Materiovigilances & radiation protection

Vigilance Day

23rd of March 2017

Isabelle De Pau

Expert Medical Application – Health Protection Service

Isabelle.depau@fanc.fgov.be

FANC AFCN

federaal agentschap voor nucleaire controle

agence fédérale de contrôle nucléaire

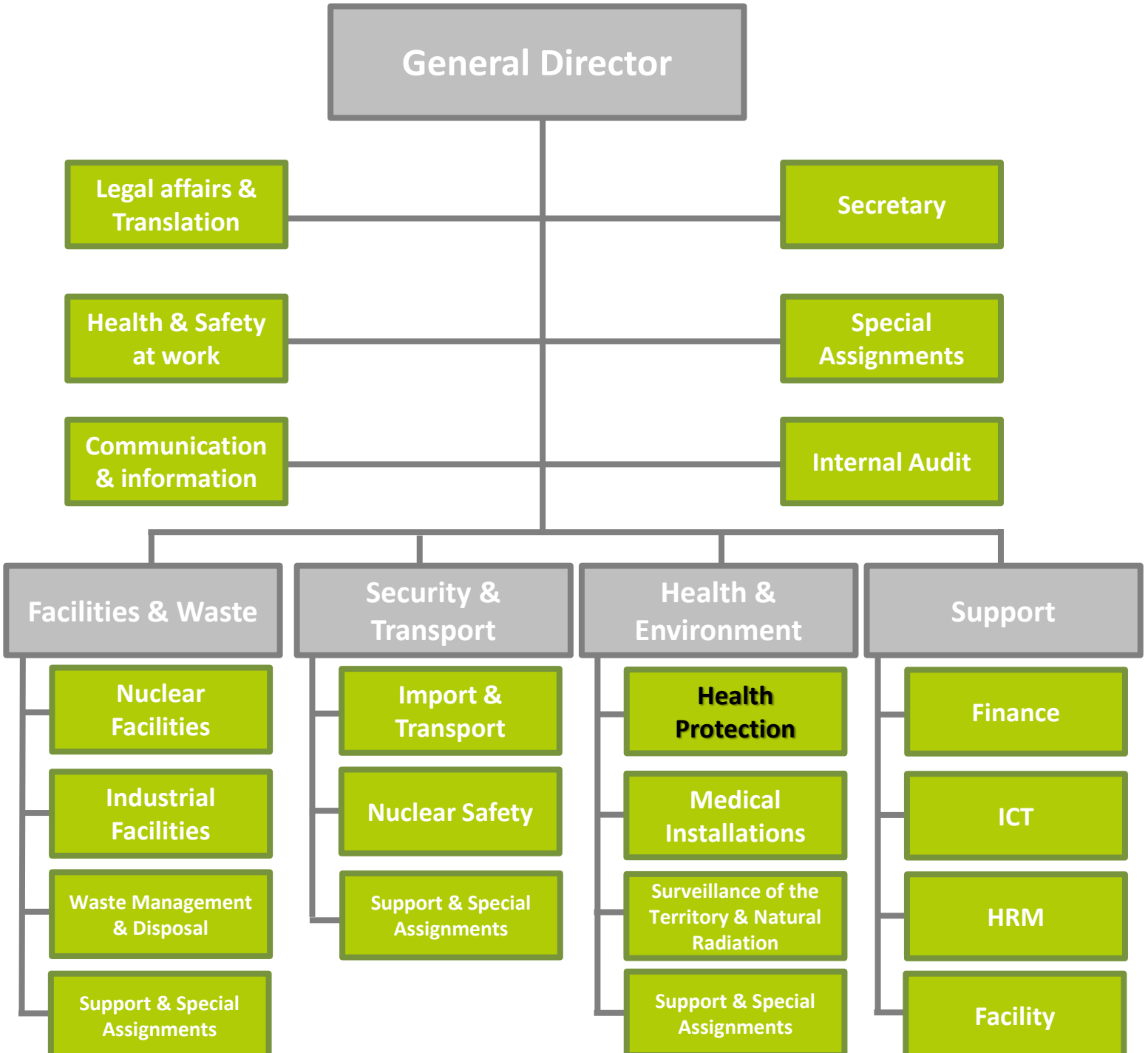
www.fanc.fgov.be

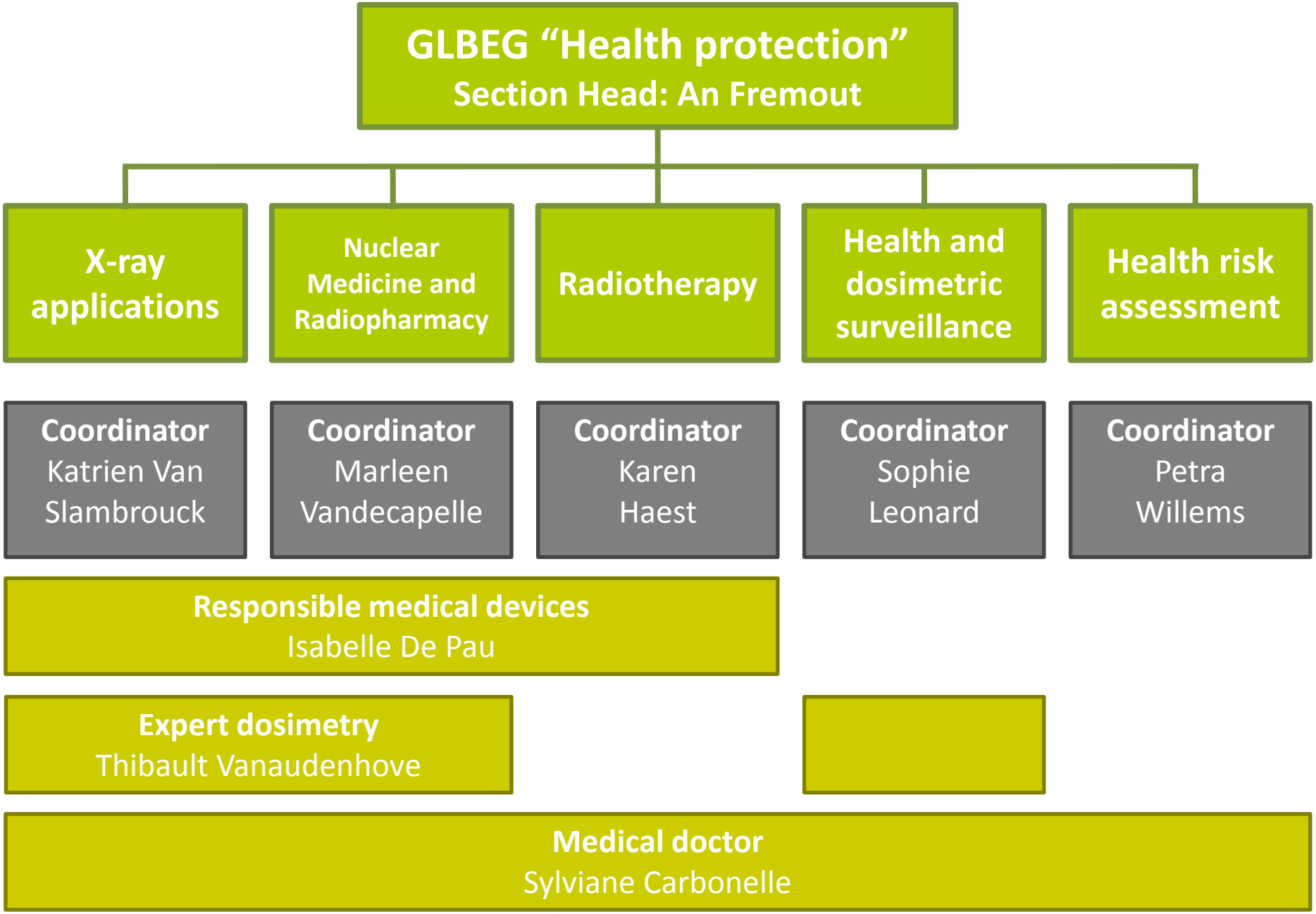
FANC / AFCN

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.**"

FANC federal agency for nuclear control


General Director
Legal affairs & Translation
Secretary
Health & Safety at work
Special Assignments
Communication & information
Internal Audit
Facilities & Waste
Security & Transport
Health & Environment
Support
Nuclear Facilities
Industrial Facilities
Waste Management & Disposal
Support & Special Assignments
Import & Transport
Nuclear Safety
Support & Special Assignments
Health Protection
Medical Installations
Surveillance of the Territory & Natural Radiation
Support & Special Assignments
Finance
ICT
HRM
Facility


GLBEG "Health protection"
Section Head: An Fremout
X-ray applications
Nuclear Medicine and Radiopharmacy
Radiotherapy
Health and dosimetric surveillance
Health risk assessment
Coordinator Katrien Van Slambrouck
Coordinator Marleen Vandecapelle
Coordinator Karen Haest
Coordinator Sophie Leonard
Coordinator Petra Willems
Responsible medical devices
Isabelle De Pau
Expert dosimetry
Thibault Vanaudenhove
Medical doctor
Sylviane Carbonelle

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

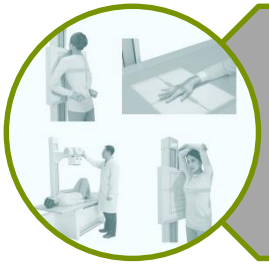
Medical Devices

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

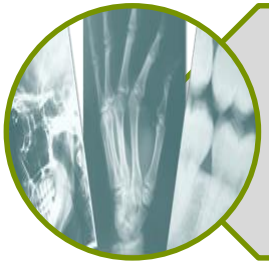


Devices or substance emitting ionising radiation or which are intended to emit ionising radiation.

(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

FANC federal agency for nuclear control

Medical Devices

+

Knowledge sharing & complementing

=

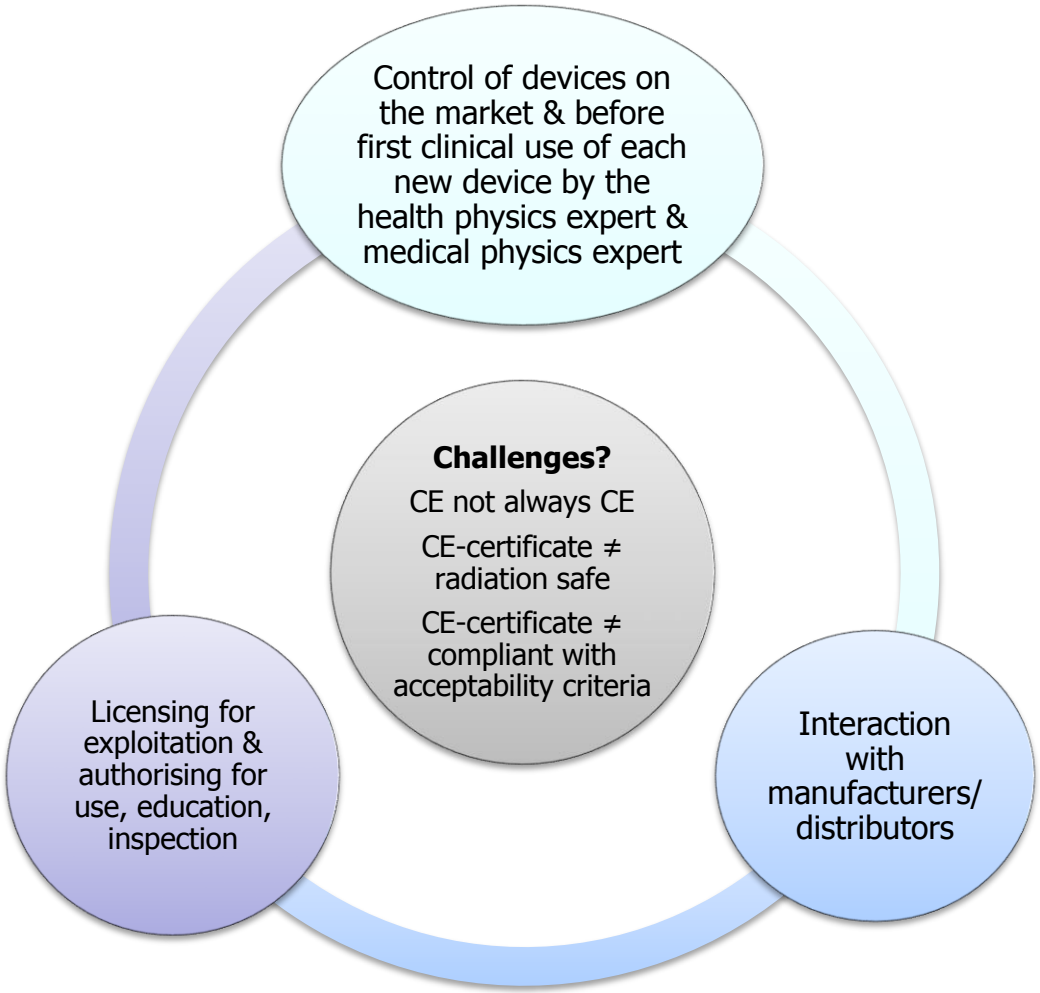
FANC
federal agency for nuclear control

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



FANC federal agency for nuclear control

Medical devices & radiation safety

No radiological risk as long as pacemaker is intact!

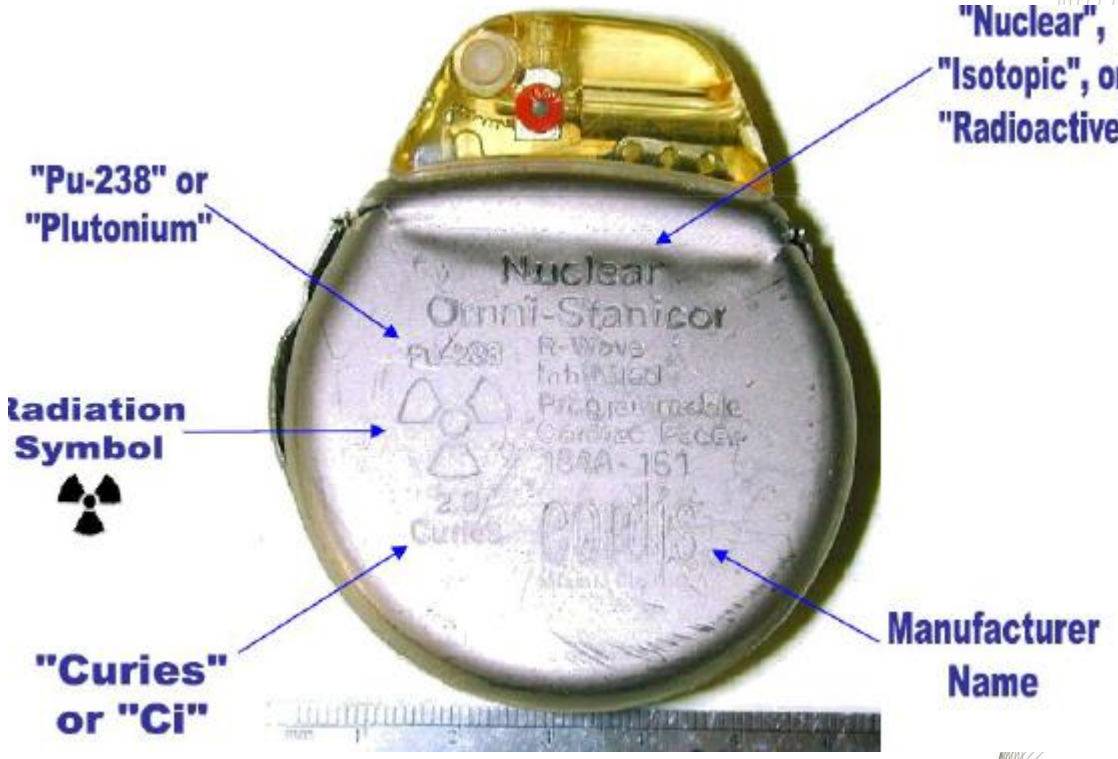
High contamination risk if Pu-238 is released!

Leaflet with more information on our website:

Dutch:
http://www.fanc.fgov.be/GED/00000000/3700/3707.pdf

French:
http://www.fanc.fgov.be/GED/00000000/3700/3708.pdf

If found in your hospital: contact your Radiation Protection Expert



FANC
federal agency for nuclear control

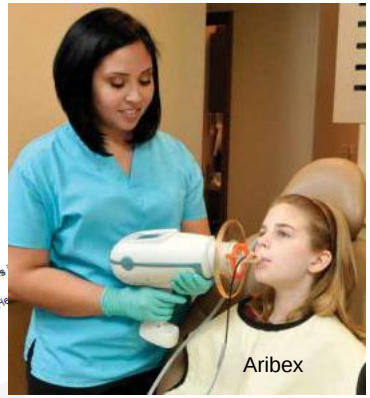
Medical devices & radiation safety

Handheld intra oral devices

Not allowed for general use:

Link Dutch: http://www.fanc.fgov.be/nl/page/1949.aspx
Link French: http://www.afcn.fgov.be/fr/page/1949.aspx

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



Waarschuwing betreffende het radiografie-toestel TIANJIE FALCON van Chinese oorsprong

Mise en garde concernant l'appareil de radiographie d'origine chinoise TIANJIE FALCON

FANC federal agency for nuclear control

Medical devices & radiation safety

Radiation leakage

Discovered by radiation protection expert during testing new dental equipment (CE marked)

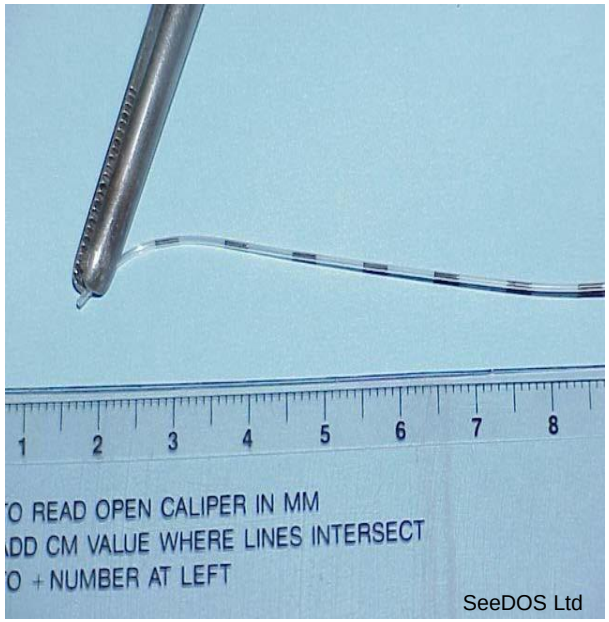
lekstraling.MOV

FANC federal agency for nuclear control

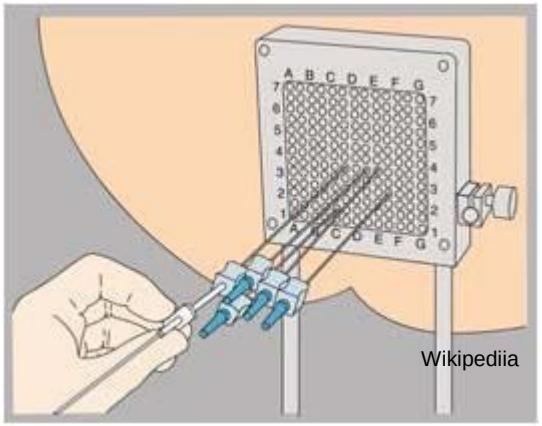
Medical devices & radiation safety

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

FANC federal agency for nuclear control

Medical devices & radiation safety

Quality problems

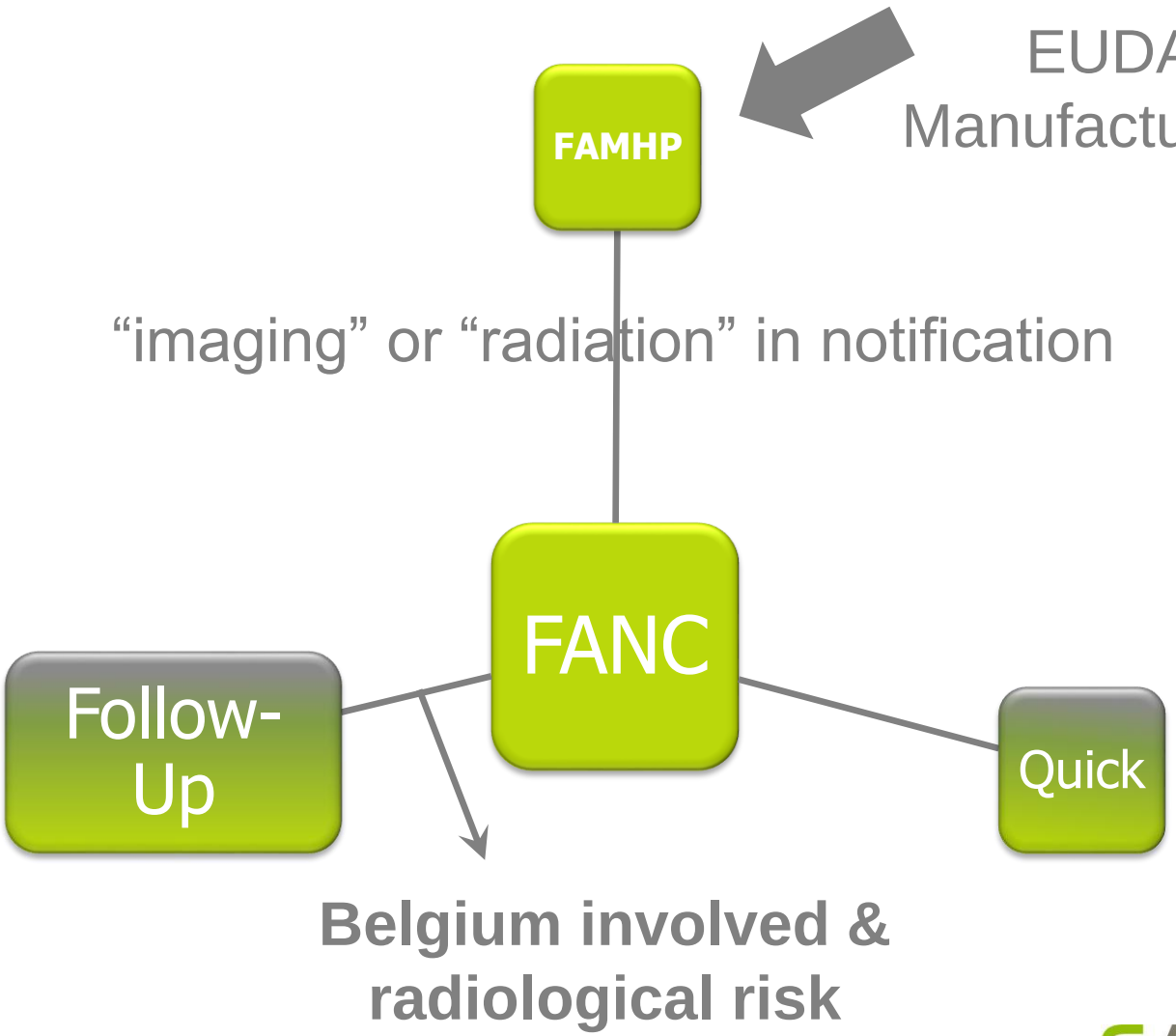
Discovered by medical physics expert during acceptance testing or routine QA

- 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

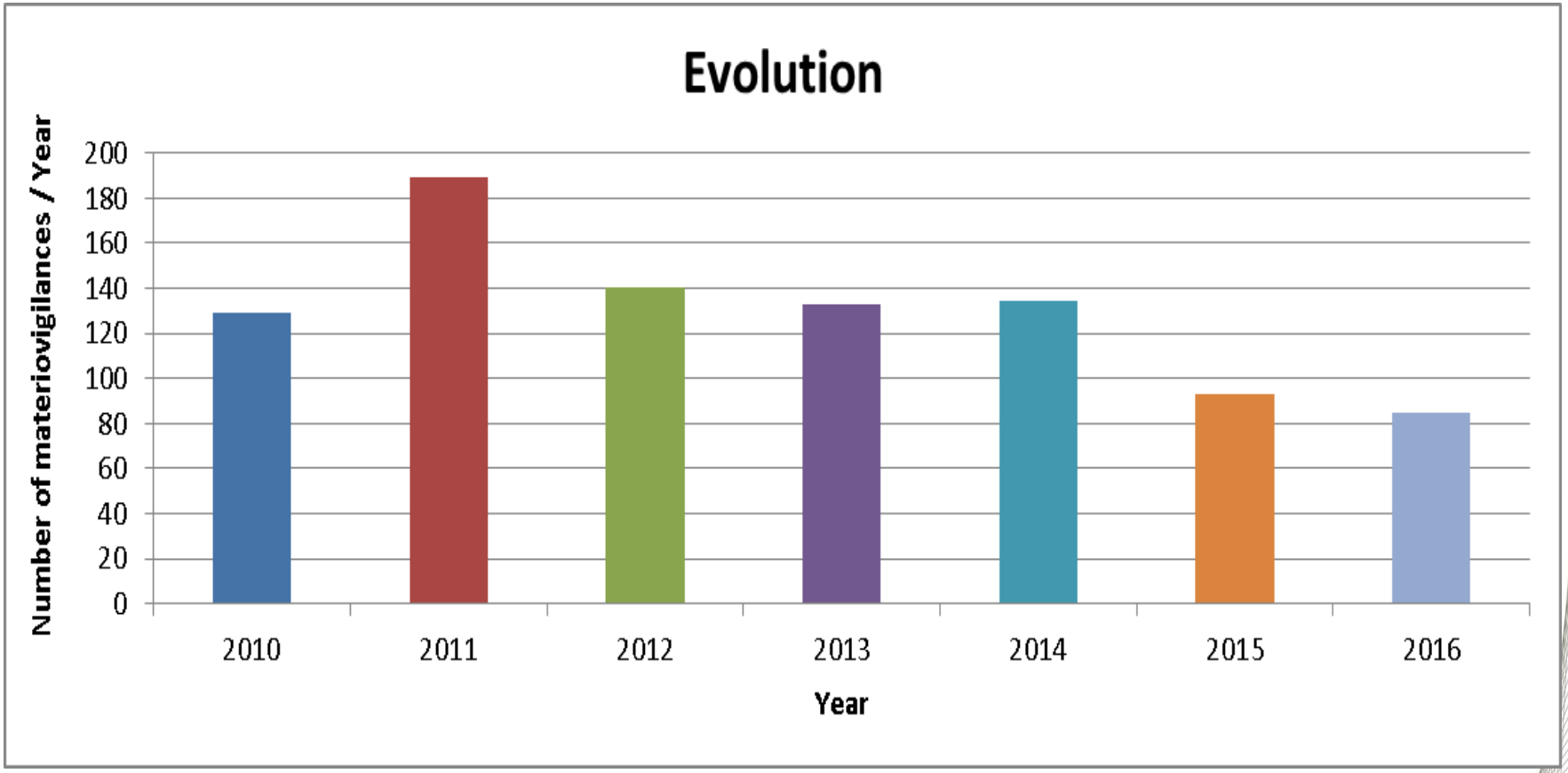
Vigilances

Practice:



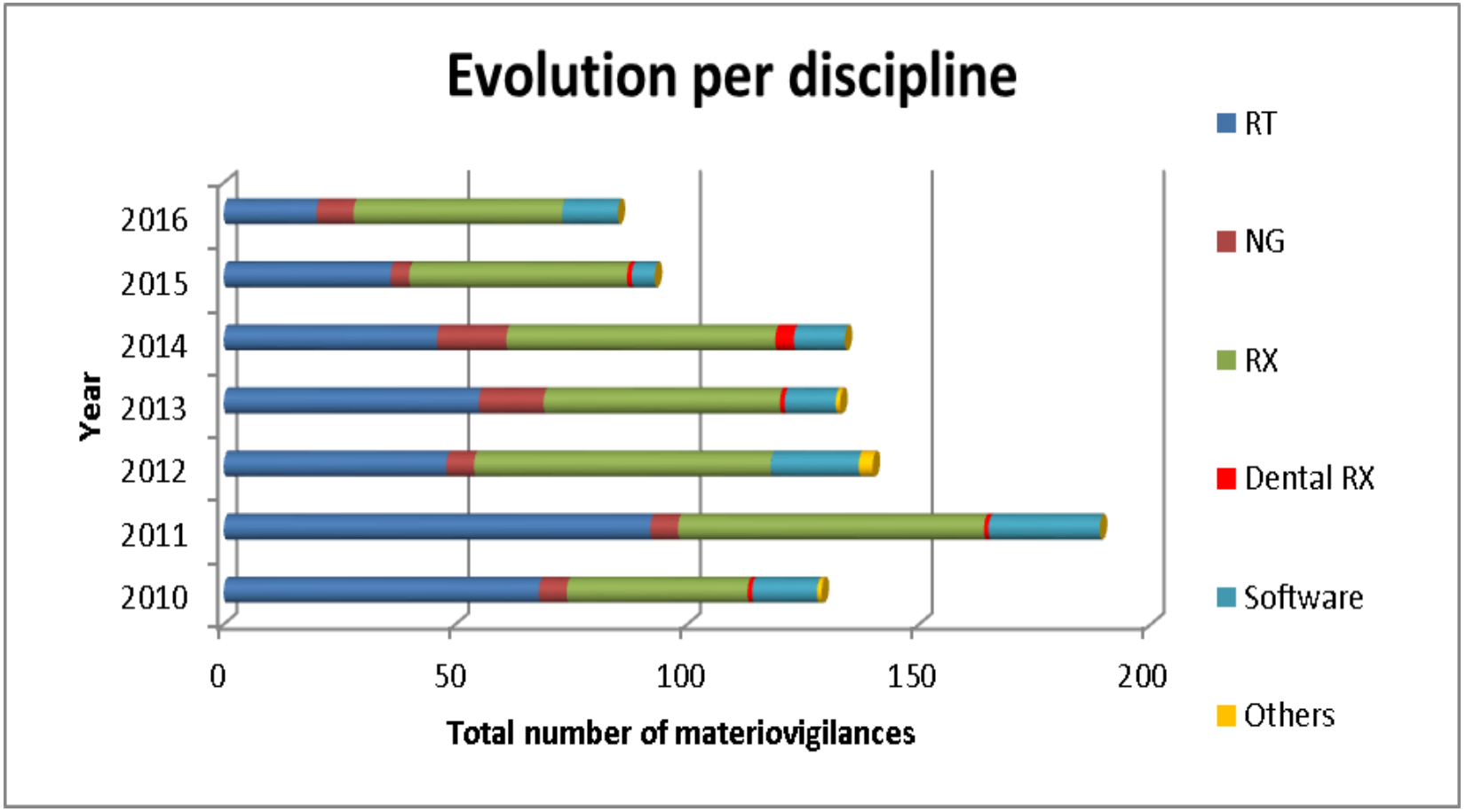
FANC federal agency for nuclear control

Vigilances



FANC federal agency for nuclear control

Vigilances



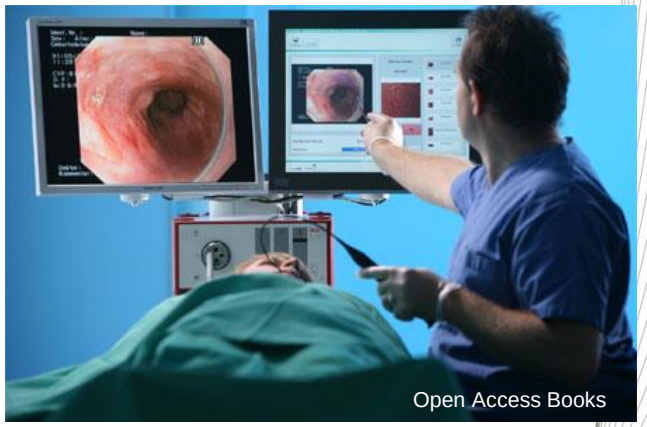
Software = PACS / RIS / stand alone software packages for imaging processing, dose management, …
Others = MRI, film, cassettes, US, swabs with radio-opaque fibre

FANC federal agency for nuclear control

Vigilances

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
- …..

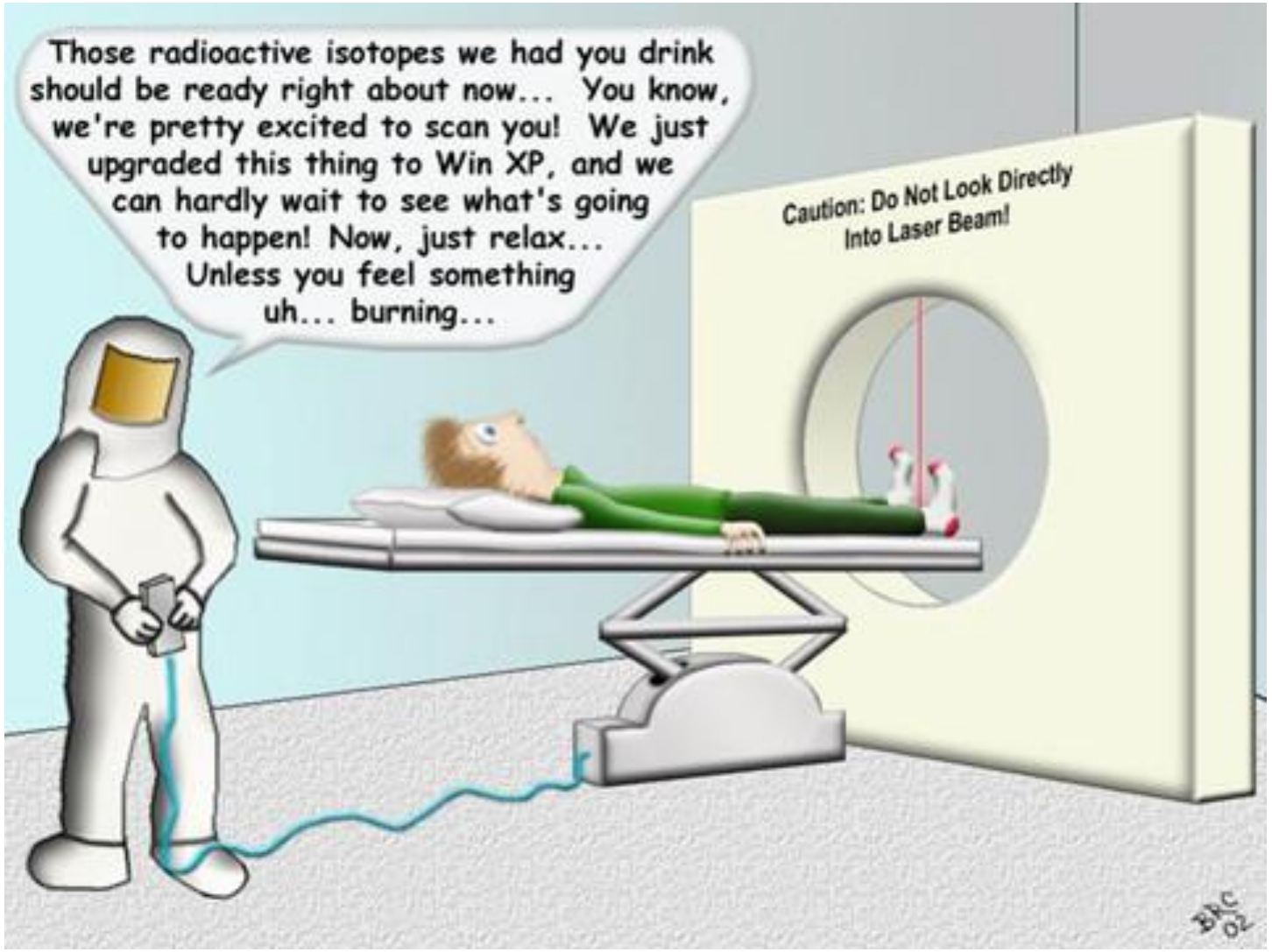
FANC approach in incidents & vigilances with radiological risk

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)

FANC federal agency for nuclear control

Vigilances



FANC federal agency for nuclear control

Vigilances

General remark:

Radiation risk underestimated by manufacturers

FANC federal agency for nuclear control

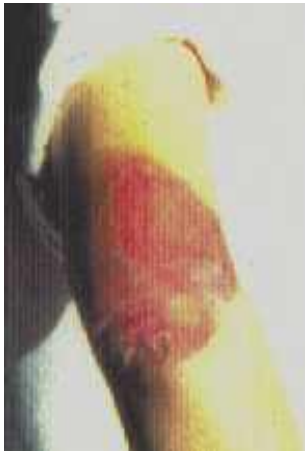
Vigilances

General remark:

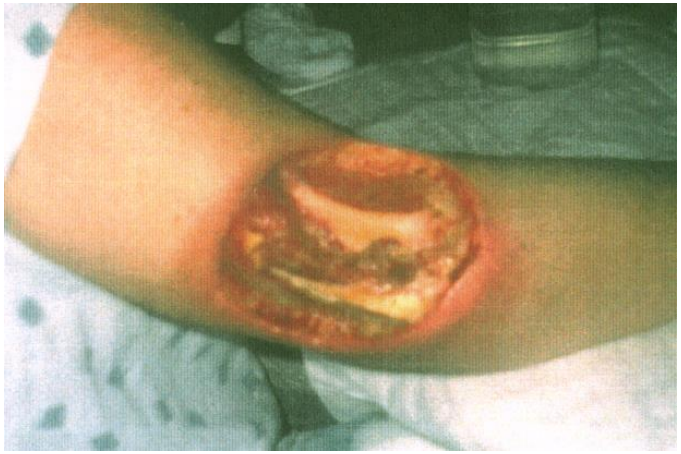
Radiation risk underestimated by manufacturers

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

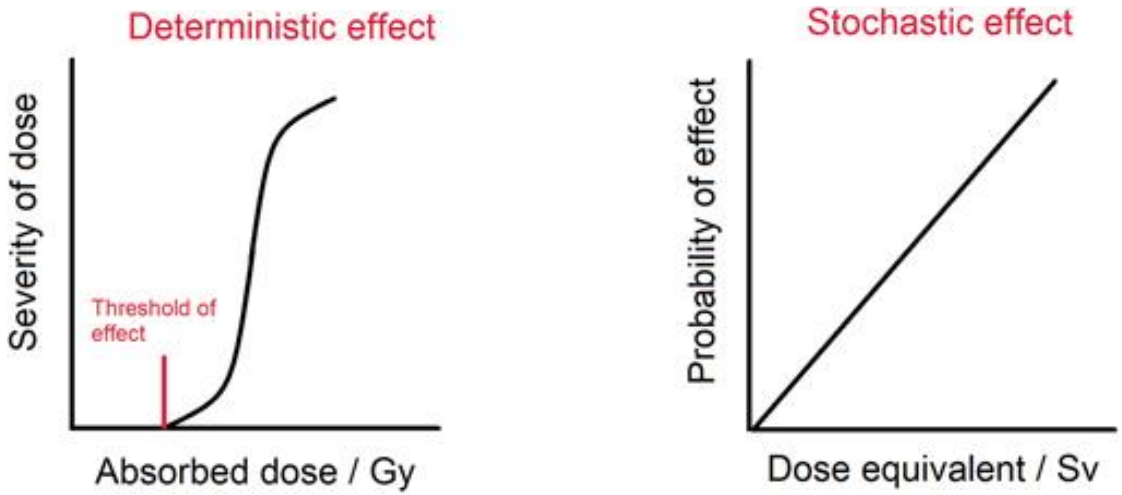
Vigilances

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, …

Vigilances

General remarks:

- 2014 U.S. FOOD & DRUG ADMINISTRATION 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 ???

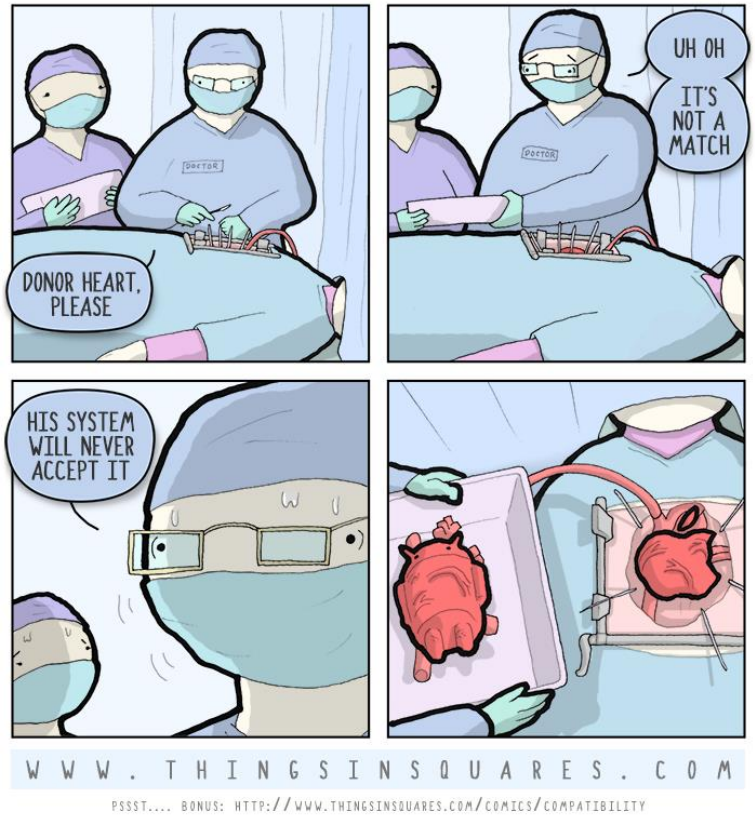
=> needs European and even international collaboration of CA's

=> need for more notification by users !!!!

Vigilances

General remarks:

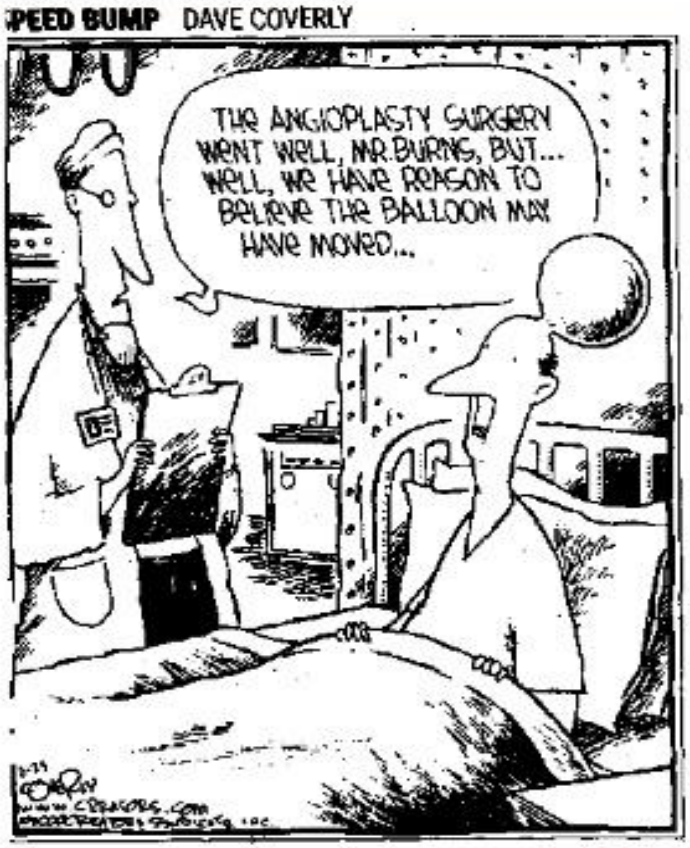
- Underreporting for dental radiological equipment
- Compatibility often a problem



FANC federal agency for nuclear control

Vigilances

Australian Government
Department of Health
Therapeutic Goods Administration



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

FANC
federal agency for nuclear control

Questions?

Isabelle.depau@fanc.fgov.be

FANC AFCN

federaal agentschap voor nucleaire controle
agence fédérale de contrôle nucléaire

www.fanc.fgov.be