Quality Assurance

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- **Quality Assurance (QA):** "All those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards".
- **Quality control (QC):** Is part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

Quality Assurance

- A quality assurance programme may be defined (WHO) as an organised effort by staff operating a facility to ensure that the diagnostic images produced by the facility are of sufficient quality so that they consistently provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation.

Quality Assurance Programme

A quality assurance programme includes :

- The selection of the equipment
- The quality control of equipment and accessories
- The evaluation of patient doses
- The adoption of optimised technique procedures

The selection of the equipment

Equipment Specifications

HOW MUST AN X-RAY SYSTEM BE SPECIFICALLY DESIGNED" FOR INTERVENTIONAL RADIOLOGY/CARDIOLOGY?

- Constant potential generator
- Arc system (X-ray tube below table)
- High efficiency intensifier
- Easy operational controls
- Good image saving and retrieving

IAEA radiation protection course

It started like this

X-ray tube and fluoroscope screen 1930

Today

Requirements for equipment (Joint WHO/IRH/CE workshop 1995 (1))

RECOMMENDED TECHNICAL SPECIFICATION (1) :

- Use of audible dose or dose rate alarms is not considered appropriate (cause of confusion)
- Dose and image quality : user selectable variables
- Additional filtration
- Removable Grid
- Pulsed fluoroscopy modes
- Image hold system
- Flexibility for AEC (IMAGE or DOSE weighted)

Requirements for equipment (Joint WHO/IRH/CE workshop 1995 (2))

- **Roadmapping** (use of a reference image on which the current image is overlayed)
- **Image simulation** (impact of changes in technique factors displayed prospectively, effect of semitransparent filters simulated)
- **Region of Interest** (ROI) fluoroscopy: a low noise image in the centre is presented surrounded by a low dose (noisy) region.
- Provision of **additional shielding** to optimize occupational protection:, etc.

Requirements for equipment (Joint WHO/IRH/CE workshop 1995 (3))

RECOMMENDED TECHNICAL SPECIFICATION (2):

- **Overcouch** image intensifier
- Source intensifier **distance tracking**
- **Concave couch** top for patient comfort
- **Dose-area product** meter
- Provision of **Staff protective shielding**
- **Display** of fluoroscopy time, total dose-area product (fluoroscopy and radiographic) and estimated skin entrance dose.

Requirements for equipment (Joint WHO/IRH/CE workshop 1995 (4))

- Computer interface for **dosimetric information**
- Provision of **iso-scatter distribution** diagrams for normal and boost modes
- All instrumentation and switches **clearly labeled**
- Maximum size of **image store**
- Availability of an **automatic injector** is desirable
- Means of **patient immobilization**

Requirements for equipment (Joint WHO/IRH/CE workshop 1995 (5))

X RAY TUBE AND GENERATOR:

- Focal spot:
- cardiology 1.2/0.5 mm
- neuroradiology 1.2/0.4 mm
- peripheral vascular 1.2/0.5 mm

- Minimum focus skin distance 30 cm
- Heat capacity of X-ray tube should be adequate to perform all anticipated procedures without time delay
- 80 kW generator
- Constant potential generator
- Pulsed fluoroscopy facility available
- Automatic collimator to the size of the I.I. surface.

Requirements for Image Intensifier (Joint WHO/IRH/CE workshop 1995 (6))

- **Cardiology**: **25 cm; max. dose rate : 0.6 µGy/s**
- **Neuroradiology**: **30 cm; max. dose rate : 0.6 µGy/s**
- **Peripheral vascular**: **35-40 cm; max. dose rate : 0.2 µGy/s**

Note : dose rate in normal mode, should be measured at the entrance surface of Image Intensifier

- 2 x **magnification** available
- low dose rate **mode** available

FDA Recommendations for IR (1994) (I) http://www.fda.gov/cdrh/fluor.html

- To establish standard operating procedures and clinical protocols for each specific type of procedure performed.
- To know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol.
- To assess the impact of each procedure's protocol on the potential for radiation injury to the patient.

FDA Recommendations for IR (1994) (II)

- To modify the protocol, as appropriate, to limit the cumulative absorbed dose to any irradiated area of the skin to the minimum necessary for the clinical tasks, and particularly to avoid approaching cumulative doses that would induce unacceptable adverse effects
- To use equipment that aids in minimizing absorbed dose
- To enlist a qualified medical physicist to assist in implementing these principles in such a manner so as not to adversely affect the clinical objectives of the procedure

The quality control of equipment and accessories

The quality control of equipment and accessories

Requires:

- Adequate testing of equipment before it is used on patients
- Adequate testing of equipment performance at appropriate intervals and after any major maintenance procedure
- Where appropriate, measurements at suitable intervals to enable the assessment of representative doses to patients

Test Types

- Critical examination → To ensure correct operation of safety features
- Acceptance test → To verify that the conditions of contract have been met
- Commissioning tests → To ensure that the equipment is ready for clinical use
- Routine tests → To detect significant changes in performance during use

Commissioning tests

- Extensive performance measurements to ensure that the equipment will perform satisfactorily in clinical practice.
- Establish baseline values as a reference for future routine quality control tests.
- Need to be performed when major items have been replaced e.g. X-ray tube, image intensifier, etc.

Commissioning tests

Tube and generator:

- kV
- mAs
- Filtration
- Focal spot
- Radiation/image field size and virtual collimation:

Alignment of the X-ray field with the image visible on the TV monitor

Commissioning tests

- Dose rate at the entrance surface of a phantom under automatic exposure control (AEC):

Measurement of absorbed dose rate under normal operating conditions at the surface of an appropriate phantom on all field sizes and commonly used fluoroscopy options (high dose rate, pulsed rate, etc.)

Commissioning tests

- Dose rate at the input face of the image receptor under AEC:

Measurement of the levels of dose rate at the input to the image receptor under AEC on all field sizes and commonly used fluoroscopy options (high dose rate, pulsed rate, etc.)

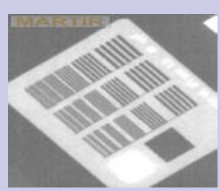
- Dose per image at the input face of the image receptor under AEC:

Measurement of the dose per image at the input face of the image receptor under automatic fluorographic exposure control

Commissioning tests

Image quality (Leeds Phantoms)

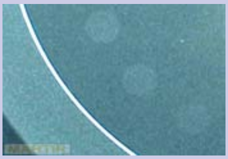
- High contrast resolution



Commissioning tests

Image quality (Leeds Phantoms)

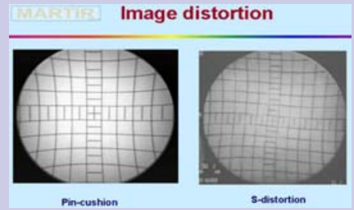
- Low contrast resolution



Commissioning tests

Image quality

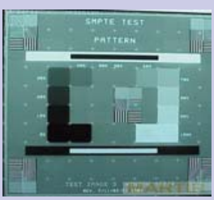
- Image Distortion



Commissioning tests

Monitors

- Resolution
- Greyscale



Routine Tests / Constancy Tests

Tests undertaken:

- Regularly
- After maintenance
- After repairs
- To detect any change in the performance of the equipment

They are a subset of the commissioning tests.

Routine Tests

- Dose rate at the entrance surface of a phantom under AEC
- Dose rate at the input face of the image receptor under AEC
- Dose per image at the input face of the image receptor under AEC
- High contrast resolution
- Low contrast resolution

CONSTANCY TEST FOR FLUROSCOPY EQUIPMENT

Ref.: Worksheet-D5.9-05-12-01 Page 1/2

Report Number:
Date:
Test performed by:

T removed.

With/without Table

Pressure 760 mm Hg
Temperature 22 °C
Kpt = 1.00

100 Focus-Intensifier d. (cm) 100

Submode	Field size (cm)	kV	mA	Filter entrance dose rate (mGy/min)	Image Intensifier entrance dose rate (mGy/min)	(µGy/s)	Filter entrance dose rate corrected and normalised at 70 cm (mGy/min)	
								2 mm Cu
								4 mm Cu

CINE/DIGITAL

Focus-Chamber d. (cm) 100 | us-Intensifier d. (cm) 100

Mode	Submode	Field size	kV	mA	Filter entrance dose (mGy)	Total number of images	Filter entrance dose/image corrected and normalised at 70 cm (µGy/frame)	
								2 mm
								Cu
								4 mm
								Cu

IMAGE QUALITY

Resolution should be assesed in the usual illumination conditions and from the operator's position. Distance to monitor: m

Leeds Test placed on

Conditions:

Fluoroscopy mode most used:

Field size	kV	mA	Monitor	Live or Last Image	High contrast groups	Low constrast groups	
							2 mm
							Cu
							4 mm
							Cu

Distortion

COMMENTS

Routine Tests / Constancy Tests

- These tests are carried out at commissioning in order to set the baseline values.
- Any deviation from the baseline values necessitates further investigation.
- They ensure the constancy of the good performance of a radiological installation.

Quality control of Lead Aprons

Quality control of Lead Aprons

Quality control of Lead Aprons

Lead Aprons should always be put away properly in order to avoid them getting damaged

The evaluation of patient doses

The evaluation of patient doses

- Regular constancy testing ensures that the patient dose is kept at an optimum level as a number of constancy tests are directly related to patient dose.
- A gradual increase in input dose rate to an image intensifier would result in an increase in patient doses but would be detected and corrected by appropriate regular testing.
- The ultimate check on whether patient doses are indeed acceptably low is to make direct assessments of dose on groups of patients and to compare the results with some acceptable standard.

Dosimetric parameters

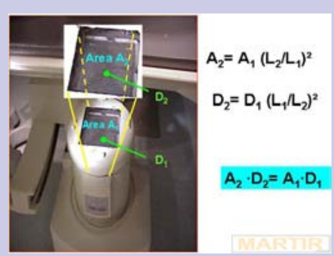
- Dose area product (for stochastic effect)
- Entrance surface dose (for deterministic effect)
- Effective dose
- On-line dose monitoring

Dose Area Product (DAP)

- **KAP (DAP) meter**
- ✓ Advantages: Easy, quick, immediate measurement
- ✓ Disadvantages: Expensive, no information on skin dose
- **Estimation from dose rate and field size**
- ✓ Advantages: Not expensive
- ✓ Disadvantages: Not accurate

IAEA radiation protection course

KAP

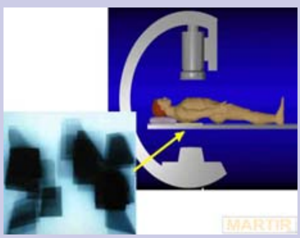


KAP

Patient skin dose

- TLD dosimeters
  - ✓ *Advantages: Accurate provided correct positioning is done.*
  - ✓ *Disadvantages: Expensive, lengthy procedure.*
- Skin dose monitor
  - ✓ *Advantages: Accurate provided correct positioning is done.*
  - ✓ *Disadvantages: Expensive, small number of detectors can be placed without causing problems in the image.*
- Film dosimetry
  - ✓ *Advantages: Low cost, accurate (provided correct calibration is done), skin dose map.*
  - ✓ *Disadvantages: Dose Limit: Kodak X-Omat V 500mGy, Kodak EDR up to 15Gy, Gafchromic 20Gy (expensive).*
- Estimation from DAP and field size
  - ✓ *Advantages: Not expensive*
  - ✓ *Disadvantages: Lengthy, not accurate.*

TLD dosimeters-Film dosimetry



Example of the data included in the study report

1 CARD FIXED Coro ND 1k 7s 15F/s 15-Jan-03 09:16:21
A 81kV 744mA 6.0ms 200CL small 0.3Cu 17cm 211.4μGym² 36.2mGy 0LAO 0CRA 105F

2 CARD FIXED Coro ND 1k 6s 15F/s 15-Jan-03 09:17:01
A 86kV 734mA 6.0ms 600CL small 0.2Cu 17cm 376.9μGym² 63.8mGy 29RAO 0CRA 94F

3 CARD FIXED Coro ND 1k 5s 15F/s 15-Jan-03 09:17:43
A 124kV 553mA 8.0ms ****** small 0.2Cu 17cm 490.3μGym² 94.1mGy 48RAO 22CRA 75F

4 CARD FIXED Coro ND 1k 6s 15F/s 15-Jan-03 09:18:16
A 115kV 591mA 8.0ms ****** small 0.2Cu 17cm 460.4μGym² 97.8mGy 48RAO 22CRA 84F

5 CARD FIXED Coro ND 1k ***** 15F/s 15-Jan-03 09:19:05
A 96kV 714mA 8.0ms ****** small 0.2Cu 17cm 9.3μGym² 1.9mGy 15RAO 30CRA 2F

6 CARD FIXED Coro ND 1k ***** 15F/s 15-Jan-03 09:19:07
A 102kV 666mA 8.0ms ****** small 0.2Cu 17cm 17.2μGym² 3.5mGy 15RAO 30CRA 3F

Example of the data processing from the study report

Ser	kV	mA	ms	filter	II	Gy.cm2	mGy	ang1 l+	ang2 cau+	fr	Gycm2/fr	mGy/fr	mGy/fr sys	microGy/mAs
1	81	744	6	0.3	17	2.11	36.2	0	0	105	0.020095	0.33	0.34	77.2
2	86	734	6	0.2	17	3.77	63.8	-29	0	94	0.040106	0.67	0.68	154.1
3	124	553	8	0.2	17	4.9	94.1	-48	-22	75	0.065333	1.09	1.25	283.6
4	115	591	8	0.2	17	4.6	97.8	-48	-22	84	0.054762	0.91	1.16	246.3
5	96	714	8	0.2	17	0.093	1.9	-15	-30	2	0.0465	0.78	0.95	166.3

The adoption of optimised technique procedures

Reference Values

Reference Values

- QA is not just about producing quality images – it also requires those images to be produced at acceptable dose levels.
- Directive 97/43: Diagnostic Reference Levels (DRLs)

These levels are expected not to be exceeded when good and normal practice regarding diagnostic and technical performance is applied

Proposed reference values (DIMOND)

	PTCA	CA
DAP ($Gycm^2$)	94	57
Minutes fluoroscopy	16	6
Number of frames	1355	1270

An example of optimisation due to reference values

- Influence of a training course on KAP values
- Influence of change of equipment on KAP values

Influence of training courses

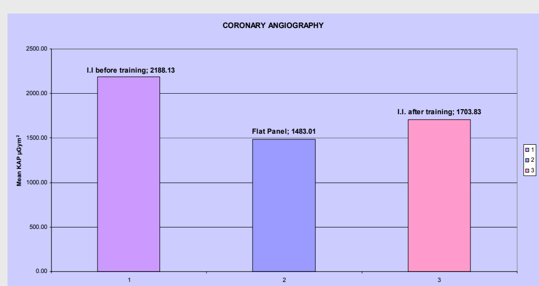
- Using the KAP information in the archive of our system, we compared the values before and after the training course addressed to the doctors of our cardiac centre.
- They were working with an Image Intensifier at the time.
- The KAP values for CA , CA+LV and CA+ PTCA were

Collected and evaluated for about 300 patients

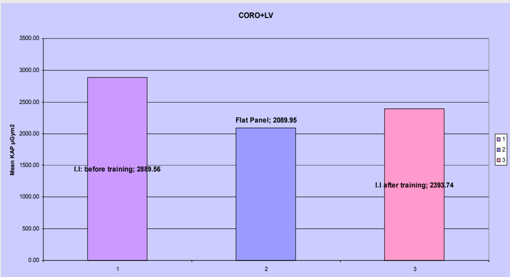
Comparison between I.I. and Flat panel Detectors

- Our system, a Siemens Axiom Artis was initially installed with an Image Intensifier and later upgraded to a dynamic flat detector.
- In order to evaluate the performance of the flat panel detector concerning the dose (KAP value), we made a small scale collection of information from around 300 patients for three medical procedures: CA , CA+LV and CA+ PTCA

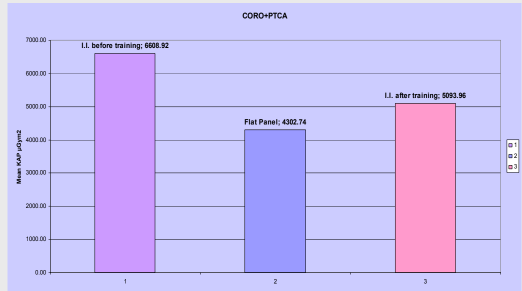
Mean KAP values for Coronary Angiography



Mean KAP values for Coro+LV



Mean KAP values for Coro+PTCA



Conclusions

- Many physical and technical factors affect greatly patient dose and image quality in interventional radiology/cardiology.
- The equipment used in these fields should comply with purchase specifications and be part of a rigorous quality assurance programme.
- Practitioners should be aware of such recommendations.