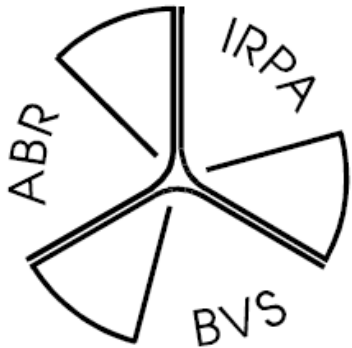




federal agency for nuclear control

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



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Service Protection of Health

Department Health & Environment



Framework of regulation



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 / RGPRI

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.

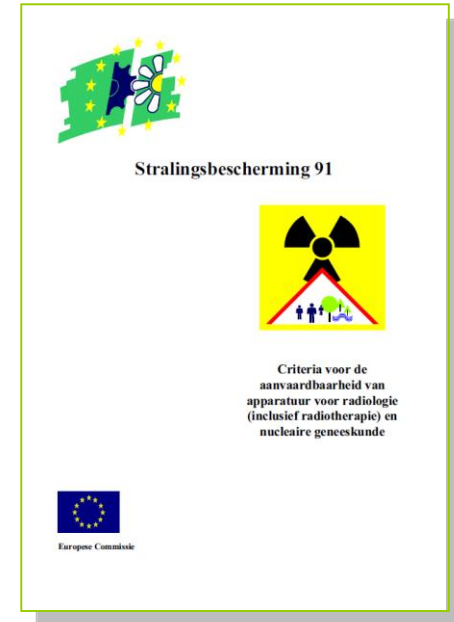
Every year, FANC receives a list of not-conform and not-tested equipment. All equipment not conform with criteria is to be put out of service as long as the deficiency is not resolved.

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

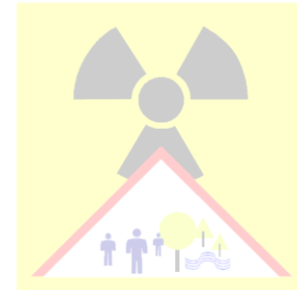


Belgian regulation on QC in radiology



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 (\leq 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,...)



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

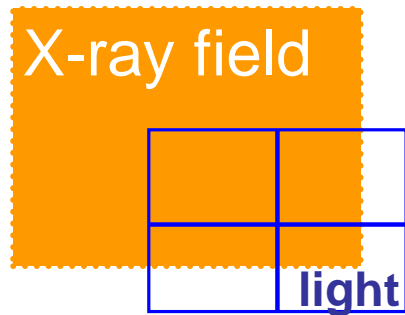
What if the x-ray equipment
is judged not conform?

According to the gradation of risk following the deficiency

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

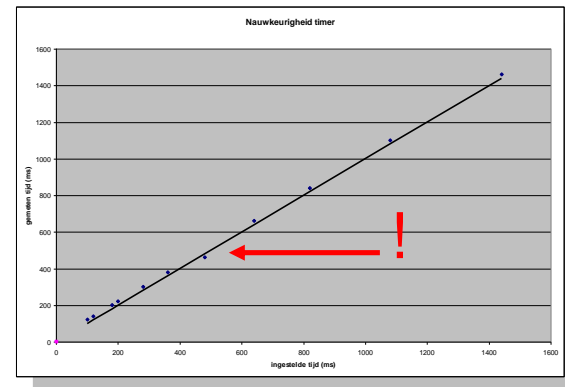
vs

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

(agreement 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)

risk

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	$\mu\text{Gy/mAs}$
5. Patient dosimetry	
- entrance skin dose	(mGy)
- DAP calibration	$\text{mGy}\cdot\text{cm}^2$
- Automatic Exposure Control	LEI
6. Image quality	(lp/mm)
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 (IgM)*
 - *GE Detector Exposure Index (DEI)*
 - *Philips/Siemens/Thompson (Trixell): Exposure indicator ($\sim S$)*
 - *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

The image displays two website screenshots. The left screenshot shows the BHPA website with a navigation menu, search bar, and a list of upcoming events including the BHPA 2012 symposium in Brussels and the VSL course on practical dosimetry for radiotherapy. The right screenshot shows the FANC website, featuring a header with the FANC logo, a navigation menu, and several news articles such as 'Detectie van jodium-131 in Noord-Europa' and 'FANC informeert het publiek tijdens de bouwbeurs Batimoi'.

BHPA website: www.bhpa.eu → protocol drafts

FANC website: www.fanc.be → FANC decrees

Acknowledgements



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medical physics experts of the
BHPA working group radiology*