Development and implementation of acceptability criteria for medical radiological equipment in Belgium

Tom Clarijs
Tom.Clarijs@fanc.fgov.be
Service Protection of Health
Department Health & Environment
Development and implementation of acceptability criteria for diagnostic radiology in Belgium

Optimalisation = obligation
Framework of regulation

Obligations in Optimisation, QA & Medical Physics

→ Optimisation of the patient dose is a legal obligation

- acceptance test of each system before first clinical use
- periodic performance test of each x-ray system
- assessment of the patient dose
- use of Diagnostic/Dose Reference Levels (DRL)
- follow-up of recommendations made by
  - the Health Physics expert (RPO-RPE)
  - the Medical Physics expert (MPE)
- application of good practice
General regulation in Belgium: ARBIS / RG PRI

Royal Decree of 20 July 2001 laying down general regulations concerning the protection of the public, workers and environment against the hazards of ionizing radiation

Official Gazette of 30 August 2001

available at http://www.jurion.fanc.fgov.be
Belgian regulation on QC in radiology

Quality control: current regulation → ARBIS Chapter VI

**Article 51.6.4:**
Before the first clinical use, **acceptance test** to be performed by a MPE (medical physics expert) certified by FANC

**Article 51.6.5:**
At least yearly **conformity testing** by a MPE certified by FANC

Report of conformity by MPE should be transferred to (internal or external) Health Physics service. Urgent reports are to be sent without delay to the FANC.

Every year, FANC receives a list of not-conform and not-tested equipment. All equipment not conform with criteria is to be put out of service as long as the deficiency is not resolved.

**Article 81.6.5:** as long as FANC has not fixed QC-criteria: EC document Radiation Protection 91 must be used.
Belgian regulation on QC in radiology

Radiation protection 91: European Commission 1999

- Based on various documents of the nineties
- Easy to apply, but ...
  - does not guarantee a good overall quality!
  - out-dated (cfr digital detectors, ...)
  - several interpretations possible
  - only criteria, no information on measurement method

- problems for practical implementation
**Belgian regulation on QC in radiology**

**Subchapters of RP 91:** specific criteria according to the modality

- Tube voltage (accuracy & precision)
- Total filtration
- Exposure time
- Output (magnitude & consistency)
- Alignment (x-ray field, light indicator, orthogonality)
- Field size (≤ boundaries of image detector)
- Automatic exposure control (voltage and thickness compensation)
- Leakage radiation
Belgian regulation on QC in radiology

**Conclusion:** new (Belgian) criteria necessary

→ Establishment of QC-protocol for radiological equipment

→ Workgroup Radiology of the **BHPA** (BVZF-SBPH)

  Belgian Hospital Physicist Association

→ All certified MPE’s were invited to participate!

→ academic, commercial, independent MPE’s involved

→ Not only QC protocols, also mutual feedback between physicists, continuing education, discussions on medical radiation physics,…

→ (subgroups CT, dental, image intensifier,…)

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Tom Clarijs - 10/30
Belgian regulation on QC in radiology

Result:

26-page elaborated protocol on:
- measurement objectives
- measurement method
- geometrical setup
- acceptability criteria (suspension, remedial)
- calculations

➡ Taken into account:
  - international recommendations and scientific publications
  - experience, Belgian measurements and local situation

Available on www.BHPA.eu
FANC Decree

Besluit houdende de aanvaardbaarheidscriteria voor röntgenapparatuur voor medisch diagnostische radiologie

Arrêté fixant les critères d’acceptabilité pour les appareils à rayons X destinés à être utilisés à des fins de radiologie diagnostique médicale

Decree holding the acceptability criteria for x-ray equipment used for medical diagnostic radiology

25th July 2011

(Official Gazette 24th August 2011)
Acceptability criteria: contents

4 Chapters:

I Scope & definitions

II Judgement of conformity

III Acceptability criteria for general radiology

VI Closure remarks
Acceptability criteria: contents

Chapter I: Scope & definitions

- Criteria to be used with x-ray equipment only for medical diagnostics

- No mammography (cfr. BE protocol for screening exists)
- No CT (separate criteria being established)
- No dental radiology (FANC Decree for dental app)
- No DEXA (separate international criteria exist)
- No image intensifier (separate criteria being established)
Acceptability criteria: contents

**Chapter I: Scope & definitions**

Examples of some definitions:

- Technical terms like
  - HVL (half value layer)
  - PMMA (polymethyl metacrylate)
  - OD (optical density)
  - LEI (Linearized exposure index)
  - ...

- Also general items like
  - “deviation”
  - “variation”
  - ...
Judgement of conformity

What if the x-ray equipment is judged not conform?

According to the gradation of risk following the deficiency

e.g.: alignment between X-ray field and light field

vs inaccurate timer

PATIENT DOSE >>> patient dose
Acceptability criteria: contents

Chapter II: Judgement of conformity

According to the gradation of risk following the deficiency

Non-compliance to minor criteria?
→ must be resolved before the next annual QC-test

Non-compliance to major criteria?
→ must be resolved within a certain time period
(agreeement between medical physics expert and the responsible < 6 months)

Not conform + no guaranteed safe clinical use?
→ must be resolved immediately
→ equipment must be put out of order as long as defect exists
→ copy of test-report to FANC (notification)
Acceptability criteria: contents

General elements that are tested (per QC): (when applicable)

1. X-ray tube tension kVp
2. Filtration HVL (mm Al)
3. Exposure time ms
4. X-ray tube output μGy/mAs
5. Patient dosimetry (mGy)
   - entrance skin dose mGy.cm²
   - DAP calibration LEI
   - Automatic Exposure Control (lp/mm)
6. Image quality
7. Image quality
8. Alignment & collimation
   - alignment X-ray and light field mm
   - orthogonality °
   - alignment centres mm
   - automatic collimation mm
Particularities
Exposure index for digital detectors (CR-DR)

- No direct indication to the patient dose
- Indication of the physical image quality
- allows optimisation of the imaging system by quantifying detector dose vs image quality
  - Fuji-Konika: Sensitivity number-value
  - Agfa: Exposure index (EI)
  - Kodak: logarithm of the Median of the histogram (lgM)
  - GE Detector Exposure Index (DEI)
  - Philips/Siemens/Thompson (Trixell): Exposure indicator (∼ S)
  - Hologic: Exam Factor, Center of Mass of Log E Histogram
  - Swissray: similar to IgM
  - IDC: log of median of histogram

⇒ LEI = linearized exposure index
Implementation

• Since 3rd of September 2011, every x-ray system for medical diagnostic radiology is tested at least once a year to these criteria

• Communication to the radiology community & medical physics community

• Active inspection of the Federal Agency to verify compliance
Useful links

BHPA website: www.bhpa.eu ➔ protocol drafts
FANC website: www.fanc.be ➔ FANC decrees
Acknowledgements

Many thanks for the large support of the medical physics experts of the BHPA working group radiology.