Materiovigilances & radiation protection

Vigilance Day
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FANC • AFCN
fédéral agentschap voor nucleaire controle
agence fédérale de contrôle nucléaire

www.fanc.fgov.be
FANC / AFCN

Together we protect

Our mission

"The Federal Agency for Nuclear Control promotes the effective protection of the general public, workers and the environment against the hazards of ionising radiation."
GLBEG “Health protection”
Section Head: An Fremout

X-ray applications
- Coordinator: Katrien Van Slambrouck

Nuclear Medicine and Radiopharmacy
- Coordinator: Marleen Vandecapelle

Radiotherapy
- Coordinator: Karen Haest

Health and dosimetric surveillance
- Coordinator: Sophie Leonard

Health risk assessment
- Coordinator: Petra Willems

Responsible medical devices
- Isabelle De Pau

Expert dosimetry
- Thibault Vanaudenhove

Medical doctor
- Sylviane Carbonelle

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GLBEG

- Medical, dental and veterinary X-ray applications
- Radiotherapy
- Nuclear medicine and radiopharmacy
- Health and dosimetric surveillance of workers (all sectors)
- Health risk assessment (population)

- Personal licenses and recognitions
- Justification & Optimization
- Information and awareness
- Stakeholder involvement
- Vigilances
- Incidents
- Regulation
- Research and development
RD 18/3/1999 – Medical Devices:

What? Any instrument, equipment, material or other item used on its own or in combination, including software required for it to function correctly, which is intended by the manufacturer to be used on humans for the following purposes:

- diagnosis, prevention, control, treatment or cure of a disease
- diagnosis, control, treatment, cure or compensating an injury or handicap
- study, replace or modify part of the anatomy or a physiological process
- conception

Annex XIII, article 3N13

Under control FANC

Devices or substance emitting ionising radiation or which are intended to emit ionising radiation.
(e.g. radiology equipment, sources & devices for radiotherapy, dental X-ray equipment)

Devices which are intended to detect the in vivo distribution of radiopharmaceuticals
(e.g. Nuclear Medicine camera’s like SPECT & PET)

Film
Medical Devices

Knowledge sharing & complementing

Clinical Trial

IN MEDICINE

Physical Control

Quality

INCIDENT REPORTING
FANC & medical devices

- Competence: limited to radiation protection aspects
- Graded approach: radioactive material more dangerous
  ⇒ Control on import, transport, distribution
- Generic justification:
  - Before distribution on BE market for unsealed & sealed sources used for medical purposes
  OR
  - Introduction application file for authorisation by undertaking (hospital, dental practice, private practice, ...)

- Reception of new equipment by radiation protection expert (RPE) = control radiation safety of user, public & environment
- Acceptance testing of new equipment by medical physics expert (MPE) = control radiation safety of patient
- Afterwards: periodic quality control of the medical devices by medical physics expert
Medical devices & radiation safety

Challenges?
CE not always CE
CE-certificate ≠ radiation safe
CE-certificate ≠ compliant with acceptability criteria

Control of devices on the market & before first clinical use of each new device by the health physics expert & medical physics expert

Licensing for exploitation & authorising for use, education, inspection

Interaction with manufacturers/distributors
Medical devices & radiation safety

No radiological risk as long as pacemaker is intact!
High contamination risk if Pu-238 is released!

Leaflet with more information on our website:

If found in your hospital: contact your Radiation Protection Expert

Medical devices & radiation safety

Handheld intra oral devices

Not allowed for general use:

- Risk for higher dose for user
- More risk on misuse and theft
- Stability ???

Medical devices & radiation safety

Radiation leakage

Discovered by radiation protection expert during testing new dental equipment (CE marked)
Medical devices & radiation safety

Quality problems

Discovered by medical physics expert during acceptance testing or routine QA

Spacing not conform

Wrong labelling disposable grid

Activity:
- Wrong batch number
- Mix-up source during exchange
- Mix-up deliveries
Medical devices & radiation safety

Quality problems

Discovered by medical physics expert during acceptance testing or routine QA

- Measured dose rate much higher than nominal dose rates in technical documentation of the manufacturer
  - Independent dosimetric control confirms results MPE
  - Manufacturer updated his technical information

  ➢ always question / investigate abnormal results
  ➢ Independent dosimetric audit on acceptance no luxury

- No direct interruption of exposure when foot switch is released
  - Manufacturer replaced footswitch
  - action taken by FANC: contact MPE of other installations & distributor => other systems were NOT affected
Vigilances

Practice:

Notification by EUDAMED, Manufacturer or user

“imaging” or “radiation” in notification

FAMHP

Follow-Up

FANC

Quick

Belgium involved & radiological risk
Vigilances

Evolution

Number of materiovigilances / Year

Year

Vigilances

**Evolution per discipline**

- **Software** = PACS / RIS / stand alone software packages for imaging processing, dose management, …
- **Others** = MRI, film, cassettes, US, swabs with radio-opaque fibre

**Software**
- **RT**
- **NG**
- **RX**
- **Dental RX**
- **Software**
- **Others**

**Total number of materiovigilances**

- 2016
- 2015
- 2014
- 2013
- 2012
- 2011
- 2010

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Examples QUICK

- Pure mechanical problems: arm loosening, collimators gamma-camera’s, tables blocking, ...
- Imaging equipment not using or detecting ionizing radiation:
  - Swabs with radio opaque fibre
  - .....
FANC approach in incidents & vigilances with radiological risk

Important
Prevention approach
NO blame, no shame

- Analyse, support & advise to FAMPH
- Dialogue with distributors & manufacturers
- Extra warning to the users or medical physics experts
- Additional advice/actions

If incident in Belgium:
- Analysis in depth (by all parties concerned) ⇒ corrective actions
- Where needed bringing all parties around the table to solve, improve, prevent!
- REX to the sector (anonymous)
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Those radioactive isotopes we had you drink should be ready right about now... You know, we're pretty excited to scan you! We just upgraded this thing to Win XP, and we can hardly wait to see what's going to happen! Now, just relax... Unless you feel something uh... burning...
General remark:
Radiation risk underestimated by manufacturers
Vigilances

General remark:
Radiation risk underestimated by manufacturers

WHY?
• Only certain deterministic effects (cell death) directly visible => very high doses and real ACCIDENTS
• Most deterministic effects only seen after days or weeks

After 3 weeks

after 6,5 month
Vigilances

General remark:
Radiation risk underestimated by manufacturers

**WHY?**

- Stochastic effects (DNA damage): late effects, no threshold, higher cancer risk, cataract, cardiovascular and vascular diseases, hereditary effects, ...

- Unborn child: abortion, birth defects, decrease IQ, cancer risk, ...

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General remarks:

• 2014 regulation strengthened

   CFR – Code of Federal Regulations Title 21
   PART 1020: Performance standards for ionizing radiation emitting products
   ⇒ more vigilances regarding infringements IEC/CE standards
   ⇒ no continuous audible signal during scopy, malfunction of 5 min timer, no emergency stop, ...

• Implementation of corrective actions takes in most cases a year or longer

• Resemblance between vigilances of same type of equipment from different manufacturers
   ⇒ shortcoming in IEC/CE standards ???
   ⇒ needs European and even international collaboration of CA’s
   ⇒ need for more notification by users !!!!

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General remarks:

- Underreporting for dental radiological equipment
- Compatibility often a problem
Vigilances

It is often difficult to determine whether an adverse event was caused by a medical device.

When in doubt it is better to report than not to report.

Session A3: Post-Market Vigilance Activities
Questions?

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