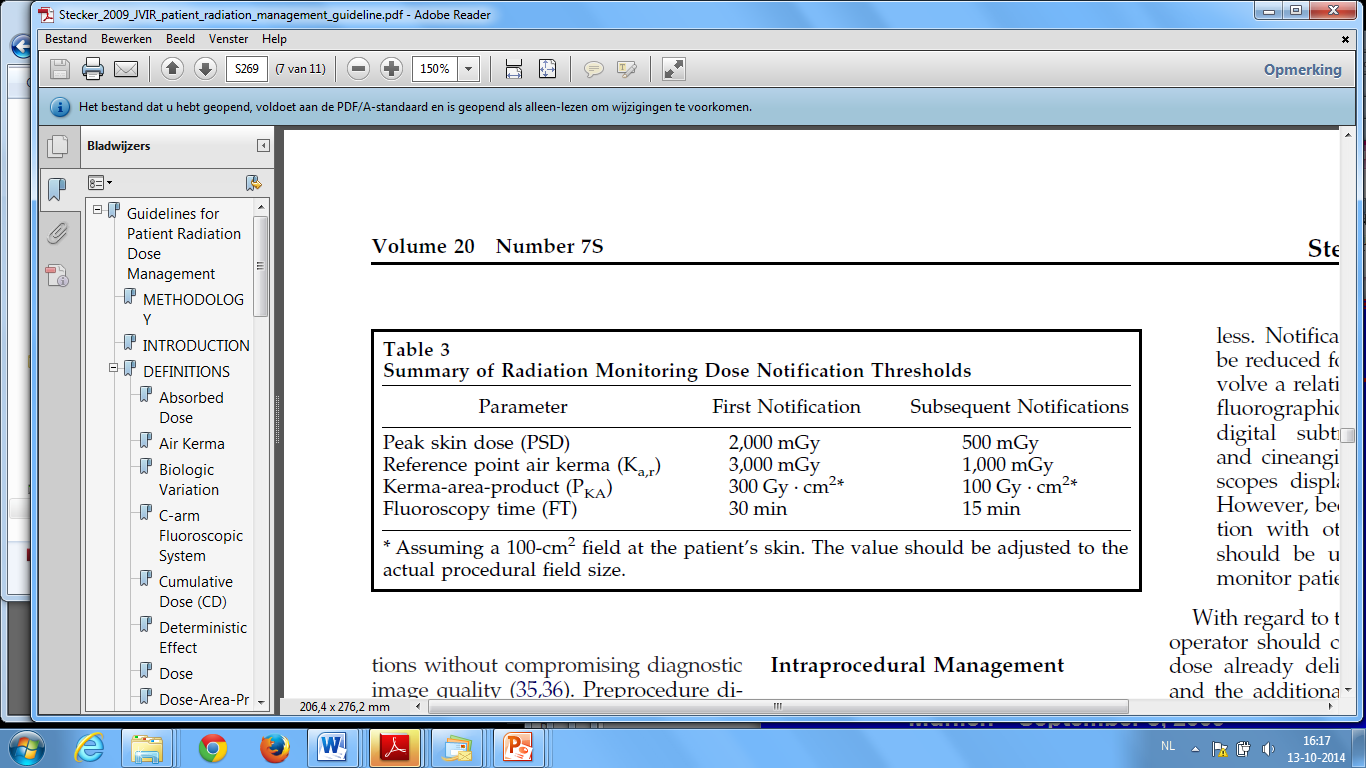
Dose reporting should be done according to the latest DICOM standards for all systems purchased after 2016. Dose structured reports should automatically be pushed forward to external electronic devices (PACS, dose registration system, ...) for all new systems purchased from 2016.

In Belgium, procedure specific dose area product (DAP) levels that correspond to 2 Gy skin entrance dose have been published and are summarized in Table 1. We encourage the MPE to use them during investigations and to inform the medical team of the existence of these data. In a recent report, the NCRP has stressed the importance of trigger levels too. We urge manufacturers to generate alarms or warning when any of these trigger levels are exceeded.

**Table 1.** Copied from: Struelens L et al., Establishment of trigger levels to steer the follow-up of radiation effects in patients undergoing fluoroscopically-guided interventional procedures in Belgium, Physica Medica (2014),



**Table 2:** Copied from NCRP report 168, Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures. July 2010



The MPE needs different measuring devices and test objects in order to perform the tests. The necessary equipment includes a dose meter which allows to measure incident doses (measurements without backscatter), entrance doses (measurements including backscatter or for direct evaluation of the back scatter factors) and entrance Air Kerma on the image receptor (measurements at very low dose rate and acquired with Cu filtration). The visualization of dose pulses as a function of time is recommended.

We welcome any comments that can further strengthen our protocol. On the long run, it is aimed for active participation in 'good clinical practice' regarding the technical implementation of RX examinations in the most critical rooms in our hospitals.

26 February 2015

Comments to this text should be sent prof. Hilde Bosmans, president of the Working Group Radiology in the BHPA, hilde.bosmans@uzleuven.be, stating "BHPA protocol fluorosocopy '

## Definitions and measurement conditions

**Reference point for dose rate measurements**

When testing systems with adjustable tube – detector distance, the distance between tube and image receptor (SID) should be as close as possible to 1.15m.

The reference point is situated 25 cm above the table (for tele-operated over-couch systems) or at 30 cm distance from the image receptor housing (C-arm configuration). For mini C-arm the reference point is situated 5cm from the image receptor housing. In this document, distances from or to the ‘detector’ mean from or to the ‘receptor housing’.

When a C-arm configuration for angiographic or cardiac catheterization applications is tested the most frequently used configuration should be used for the tests (usually under couch configuration, table in the beam). Other C-arms, used in combination with different types of tables, for example in the operating theater, can be tested without table between the x-ray tube and the image receptor. The report of the measurements shall always indicate the presence or absence of the table in the measurement set-up.

For mini C-arms, with a smaller focus-image receptor distance than usual, the test and the limiting values should be adjusted to the specific situation.

On some systems, there is next to a fluoroscopy mode also a single shot mode and ciné mode. All modes that are clinically used have to be tested.

**Viewing conditions in the room**

Test objects that are read out in the room should maximally include the routine ambient light conditions. This is especially the case at the level of the monitor. If read-out conditions are not acceptable, this should be discussed with the staff. A protocol on monitors, light boxes and ambient light will be developed later.

**Good practice during the annual test**

Standard setup:

Work without table in the beam if possible and document the geometry of the set-up.

Focus – image receptor distance should be minimal; PMMA test slabs should be as close as possible to the image receptor. The dose meter should not influence the working of the AEC. Patient entrance doses are recalculated to the reference point. Patient entrance dose includes backscatter. Make sure you have a procedure available to have the backscatter included (if necessary via backscatter factors, see Table 3).

## Tube Voltage

### Accuracy

1. Purpose

This test checks whether the measured tube voltage corresponds to the value indicated on the control panel.

If the tube has already been tested for the radiography mode, then this test is only carried out for one tube voltage. The tube voltage is measured without a table between focus and measuring device, if such a configuration can be realized.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | kVp meter. |
| *Methods* | The kVp meter is positioned according to the manufacturer's instructions. |
| *Acceptability criteria* | Deviation ≤ 10 %. |

3. Methods

* The kVp meter is placed centrally in the beam. Light field or fluoroscopy can be used for correct positioning.
* At least three tube voltages are tested. The test is preferably repeated for all tube voltages in increments of 10 kV between 60 kV and 120 kV. If the tube voltage cannot be adjusted manually, a kV variation is obtained by placing more PMMA plates (various thicknesses), copper or lead in the X-ray beam between the kVp meter and the image receptor.

4. Calculations

The deviation expressed in percentage should be less than 10 %:



### Reproducibility

1 Purpose

Checks whether the tube voltage is reproducible. It is acceptable to perform this test for the radiography mode only.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | kVp meter. |
| *Methods* | The kVp meter is placed according to the manufacturer's instructions. |
| *Acceptability criteria* | Deviation ≤ 5 %. |

3. Methods

* The kVp meter is placed centrally in the beam. Light field or fluoroscopy can be used for correct positioning.
* The tube voltage is set to a specific, clinically used voltage and at least four measurements are performed.

4. Calculations

For all four measurements, the deviation is calculated using the following formula:



The maximum deviation is calculated, and should be smaller than 5 %.

## Half Value Layer (HVL) and total filtration

1. Purpose

The X-ray beam quality is determined in terms of its half value layer for a setting of 80kV. This test can also be performed in radiography mode.

All available filters are listed and their use in frequently used programs is documented. If the filters are not pre-programmed where they should be programmed according to good clinical practice, this will be noted as action point in the report.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Dose meter  Aluminium sheets of 1 mm thickness with a measuring stand or validated automatic filtration determination. |
| *Methods* | Create a set-up so that a tube voltage as close as possible to 80 kV is obtained and this with minimal filtration (eg without copper filter and, if possible, without a table between the tube and the dose meter). |
| *Acceptability criteria* | The total filtration must be greater than 2.5 mm Al equivalent. |

3. Methods

* + - Create a measurement set-up so that Al sheets can be put easily between focus and dose meter while the exposure settings stay fixed.
    - Consecutive measurements are made with increasing Al in the beam (between focus and dose meter). In case the kV cannot be set manually, it is first determined which quantity of Al sheets generates a tube voltage as close as possible to 80 kV. In successive measurements, the total amount of Al sheets remains unchanged, but their position in the X-ray beam changes: between focus and dose meter or between dose meter and image receptor. Verify whether the displayed kV and mA don’t change. The Al sheets must completely cover the measuring cell of the dosimeter. A series of measurements is carried out with increasing amount of Al between focus and dose meter. This procedure is very difficult for solid state dosimeters that include a lead back scatter protector.
    - Automatic measurement of HVL and total filtration is permitted provided earlier validation.

4. Calculations

The half-value layer and total filtration are calculated.

The total filtration must be greater than 2.5mm Al equivalent.

5. Remark

Note that the anode angle correction is especially relevant for cardiovascular systems. The effect of anode angle on beam quality and HVL can be taken into account. There are tools available on the web, such as ‘spekcalc’, http://spekcalc.weebly.com/ or from IPEM 78, http://linux.fjfi.cvut.cz/~madlenka/medphys.htm

For some dosimeters it is important to use narrow beam conditions.

**Table 3.** Overview of HVL values that guarantee a total filtration of 2.5 mm Al.

This table assumes an anode angle of 14 °, and a W-anode.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Ripple | | | | | | | |
|  |  | 0% | 5% | 10% | 15% | 20% | 25% | 30% |
| kV | 30 | 0.94 |  |  |  |  |  |  |
| 40 | 1.37 |  |  |  |  |  |  |
| 50 | 1.74 |  |  |  |  |  |  |
| 60 | 2.08 | 2.03 | 1.99 | 1.94 | 1.90 | 1.85 | 1.81 |
| 70 | 2.41 | 2.36 | 2.30 | 2.25 | 2.20 | 2.15 | 2.10 |
| 80 | 2.78 | 2.71 | 2.63 | 2.57 | 2.51 | 2.45 | 2.40 |
| 90 | 3.17 | 3.09 | 3.00 | 2.92 | 2.84 | 2.77 | 2.71 |
| 100 | 3.58 |  |  |  |  |  |  |
| 110 | 4.00 |  |  |  |  |  |  |
| 120 | 4.42 |  |  |  |  |  |  |
| 130 | 4.84 |  |  |  |  |  |  |
| 140 | 5.27 |  |  |  |  |  |  |
| 150 | 5.70 |  |  |  |  |  |  |

**Table 4.** Overview of HVL values that guarantee a total filtration

of 2.5 mm Al for a ripple of 0 % and 80 kV.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Anode angle | 6° | 10° | 14° | 18° | 22° |
| HVL (mm Al) | 3.44 | 3.01 | 2.78 | 2.63 | 2.53 |

## Timer

1. Purpose

1. The user must be notified in case of prolonged exposure of patients. It has to be verified whether an audible signal goes on automatically at a cumulative fluoroscopy time of maximum 5 minutes.

At acceptance test, it should also be tested whether after an additional 5 minutes there is again an audible signal.

2. In the case of cardiac procedures, information on DAP levels or air kerma values in the reference point that are possibly equivalent to skin entrance doses above 3Gy should be available in the room

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | No additional material. |
| *Methods* | Perform a series of fluoroscopy exposures and verify whether there is an acoustic signal. |
| *Acceptability criteria* | There must be an acoustic signal after 5 minutes.  At acceptance: there must also be an acoustic signal after 10 minutes. |

3. Methods

* + - Perform a series of fluoroscopy exposures and verify whether there is an acoustic signal.

## Radiation field size – image field size

1. Purpose

Verify whether the imaged area corresponds to the area of the X-ray field.

The RP162 requires that the ratio between X-ray field and imaged area < 1.25. For square collimators and a round image receptor, which is still frequently used in conventional radiology, we recognize that this value may not be achieved, and is 1.27.

Positioning aids should properly indicate the borders of the X-ray field. The virtual collimation system should perform conform its intended use.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Equipment to measure the X-ray field. Equipment that allows to calibrate the visualized sizes of an X-ray image |
| *Methods* | Irradiate the X-ray field meter for different magnifications.  Verify whether the positioning lines function according to their intended use (example: show the borders of the radiation field, show the center of the radiation field, ..) |
| *Acceptability criteria* | In case of square collimators and a round image receptor, the field must be collimated in such a way that the (primary) collimators are visible on the image. The ratio of the surface of the irradiated field to the surface of the visualized image is < 1.27.  In case of non-square collimators and a round image receptor, the ratio of the surface of the irradiated field to the surface of the visualized image is:  < 1.15 for field sizes with inner diameter > 24 cm;  < 1.20 for field sizes with inner diameters between 18 and 24 cm;  < 1.25 for field sizes with inner diameter < 18 cm.  For systems with a rectangular image receptor, the ratio of the surface of the irradiated field to the surface of the visualized image is < 1.15.  The virtual collimation system should perform conform its intended use, i.e. positioning lines in the Last Image Hold should correspond to their real position. The deviation between position of the virtual collimator and the irradiation field should not be larger than 1% of the distance between focus and detector housing. |

3. Methods

* + - This test involves the measurement of the surface of the radiation field and the imaged area for all possible magnifications.
    - Use an irradiation field indicator (example gafchromic films or CR plates) and perform exposures with all magnifications.
    - Measure the areas of the irradiation fields
    - For the same acquisitions the area of the field shown on the monitor is determined.
    - Put a ruler on the detector, perform fluoroscopy, collimate with your virtual collimator (without the use of fluoroscopy) to a fixed position of the ruler, perform fluoroscopy again and verify on the monitor for the correspondence between the imaged part of the ruler and the position of the virtual collimator on the ruler.

4. Calculations

* + - Calculate the ratios between irradiation field and imaged area. The ratios must comply with the limits.
    - Calculate the deviations between the position of the virtual collimator and the irradiation field.

5. Remark

* + - If there is a light field indicator, verify its deviations or calibrate it for all sides of the irradiation fields. Correspondence between irradiation field and imaged area can then be verified by means of the light field indicator.

## Orthogonality

1. Purpose

Verification of the beam geometry:

Is the X-ray beam perpendicular to the image receptor?

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Test object with two marker points at different distances from the x-ray tube. The marker points result, in case of correct geometry of the x-ray beam, in a coincidence. |
| *Methods* | Tube at 1m distance from the test object or according to the manual of the test object. |
| *Acceptability criteria* | The angle between the central axis of the x-ray beam and the image plane should be 90 ° ± 1.5 °. |

3. Methods

The tube is placed perpendicular to the test object with the marker points in the center of the X-ray field (or according to the manual of the test object).

Make an exposure according to the instructions in the manual of the test object.

4. Calculations

Compare the position of both mark projections according to the manual of the test object and compare with the standards.

5. Remarks

The position of the X-ray tube and image receptor will in general be vertical, but may differ from this set-up.

## Patient entrance dose rate in fluoroscopy mode and cine mode for frequently used clinical programs

1. Purpose

* + - Define and describe the most frequently used adult clinical programs (in terms of protocol name, magnification, frame rate, dose level, ...).
    - For the top 5 of the most frequently used clinical programs and separately for fluoroscopy and cinégraphy, register the dose values for 20cm PMMA and without magnification. The limiting values apply, except if these programs are flagged as ‘high dose or boost mode’.
    - In addition, the doses are measured for pediatric modes and the boost program.
    - For a selection of routine programs, register patient entrance dose for different pulse rates, for different dose levels, for different filters and different field sizes.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Dose meter, 20 cm of PMMA, typically 20cm x 20cm.  For mini-C arms, 5cm of PMMA is used. |
| *Methods* | Standard set-up. |
| *Acceptability criteria* | When fluoroscopy is used, the patient entrance dose rate without magnification and with backscatter in the reference point is ≤ 40 mGy / min.  With C-arms –where the focus to image receptor distance is less than 45 cm- the patient entrance dose is ≤ 10 mGy / min.  In cine mode (no cardio), the patient entrance dose rate at the largest field size and including backscatter is ≤ 2 mGy / frame.  For cine cardio systems, the patient entrance dose rate at the largest field size and including backscatter is  ≤ 0.2 mGy / frame at 15 frames / s.  Dose changes of 25% compared to the previous tests have to be investigated and/or remediated. |

3. Methods

* + - Use 20 cm of PMMA.
    - Consecutive annual testing should be done with the same set-up.
    - Measure the PMMA entrance dose for 5 frequently used clinical programs.
    - For a selection of routine programs, measure the entrance doses for at least the following conditions:

• all dose modes (low, medium and high)

• a variety of pulse rates (at acceptance test)

• all filtrations (at acceptance test)

• all magnifications

verify whether the dose levels are logically programmed and evaluate trends. Ask for remediation if needed.

4. Calculations

* + - Doses are adjusted as if they were measured in the reference point
    - If incidence dose is being measured (rather than entrance dose), apply a back scatter factor of 1.4 to obtain an estimate of entrance dose.
    - Report the entrance dose rate per frame and per minute.
    - Compare to the limiting values
    - Compare with the values from the previous test and report discrepancies.

5. Remarks

* + - In order to avoid any systematic errors due to back scatter (example in case of accidental or patient case specific investigations) Table 5 can be used.

**Table 5:** Backscatter factors according to the ICRU.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | fieldsize | 100 mm x 100 mm | | | 200 mm x 200 mm | | | 250 mm x 250 mm | | |
| kV | **filter** | **HVL** | **Water** | **ICRU tissue** | **PMMA** | **Water** | **ICRU tissue** | **PMMA** | **Water** | **ICRU tissue** | **PMMA** |
| 50 | 2.5 mm Al | 1.74 | 1.24 | 1.25 | 1.33 | 1.26 | 1.27 | 1.36 | 1.26 | 1.28 | 1.36 |
| 60 | 2.5 mm Al | 2.08 | 1.28 | 1.28 | 1.36 | 1.31 | 1.32 | 1.41 | 1.31 | 1.32 | 1.42 |
| 70 | 2.5 mm Al | 2.41 | 1.3 | 1.31 | 1.39 | 1.34 | 1.36 | 1.45 | 1.35 | 1.36 | 1.46 |
| 70 | 3 mm Al | 2.64 | 1.32 | 1.32 | 1.4 | 1.36 | 1.37 | 1.47 | 1.36 | 1.38 | 1.48 |
| 70 | 3 mm Al + 0.1 mm Cu | 3.96 | 1.38 | 1.39 | 1.48 | 1.45 | 1.47 | 1.58 | 1.46 | 1.47 | 1.59 |
| 80 | 2.5 mm Al | 2.78 | 1.32 | 1.33 | 1.41 | 1.37 | 1.39 | 1.47 | 1.38 | 1.39 | 1.5 |
| 80 | 3 mm Al | 3.04 | 1.34 | 1.34 | 1.42 | 1.39 | 1.4 | 1.51 | 1.4 | 1.41 | 1.52 |
| 80 | 3 mm Al + 0.1 mm Cu | 4.55 | 1.4 | 1.4 | 1.49 | 1.48 | 1.5 | 1.61 | 1.49 | 1.51 | 1.63 |
| 90 | 2.5 mm Al | 3.17 | 1.34 | 1.34 | 1.43 | 1.4 | 1.41 | 1.51 | 1.41 | 1.42 | 1.53 |
| 90 | 3 mm Al | 3.45 | 1.35 | 1.36 | 1.44 | 1.42 | 1.43 | 1.53 | 1.42 | 1.44 | 1.55 |
| 90 | 3 mm Al + 0.1 mm Cu | 5.12 | 1.41 | 1.41 | 1.5 | 1.5 | 1.51 | 1.62 | 1.51 | 1.53 | 1.65 |
| 100 | 2.5 mm Al | 3.24 | 1.34 | 1.34 | 1.42 | 1.4 | 1.41 | 1.51 | 1.41 | 1.42 | 1.53 |
| 100 | 3 mm Al | 3.88 | 1.36 | 1.37 | 1.45 | 1.44 | 1.45 | 1.55 | 1.45 | 1.46 | 1.57 |
| 100 | 3 mm Al + 0.1 mm Cu | 5.65 | 1.41 | 1.42 | 1.5 | 1.51 | 1.53 | 1.64 | 1.53 | 1.55 | 1.66 |
| 110 | 2.5 mm Al | 3.59 | 1.35 | 1.35 | 1.43 | 1.42 | 1.43 | 1.53 | 1.43 | 1.44 | 1.55 |
| 120 | 3 mm Al | 4.73 | 1.37 | 1.38 | 1.46 | 1.46 | 1.48 | 1.58 | 1.48 | 1.49 | 1.6 |
| 120 | 3 mm Al + 0.1 mm Cu | 6.62 | 1.41 | 1.42 | 1.5 | 1.53 | 1.54 | 1.64 | 1.54 | 1.56 | 1.67 |
| 130 | 2.5 mm Al | 4.32 | 1.36 | 1.36 | 1.44 | 1.44 | 1.45 | 1.55 | 1.45 | 1.47 | 1.57 |
| 150 | 2.5 mm Al | 4.79 | 1.36 | 1.36 | 1.44 | 1.45 | 1.46 | 1.55 | 1.46 | 1.48 | 1.58 |
| 150 | 3 mm Al | 6.8 | 1.39 | 1.39 | 1.47 | 1.5 | 1.51 | 1.61 | 1.52 | 1.53 | 1.63 |
| 150 | 3 mm Al + 0.1 mm Cu | 8.5 | 1.4 | 1.41 | 1.48 | 1.53 | 1.54 | 1.64 | 1.55 | 1.57 | 1.67 |

N Petoussi-Henss, M Zankl, G Drexler, W Panzer and D Regulla. Calculation of

backscatter factors for diagnostic radiology using Monte Carlo methods.

Phys. Med. Biol. 43 (1998) 2237–2250

## Maximum dose rate in fluoroscopy

1. Purpose

Check whether the maximum dose rate for fluoroscopy (not for ciné imaging) is within the norm.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Dose meter.  Lead patches/flaps, PMMA and eventually any other material until the dose is maximal, defined as the situation in which doses don’t further increase upon addition of extra attenuation. With mini C-arms 5 cm PMMA and some lead patches are sufficient. |
| *Methods* | Standard setup. |
| *Acceptability criteria* | The incidence dose rate in the reference point (without backscatter) should be less than 88 mGy / min (standard copied from the FDA). This value assumes no table between tube and PMMA but it can also be applied in a under couch configuration.  This limiting value can be exceeded provided that there is a continuous auditive warning, and that it requires manual activation. In any case, the dose rate should not be greater than 176 mGy / min. |

3. Methods

* + - Lead patches/flaps, PMMA and eventually any other material are put on the table and a program is used with high dose level and high pulse rate, until the dose is maximal, defined as the situation in which doses don’t further increase upon addition of extra attenuation.

If there is no fixed table, this test can be performed without table. The attenuating material is then put on the detector housing. Consecutive annual tests should be done with the same setup.

* + - A clinical fluoroscopy mode with high dose level, high pulse rate with maximal magnification is set, and the measured dose rate should be less than 88 mGy / min.
    - For high dose modes with warning (continuous sound and manual activation) the measured dose rate should be less than 176 mGy / min.
    - For mini C-arms, the maximum (accidental) dose rate (at minimum focus - skin distance) is calculated for 5cm PMMA.

4. Calculations

* + - The measured dose rate is recalculated to the dose rate at the reference point. This value is compared with the limit.

## Image receptor Air Kerma rate

1. Purpose

Check whether the Detector Air Kerma (DAK) rate on the image receptor is acceptable for the top 5 of the most frequently used clinical programs (fluoroscopy and ciné imaging). At acceptance, the measurements are also compared with the manufacturer's specifications. Optionally, the measuring procedure is adjusted.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Dose meter. The dose meter needs to be appropriate for measurement in a low dose domain and with Cu filtration.  Cu-filters are attached to the tube (for attenuation and beam hardening) so that there is minimal scatter radiation at the height of the image receptor. |
| *Methods* | Position the dose meter according to the manual. |
| *Acceptability criteria* | The DAK rate should be below the limits, see Table 6. |

3. Methods

* + - The dose meter is positioned so that the AEC cells are not affected.
    - A Cu filter of 2 mm is placed on the tube exit.
    - Perform the measurement for the largest field size on the image receptor.

4. Calculations

* + - Record the doses and compare with the table below. Record and comment on variations in time.
    - At acceptance: eventually calculate according to the manufacturer's guidelines and compare with specifications.

**Table 6.** Air Kerma rate at the height of the image receptor for different applications (typical values and limits)

|  |  |  |  |
| --- | --- | --- | --- |
| DAK rate at the image receptor | Typical value  (without grid) | Limit  RP162 (without grid) | Deduced values, with grid (preliminary standard) |
| Fluoroscopy (positioning, etc.) | 0.2 – 0.8 µGy/s | < 1 µGy/s | < 2 µGy/s |
| Cardiac acquisitions | 0.1 – 0.2 µGy/frame | < 0.5 µGy/frame | < 1 µGy/frame |
| Barium acquisitions, no subtraction, examinations with iodine contrast | 0.4 – 0.8 µGy/frame |  |  |
| DSA | 0.8 – 2 µGy/frame |  |  |

## Verification of the integrated dose-indicator calibration

1. Purpose

Verification of the dose indications displayed on the system: DAP, dose at the reference point, DAP in the DICOM header, DAP in MPPS or on print outs, etc. In other words, dose measurements are made for all dose indications that may be used in the practice of the medical practicioner, the imager or the medical physicist.

Measure correction factors between the specified and actual measured value if needed.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | For DAP meter calibration: Dose meter and system for measuring the size of the irradiated surface.  Alternative: a separate calibrated DAP meter.  PMMA  For other dose indicators: defined by the dose indicator |
| *Methods* | Position the dose meter according to the instructions of the manufacturer.  Measure the dose at the different tube voltages, typical 60 to 100 kV at intervals of ± 10kV. |
| *Acceptability criteria* | Each dose indicator must be within 20 % of the measured values. |

3. Methods

* + - The correct meaning of the dose indicator is retrieved from the manual of the system and a set-up is made to allow verification of measured and displayed dose indicator.
    - The verification of the calibration of the DAP meter is performed without the table in the beam. For under couch systems it can be deviated from this set-up. This will then be explicitly stated in the report. Optionally, a default value may be used for the attenuation of the table.
    - Calculate the product of the measured incident dose at a point in the beam and the irradiated surface through the same point and perpendicular to the beam. The measurement of incident dose or area can also be performed at a different distance and has then to be recalculated to the foreseen position. The product of incident dose and area is compared with the indication on the DAP meter.
    - For other dose indications: see instructions regarding their meaning or definition.

4. Calculations

* + - Calculate the correction factor:
    - The measurements are repeated at different tube voltages.
    - In any case, in the report, the circumstances in which the dose indications were verified are specified (with or without table).

## Characteristic curve

1. Purpose

Verify whether the preset kV-mA curves for different thicknesses of PMMA are logically set.

This test will provide insight on the AEC of the system and contains a lot of information with direct clinical relevance. The measurements will occasionally be used to require a better pre-programming of the system.

Upon acceptance of the device, all common clinically used modes are verified and compared with the manufacturer's specifications.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Dose meter  A total thickness of 25 cm PMMA (minimal 25 cm x 25 cm, sufficiently large to cover the AEC) |
| *Methods* | Choose a frequently used clinical program in both fluoroscopy and cinégraphy mode and use the standard set-up.  At acceptance: all frequently used clinical programs are tested.  The PMMA plates are placed on the table in increments of 5 cm. |
| *Acceptability criteria* | Every clinical program must have a logical choice of beam quality and dose level. |

3. Methods

* + - The plates are sequentially placed on the table.
    - If there is no fixed table, the measurements can be performed without a table. Consecutive annual tests should be done with the same set-up.
    - Measure the entrance dose rate values in fluoroscopy and cinégraphy mode for different PMMA thicknesses ranging from 10 cm to 25 cm in steps of 5 cm.
    - Write down kV, mA, filtration, incidence dose rate and possibly pulse duration for different thicknesses and programs.

4. Calculations

* + - The kV - mA combinations must be according to the specification of the manufacturer and be logical, with doses and beam quality increasing if thickness increases.

## Low and high contrast resolution of the system

1. Purpose

Low and high contrast resolution of the entire system, including beam quality, scattered radiation, geometry are verified for the most common clinical operation modes. This test verifies low and high contrast on the basis of a test object which contains low and high contrast inserts (eg TOR 18FG) incorporated in material which simulates a typical patient (eg 20 cm PMMA).

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Test object with low and high contrast inserts, 20 cm PMMA for general fluoroscopy systems and 5 cm PMMA for devices with focus - image receptor distance less than 45cm (mini C-Arm). |
| *Methods* | The measurement set-up is as follows:  tube - test object - PMMA - image receptor.  The test is performed with the most clinically used fluoroscopy and cine programs.  Imaging is done with automatic exposure mode. |
| *Acceptability criteria* | *(The following limits have to be further verified.)*  Fluoroscopy: the low contrast resolution should be better than 3.9 % (8 contrast objects in TOR 18FG phantom visible) and the high contrast resolution is recorded and compared to the image receptor resolution (paragraph 14) for further interpretation.  Cinégraphy: the low contrast resolution should be better than 2.70 % (10 objects in contrast phantom TOR) and the high contrast resolution is recorded and compared to the image receptor resolution (paragraph 14) for further interpretation.  These values assumes no table between tube and image receptor, but will also be applied in a under couch configuration. |

3. Methods

* + - Make the following measurement setup: tube - test object - PMMA - image receptor. If there is no fixed table, the test can be done without a table.
    - Use the most common clinically used modes in fluoroscopy and cinégraphy.
    - Study the viewing conditions at the level of the monitor where the read-out occurs. Read out in clinical circumstances.
    - Measure the low and high contrast resolution.

. 4. Calculations

* + - Compare with the limits (low contrast).
    - For high contrast resolution, the results are compared with the results of the image receptor resolution.

## Low contrast resolution of the image receptor

1. Purpose

Verification of the contrast resolution of the image receptor under standardized, scatter free conditions.

These results are compared with the values of the system contrast (section 11).

For mini C-arms, the Cu filtration can be replaced by 5 cm PMMA on top of the test object.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Copper filtration according to the manual of the test object.  TOR 18FG test object or equivalent. |
| *Methods* | The test is performed in fluoroscopy and cinégraphy mode.  The tube voltage should (if possible) be between 70 and 80 kV (according to the manual of the test object). If this is not possible, the test can be done with another program but this will require to recalculate the limiting values of the contrast threshold.  The test object is placed on the image receptor; the Cu filtration is attached to the tube (scatter free conditions at the level of the image receptor).  Imaging is done with automatic exposure. |
| *Acceptability criteria* | Fluoroscopy: the low contrast resolution should be better than 4 % (8 contrast objects in TOR 18FG phantom).  Cinégraphy: the low contrast resolution should be better than 2.70 % (10 objects in contrast phantom TOR).  If the low contrast resolution of the image receptor deviates significantly from the low contrast resolution of the system, this must be examined.  These values assume no table between tube and image receptor, but will also be applicable in a tube under fixed table configuration. |

3. Methods

* + - The test object is placed on the image receptor; the Cu-filtration is attached to the tube (scatter free conditions at the level of the image receptor). The test is preferably done without a table in the beam. Consecutive annual tests should be done with the same setup.
    - The tube voltage should typically be between 70 and 80 kV, cf. manual of the test object.
    - The measurement is performed for the most common fluoroscopy and cinégraphy modes.
    - Study the viewing conditions at the level of the monitor where the read-out occurs. Read out in clinical circumstances.

4. Calculations

* + - Compare with the limits.

## High contrast resolution of the image receptor

1. Purpose of the measurement

Verification of the intrinsic spatial resolution of the image receptor at a central point. In case of doubt, also in peripheral points.

Optionally, an exposure is made with a mesh phantom to detect localized blur.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | TOR 18FG or Huttner line pair test TO object or other test object with similar patterns |
| *Methods* | The test object is placed on the image receptor according to the manual. The test pattern is placed at an angle of 45 ° to the pixel rows.  The test is performed in fluoroscopy and cinégraphy mode and for the various magnifications. |
| *Acceptability criteria* | In fluoroscopy mode:  Resolution > 1.0 lp / mm for > 30 cm field sizes.  Resolution > 1.4 lp / mm for field sizes 24 – 30 cm, 30 cm included  Resolution > 1.6 lp / mm for field sizes 18 – 24 cm, 24 cm included  Resolution > 1.8 lp / mm for field sizes 15 – 18 cm, 18 cm included  Resolution > 2 lp / mm for < 15 cm field sizes.  For systems in interventional cardiology (fluoroscopy): Resolution > 2 lp / mm for > 23 cm field sizes  Resolution > 2.5 lp / mm for field sizes 15 – 23 cm, 23 cm included  Resolution > 3.1 lp / mm for field sizes < 15 cm (Optional)  If the systems fails, check if the failure is due to the Nyquist criterion (professional judgment) and if necessary make an alternative test.  Recordings with the mesh phantom should not show significant abnormalities. |

3. Methods

* + - The test object is placed on the image receptor; optionally Copper must be attached to the tube (until the image is readable, not saturated). If there is no fixed table, the test can be done without a table. Consecutive annual tests should be done with the same set-up.
    - Position the test object as specified in the manual. Take images with the different magnifications and write down the number of visible line pairs.
    - Study the viewing conditions at the level of the monitor where the read-out occurs. Read out in clinical circumstances. Determine the spatial resolution.
    - Make an exposure with the mesh phantom.

4. Calculations

* + - Compare the spatial resolution with the limits.
    - Evaluate the image with the mesh phantom.

## Global evaluation of image quality

1. Purpose

Global inspection of image quality: artifacts, distortion, non-uniformities (ghost), etc.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Homogeneous plates, test object for evaluation of distortion. |
| *Methods* | Position the test object according to the manual. Make an exposure with a clinically used program. |
| *Acceptability criteria* | Visual inspection. |

3. Methods

* + - Position the test object as specified in the manual. Take an image with a clinically used program and do a visual inspection.
    - Interpret and report the severity of observed artifacts.

## Overall quality of the digital image receptor (optional)

1. Purpose

*Verification of the overall quality of the digital image receptor: image receptor response, MTF and noise power.*

Manufacturers are encouraged to implement a physics mode (as defined by MITA) or to give access to raw (for processing) data. This is mandatory for new systems from 2016 onwards

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Homogeneous plates and edge test object. |
| *Methods* | Make a setup in accordance (as close as possible ) with the IEC standard but adapted to the clinical situation (non-invasive test).  Access to "for processing" (raw) images is required. |
| *Acceptability criteria* | Record of parameters and observe variations in time. |

3. Methods

* + - Make an exposure in manual mode with fixed tube voltage and increasing mAs. Calculate the pixel value and the noise in a central ROI. Determine the pixel value offset and verify the linearity of the image receptor or any other monotonous relationship between pixel value and DAK described by the manufacturer. Linearize the images.
    - Make an exposure with an edge test object (MTF calculation) and a corresponding exposure of the homogeneous plate for noise power calculations.

4. Calculations

* + - Calculations are made according to IEC standard and where available the IEC limits are applied.
    - The frequency where the MTF reaches 0.5 and 0.10 are recorded and followed over time.

## Image Receptor lag (optional)

1. Purpose

Quantification of image receptor lag, and ghosting if relevant

Lag = signal transmission from a previous image in the current image.

Ghosting = reduction of the sensitivity of the image receptor by all previous exposures.

Manufacturers are encouraged to make raw (for processing) data available or to implement the MITA working group documents.

The test must be carried if problems are suspected.

2. Material, methods, acceptability criteria

|  |  |
| --- | --- |
| *Material* | Lead test object to completely stop the X-ray beam and a thin test object. |
| *Methods* | Access to "for processing" (raw) data is necessary. |
| *Acceptability criteria* | Record of parameters and follow up in time. |

3. Methods

* + - Select a program with a very low frame rate.
    - Make a fluoroscopy series of the thin test object with only one pulse. This is done blocking the other pulses with lead test object.
    - Measure the signal in the set of images on the same place. Compare the signal in the second image and all other successive images with the signal in the first frame.

4. Calculations

* + - Calculate:

where

Ln is defined as the "lag" in the n-th image

In is the pixel value in the n-th image,

I0 is the pixel value in the first image.

B ???

* + - Compare with basic values or with data of similar devices.