



New and expected requirements in legislation

Katrien Van Slambrouck, *PhD*

katrien.vanslambrouck@fanc.fgov.be

Health and Environment – Service Health Protection

Theme coordinator medical X-ray applications

FANC AFCN

federaal agentschap voor nucleaire controle
agence fédérale de contrôle nucléaire

www.fanc.fgov.be

Overzicht

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- Conclusion

Euratom/2013/59

17.1.2014	EN	Official Journal of the European Union	L 13/1
II			
(Non-legislative acts)			
DIRECTIVES			
COUNCIL DIRECTIVE 2013/59/EURATOM			
of 5 December 2013			
laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom			

For members states of the EU:

- Obligatory to be **transposed** in national legislation before February 6th 2018
- The directive as such is not legislation

Belgian transposition

Proposal: Royal Decree on **medical exposures** by ionising radiation and exposure with non-medical imaging using medical radiological equipment

www.fanc.fgov.be > Professionelen > Regelgevende projecten

www.afcn.fgov.be > Professionnels > Projects réglementaires



The screenshot shows the FANC website interface. At the top, the FANC logo is on the left, and navigation links (JURION, Nieuws, Vacatures, Publicaties, Contact) and language options (nl | fr) are on the right. Below the logo is the tagline 'federaal agentschap voor nucleaire controle' and the slogan 'Samen beschermen'. A green navigation bar contains links to HOME, OVER ONS, INFORMATIEDOSSIER, NOODSITUATIES, and a highlighted 'PROFESSIOENEL' button. A search bar is on the right of the navigation bar. Below the navigation bar, the breadcrumb 'Home > Professionelen > Regelgevende projecten' is displayed. On the left, a sidebar lists 'Regelgevende projecten' with sub-links: 'Herziening fysische controle', 'KB diergeneeskundige toepassingen', 'Medische blootstelling', and 'Dosimetrisch toezicht van werknemers'. The main content area, titled 'Regelgevende projecten', lists six items:

1. [Regelgevend project 'herziening fysische controle'](#)
2. [Regelgevend project 'koninklijk besluit diergeneeskundige toepassingen'](#)
3. [Ontwerp van aanpassing van het reglementair kader m.b.t. de medische blootstellingen en de blootstellingen bij niet-medische beeldvorming met medisch-radiologische uitrustingen](#)
4. [Ontwerp van aanpassing van het reglementair kader m.b.t. het dosimetrisch toezicht van werknemers](#)
5. [Ontwerp van koninklijk besluit betreffende radioactieve producten voor in vitro of in vivo gebruik in de geneeskunde, in de diergeneeskunde in een klinische proef of in een klinisch onderzoek](#)
6. [Ontwerp van koninklijk besluit tot vaststelling van de bedragen van de retributies die verschuldigd zijn voor de veiligheidsmachtigingen, veiligheidsattesten en veiligheidsadviezen](#)

Belgian transposition

- Prior discussion with the stakeholders
- 06-10/2017 stakeholder consultation, with round table
- 06/2018: official advice round
- **Processing official advices**
- Publication Royal Decree Medical Applications

Belgian transposition

Different axes in the Royal Decree

- Justification
- Information
- Optimisation
- Medical radiation physics
- Quality assurance
- Education

➔ More extensive information on our website!

Subject of this presentation: X-ray applications

The text is not yet finalised.

Changes can still be made based on the advice given.

Overview

- Euratom/2013/59 directive & Belgian transposition
- **Why all those rules?**
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- Conclusion

Why all those rules?

Table 3 Standard average reference doses of common cardiological examination

	Diagnostic procedures	Effective dose (mSv)	Equivalent CXRs	Background radiation (years)	Reference
Adult	Conventional radiography				
	CXR (PA)	0.02	1	2–3 days	Mettler et al. ²⁵
	Invasive fluoroscopy				
	Diagnostic coronary angiography	7 (2–16)	350	2.9	Mettler et al. ²⁵
	PCI	15 (7–57)	750	6.3	Mettler et al. ²⁵
	Thoracic angiography (pulmonary or aorta)	5 (4–9)	250	2.1	Mettler et al. ²⁵
	Abdominal angiography or aortography	12 (4–48)	600	5.0	Mettler et al. ²⁵
	Pelvic vein embolization	60 (44–78)	3000	25.0	Mettler et al. ²⁵
	TIPS placement	70 (20–180)	3500	29.3	Mettler et al. ²⁵
	Aortic valvuloplasty	39	1950	16.2	Signorotto et al. ³³
	Dilation chronic coronary occlusion	81 (17–194)	4050	33.7	Suzuki et al. ³⁴
	ETAAAR procedure	76–119	3800–5950	31.6–49.5	Panuccio et al. ³⁵
Paediatric	Renal angioplasty	54	2700	22.5	Rehani et al. ³⁷
	Iliac angioplasty	58	2900	24.1	Rehani et al. ³⁷
	Diagnostic cardiac catheterization	6.0 (0.6–23.2)	Age-dependent	2.5	Bacher et al. ³⁶
	Closure of ASD	2.8 (1.8–7.4)	Age-dependent	1.1	Bacher et al. ³⁶
Adult	Patent ductus arteriosus occlusion	7.6 (2.1–37)	Age-dependent	3.2	Bacher et al. ³⁶
	Balloon valvuloplasty	8.1 (2.9–20)	Age-dependent	3.3	Bacher et al. ³⁶
	Cardiac electrophysiology				
	Diagnostic EP studies	3.2 (1.3–23.9)	160	1.2	Heidbuchel et al. ³⁹
Adult	Ablation procedure:	15.2 (1.6–59.6)	760	5.7	Heidbuchel et al. ³⁹
	AF	16.6 (6.6–59.2)	830	6.9	Heidbuchel et al. ³⁹
	AT-AVNRT-AVRT	4.4 (1.6–25)	220	1.8	Heidbuchel et al. ³⁹
	VT	12.5 (3 to ≥45)	625	5.2	Heidbuchel et al. ³⁹
	Regular PM or ICD implant	4 (1.4–17)	200	1.6	Heidbuchel et al. ³⁹
	CRT implant	22 (2.2–95)	1100	9.1	Heidbuchel et al. ³⁹

Why all those rules?

Table 6 Terminology that should be used

Investigation (example)	Effective dose range	Additional lifetime risk of fatal and non-fatal cancer	RCR symbolic representation	Proposed risk term
CXR	<0.1 mSv	1:1 million		Negligible
Abdominal X-ray	0.1–1 mSv	1 in 100 000 to 1 in 1 million		Minimal
Chest CT	1–10 mSv	1 in 10 000 to 1 in 1000		Very low
PCI	10–100 mSv	1 in 1000 to 1 in 100		Low

These examples relate to a healthy 50-year-old man. Multiply by 1.38 for women, by 4 for children, and by 0.5 (reduced by 50%) in an 80-year-old man. Adapted from references 18,48, and 49.

CXRs, chest X-rays; RCR, Royal College of Radiology; PCI, percutaneous coronary intervention.

 <0.1 mSv;  0.1–1 mSv;  1–10 mSv;  >10 mSv.

Why all those rules?

Skin injury in a patient with chronic total occlusion (CTO).
Patient underwent repeated percutaneous coronary interventions three times in recent 2 years but 5 times in past 12 years

SKIN INJURIES IN INTERVENTIONAL PROCEDURES



Figure 1. Skin injury in a patient with chronic total occlusion. a) 2 mths, b) 6 mths, c) 8 mths after last PCI, and d) after the flap surgery.

Overview

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - **Information towards the patient**
 - Procedures in interventional settings
 - Medische radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- Conclusion

Information towards the patient

17 Dutch patient brochures PCI (< Belgium)

- Sample in April 2019

3 questions

- Does the brochure mention the use of X-rays?
- Does the brochures mention a risk of cancer due to the use of X-rays?
- Does the brochures mention a risk of skin effects due to the use of X-rays?

Information towards the patient

Outcomes

- Does the brochure mention the use of X-rays?
YES: 10/17 NO: 7/17
- Does the brochures mention a risk of cancer due to the use of X-rays?
YES: 0/17 NO: 17/17
- Does the brochures mention a risk of skin effects due to the use of X-rays?
YES: 0/17 NO: 17/17

Information towards the patient

Communication with your patient

Prior to exposure, the referrer person and practitioner, each at their level, ensure that the patient is provided with adequate information about the benefits and risks associated with medical exposure, in a way that is understandable to him

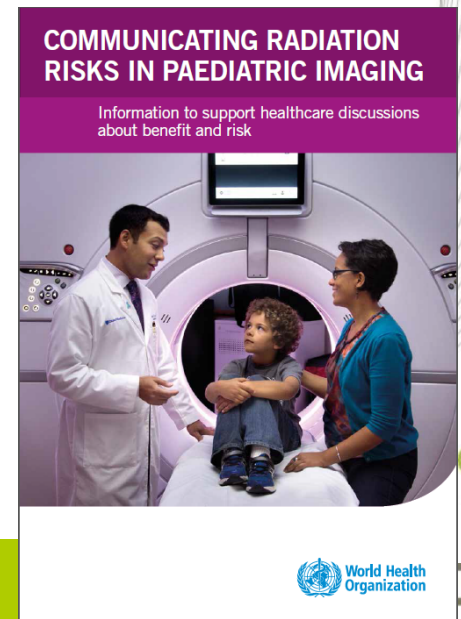
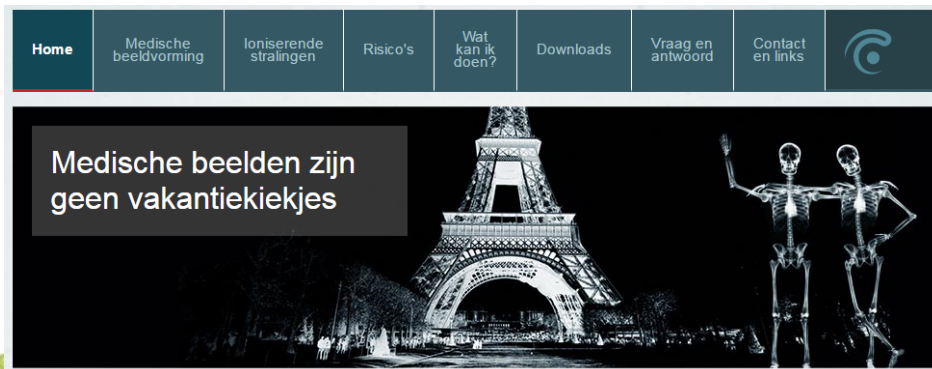
In addition, written for

- Interventional procedures
- In case of children:
 - CT
 - Nuclear medicine
- Radiotherapy

Information towards the patient

Inform you patient: how do you start?

- Introduce the necessary steps in your working procedures
- Provide adequate training for staff on
 - the working procedures
 - radiation protection
 - how to inform patients and how to respond to questions
- Provide the necessary supporting material



Information towards the patient

Inform you patient: how do you start?

Toolkit

**OLV-ziekenhuis Aalst-Asse-Ninove
with
FANC & BVR**

Overview

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - **Procedures in interventional settings**
 - Medical radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- Conclusion

Procedures in interventional settings

Under the medical responsibility of the practitioner there exist for every medical radiological practice:

- A written clinical procedure [...]
- For interventional radiology: a written procedure to **prevent or minimise skin effects** and to identify persons at risk, including **aftercare** procedures, following a graded approach related to the estimated risk
- [...]

Procedures in interventional settings

Interventional applications: skin effects

Effect	Approximate threshold dose (Gy)	Time of onset
Skin		
Early transient erythema	2	2–24 h
Main erythema reaction	6	~ 1.5 weeks
Temporary epilation	3	~ 3 weeks
Permanent epilation	7	~ 3 weeks
Dry desquamation	14	~ 4 weeks
Moist desquamation	18	~ 4 weeks
Secondary ulceration	24	>6 weeks
Late erythema	15	8–10 weeks
Ischemic dermal necrosis	18	>10 weeks
Dermal atrophy (1st phase)	10	>52 weeks
Telangiectasis	10	>52 weeks
Dermal necrosis (delayed)	>12	>52 weeks
Skin cancer	Unknown	>15 years



Procedures in interventional settings

Interventional applications: identify patients and examinations at risk

- Type of examination / procedure

Identify in advance procedures with low and high risks based on the complexity (typically high fluoroscopy time) and region of the body.
Procedures with typically high skin doses: neuro-embolisation, pelvic and abdominal embolization and EVAR

- Pathology of the patient

Identify complex situations with potentially long fluoroscopy time – look at your patient's history.

Repeated procedures increase the risk!

- Physical characteristics of the patient

Higher risk: high BMI and older patients

Procedures in interventional settings

Interventional applications: optimise the procedures

- The equipment used

Newer equipment has typically dose reductions features: pulsed fluoroscopy, last image hold, virtual collimation, ...

- The usage of the equipment

Use the available options!

Optimise the exposure: patient-detector distance, patient-source distance, avoid magnifications, avoid oblique angles, ...

- ***Optimize together with your recognised expert medical radiation physics***
- ***Ensure adequate training of the staff***

Procedures in interventional settings

Interventional applications: optimise the procedures

<https://www.iaea.org/sites/default/files/documents/rpop/poster-patient-radiation-protection.pdf>

10 Pearls: Radiation protection of *patients* in fluoroscopy

- Maximize distance between the X ray tube and the patient to the extent possible**
Diagram showing X-ray tube at distance $d/8$ from patient, and image receptor at distance d . Intensity units: 64 units at $d/8$, 16 units at $d/4$, 4 units at $d/2$, 1 unit at d .
- Minimize distance between the patient and the image receptor**
Diagram showing patient at distance $d/4$ from image receptor, and image receptor at distance d . Intensity units: 4 units at $d/4$, 1 unit at d .
- Minimize fluoroscopy time**
Keep records of fluoroscopy time and DAP/KAP (if available) for every patient.
- Use pulsed fluoroscopy with the lowest frame rate possible to obtain images of acceptable quality**
Diagram showing X-ray pulses at 15 pulses per second (1 second) and 30 pulses per second (1 second).
- Avoid exposing the same area of the skin in different projections**
Vary the beam entrance port by rotating the tube around the patient. Diagram shows 'Hot spot' and 'Non-optimized technique' vs 'Optimized technique'. Figure adapted from L. K. Wagner.

IAEA RPOP *Related Poster!* 10 pearls! Radiation protection of *staff* in fluoroscopy <http://www.iaea.org/sites/default/files/documents/rpop/poster-staff-radiation-protection.pdf> <http://rpops.iaea.org> Page 1 of 2 Fluoroscopy Patient Radiation Protection

10 Pearls: Radiation protection of *patients* in fluoroscopy

- Larger patients or thicker body parts trigger an increase in entrance surface dose (ESD)**
Diagram showing ESD increasing with patient thickness: 15 cm (1 unit), 20 cm (2-3 units), 25 cm (4-6 units), 30 cm (8-12 units).
- Oblique projections also increase ESD**
Be aware that increased ESD increases the probability of skin injury. Diagram shows $h_1 < h_2 < h_3$.
- Avoid the use of magnification**
Decreasing the field of view by a factor of two increases dose rate by a factor of four. Table below:
- Minimize number of frames and cine runs to clinically acceptable level**
Avoid using the acquisition mode for fluoroscopy. Documentation should be performed with last image hold whenever possible and not with cine images. Cine dose rate = (10-60) × normal fluoroscopy dose rate.
- Use collimation**
Collimate the X ray beam to the area of interest. Diagram shows collimated beam.

INTENSIFIER Field-of-view (FOV)	RELATIVE PATIENT ENTRANCE DOSE RATE FOR SAME UNITS
12" (32 cm)	100
9" (22 cm)	177
6" (16 cm)	400
4.5" (11 cm)	711

IAEA RPOP *Related Poster!* 10 pearls! Radiation protection of *staff* in fluoroscopy <http://www.iaea.org/sites/default/files/documents/rpop/poster-staff-radiation-protection.pdf> <http://rpops.iaea.org> Page 2 of 2 Fluoroscopy Patient Radiation Protection

Procedures in interventional settings

Interventional applications: trigger levels

Table 2 Substantial radiation dose levels which should trigger follow-up of patients in order to detect clinically relevant skin reactions. Adapted from NCRP report Nr 168 (2010)

Peak skin dose	3 Gy
Cumulative air KERMA at RP	5 Gy
Kerma area product	500 Gy cm ²
Fluoroscopy time	60 min ^a

NCRP National Council on Radiation Protection and Measurements, Bethesda, USA

^a Institutions performing procedures with potentially high dose levels shall measure and record dose metrics, and shall not rely on fluoroscopy time alone

Procedures in interventional settings

TRIGGER NIVEAUS		DAP (Dose-area product)	
		cGy.cm ² μGy.m ²	mGy.cm ²
TIPS & chemo embolisatie van de lever (TIPS : intrahepatische shunt via de vena transjugulaire)		33.000	330.000
Cerebrale embolisaties	monoplane	17.500	175.000
	biplane	24.000	240.000
RF ablatie		18.000	180.000
Biliaire drainage	conventioneel	16.000	160.000
	PTC	18.000	180.000
Embolisatie vena spermatica		27.000	270.000
ERCP (endoscopische retrograde cholangio-pancreatografie)		29.500	295.000
CA & PTCA (coronaire angiografie & coronaire transluminale percutane)		12.500	125.000

Procedures in interventional settings

Interventional applications: aftercare

Skin dose	Action
0-2 Gy	No specific actions. No visible effects expected.
2-5 Gy	Inform patient that transient erythema and transient hair loss may be observed. This should fade away in time.
5-10 Gy	Ask patient to follow-up the body zones at risk from 2 tot 10 weeks after the procedure. Ask to take contact if skin effects are observed. Typical effects: erythema and itching.
10-15 Gy	Active medical follow-up. Skin effects may be prolonged, pain and necrosis may occur
>15 Gy	Active medical follow-up by a specialised dermatologist. Radiation-induced wound may progress to ulceration and necrosis

- When peak skin dose > 2 Gy: inform family doctor and referrer
- Provide contact point for questions from patients and referring physicians

Procedures in interventional settings

Interventional applications: aftercare

The risk of skin injuries is small but often disregarded (estimated 1 in 10 000, large error margin)



- Patients with mild effects should be reassured
- Patients with serious skin injuries should receive an adequate treatment
→ different treatment when injuries are caused due to ionising radiation

Overview

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - **Medical radiation physics**
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- Conclusion

Medical radiation physics

Department of Medical Radiation Physics

*This department is responsible for the **organisation of the medical radiation physics** in the establishment, including identification of resources needed to fulfil the regulatory requirements set by the kind and the objectives of the establishment in the field of medical radiation physics*

Exemptions:

Class III establishments, unless they have a computer tomography or interventional radiology device

FANC law, already published

Medical radiation physics

Department of Medical Radiation Physics - head

Task

- Performing the assignments of the department
- Specific tasks:
 - Responsible that all equipment is commissioned before first usage
 - Informing the “exploitant” when equipment does not fulfil the regulatory requirement or cannot be used safely
 - Involvement of the different recognised experts, especially in case of hybrid equipment
 - Regular consultations with heads of the medical departments

Medical radiation physics

Department of Medical Radiation Physics - head

Who?

- Recognised medical physics expert, employee of the hospital
- ?

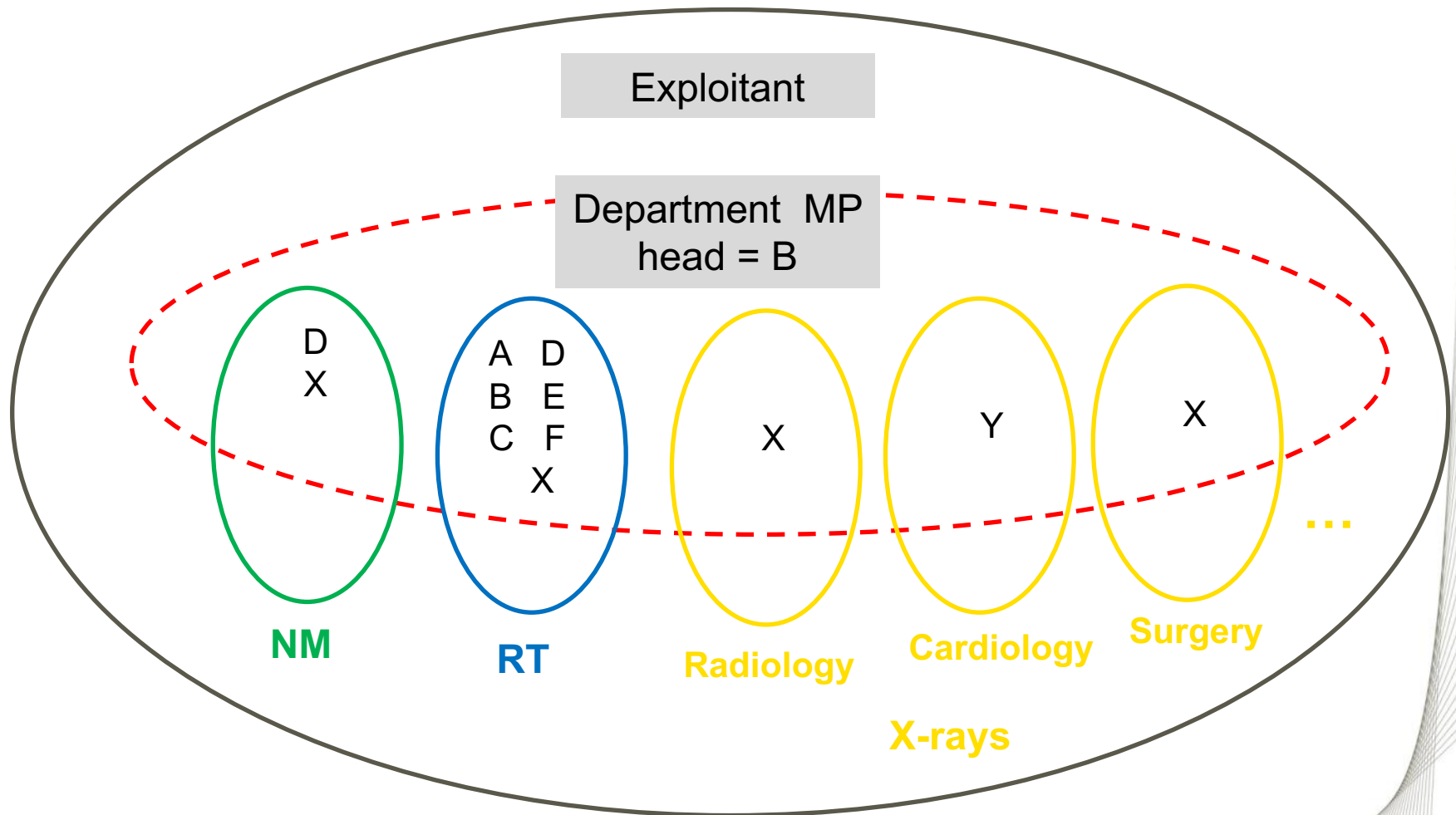
Possibility for common departments between hospitals with a common head (MPE)

Medical radiation physics

Department of Medical Radiation Physics - head

- Internal expert(s) MP
 - obligatory for radiotherapy
 - possibility for nuclear medicine
 - possibility for radiology (all X-ray applications)
- External expert(s) MP
 - possibility for nuclear medicine
 - possibility for radiology (all X-ray applications)

Medical radiation physics



Medical radiation physics

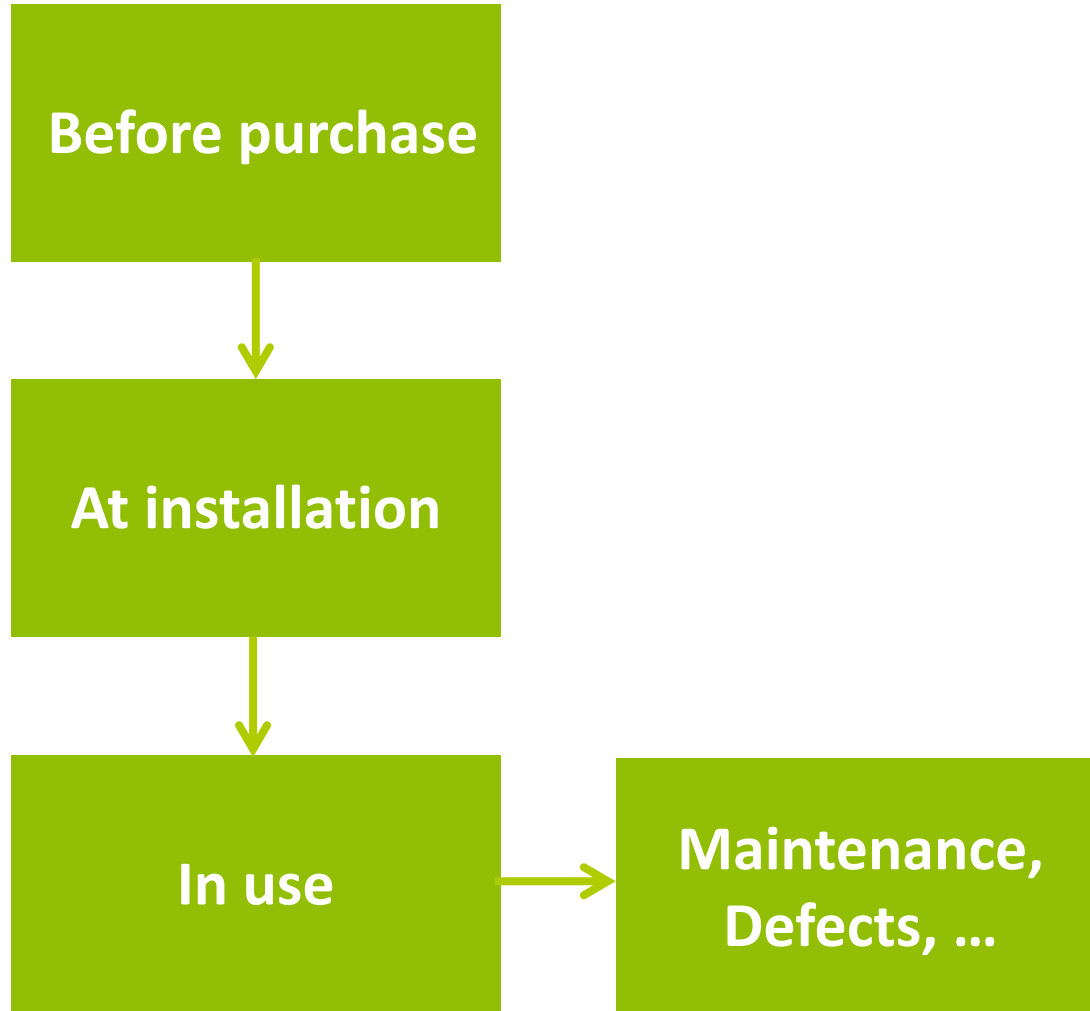
Department of Medical Radiation Physics – task for the experts

General

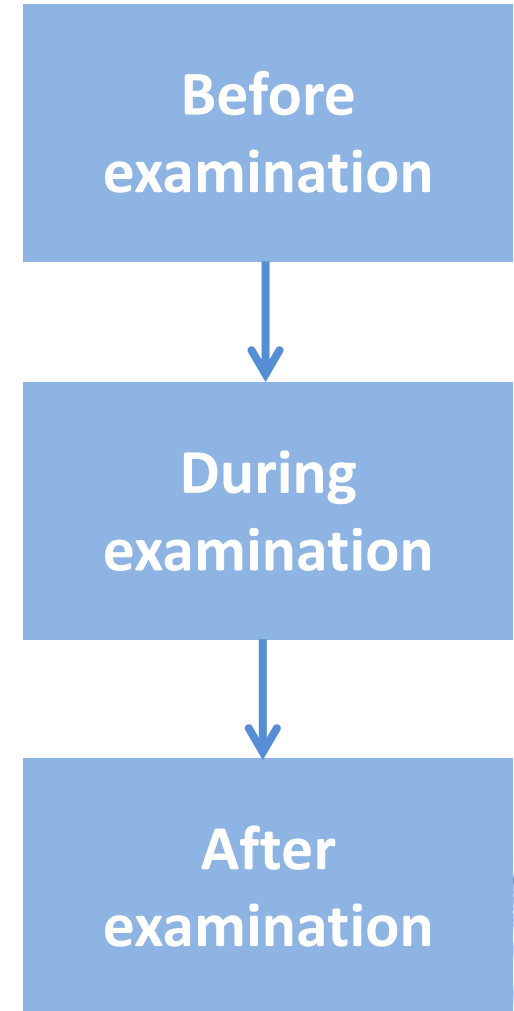
The recognised expert MP contributes to the optimisation of the radiation protection of person undergoing a medical exposure

Medical radiation physics

Equipment



Patient



Medical radiation physics

Subsection 8 – Tasks medical radiation physicist for radiological applications

More than quality control !

- Quality of their own equipment (art. 50)
- Technical specificities before purchasing (art 51.)
- Commissioning and permission for clinical use (art. 51)
- Training staff new equipment (art. 51)
- Role in preventive and corrective maintenance plan (art. 52)
- Quality control (art. 52)
- Patient dosimetry (art. 53)
- Validation doses studies (art. 53)
- Assistance accidental and unintended exposures (art. 54)

Medical radiation physics

In departments where CT or interventional applications are used

- Obligatory documentation of two optimisation projects
- Obligatory involvement of the MPE
- Elements:
 - Collection and analysis of data
 - Identification of optimisation possibilities
 - Implementation of actions for optimisation

© MARK ANDERSON

WWW.ANDERSTOONS.COM



"It's a very nice bird, but it makes it difficult to see what's wrong."

Overview

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - **Accidental and unintended exposures**
 - Clinical audits
- What about the staff?
- Conclusion

Accidental and unintended exposures

Accidental exposure (general)

= exposure in the event of an accident (ARBIS/RGPRI)

Unintended exposure (medical)

Medical exposures that differs significantly from the medical exposure intended for a given purpose

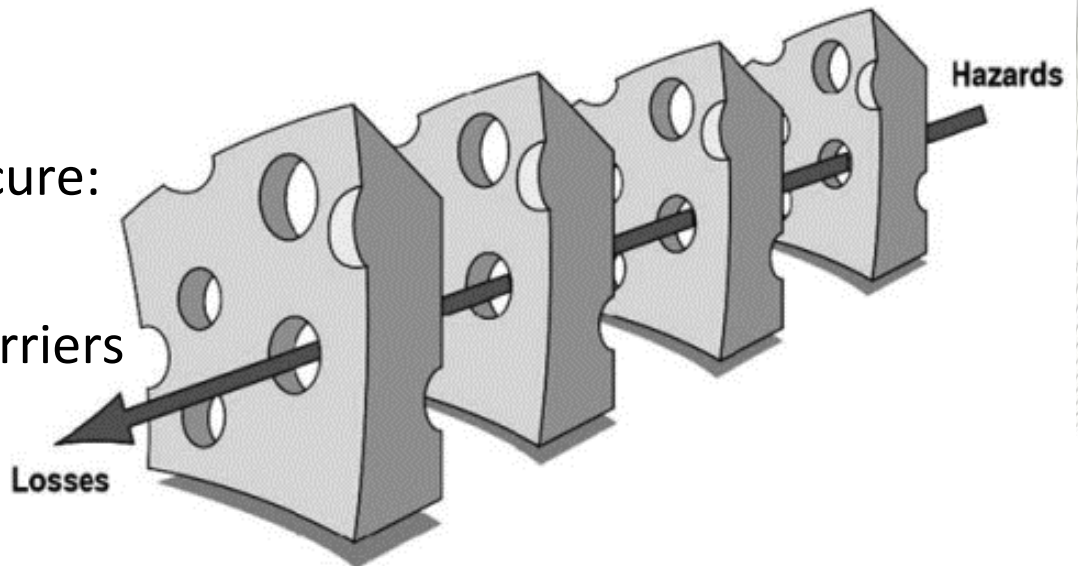
Accidental and unintended exposures

Proactive

All reasonable measure need to be taken to minimise the probability and the magnitude of accidental or unintended exposures of individuals subject to medial exposure

Prevention is better than cure:

- identify the risk
- install the necessary barriers

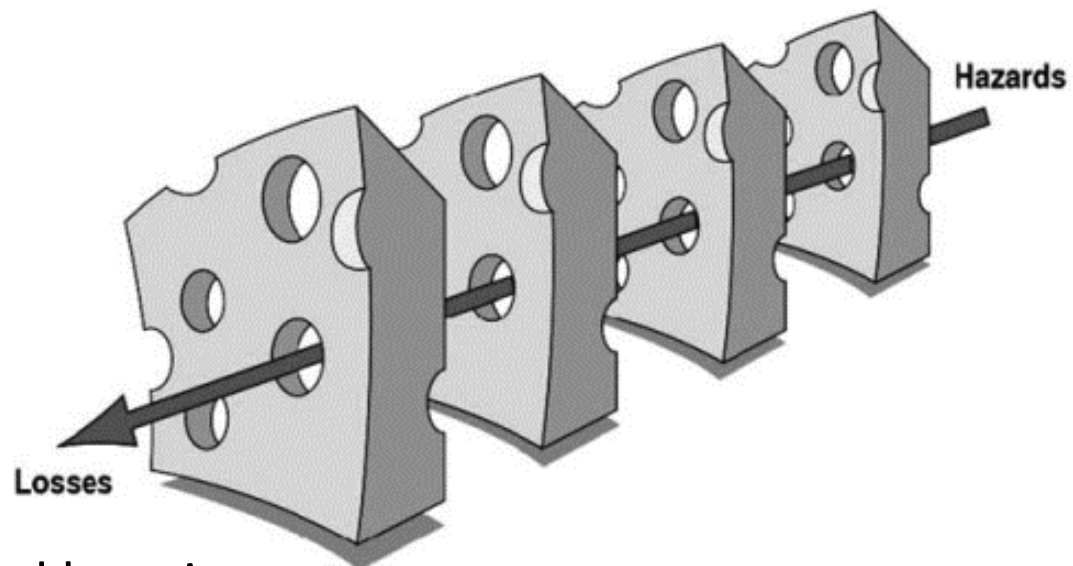


Accidental and unintended exposures

Reactive

Which barrier has failed?

How can we improve the preventive measures?



Requirements

- Internal reporting and learning system
- Significant? Notification to patient and FANC

Accidental and unintended exposures

Internal reporting and learning system

Nobody is perfect, no device is perfect

BUT... Learn from (your) mistakes and avoid new mistakes!

→ Incident notification systems = more than registration software

1. Notification and registration
2. Reporting and analysis
3. Solution development
4. Implementation
5. Audit & monitoring
6. Feedback



System:

- User friendly
- Accessible
- Non-punitive

Accidental and unintended exposures

Internal reporting and learning system

FANC will provide:

- For hospitals: an extension of the existing notification systems
- For other centres: basic notification system

Accidental and unintended exposures

Obligatory notifications

For every clinical significant accidental or unintended exposures the practitioner informs:

- Patient
- Referring physician

about

- The event
- The results of the analysis
- (where applicable) the clinical follow-up

Clinical significant = clinical implications for the patient → evaluation performed by the practitioner

Accidental and unintended exposures

Obligatory notification to FANC

Already in force

All notifications regarding medical exposures are the responsibility of the practitioner*.

One obligatory notification for X-ray applications

Accidental exposure of unborn child $> 1\text{mSv}$
caused by a medical exposure of the mother
(= pregnancy unknown for the medical team)

*other obligatory notification exist for the “exploitant” (e.g. exceedance dose limit for staff))

Accidental and unintended exposures

Voluntary notifications to FANC

Already in force

Incidents

- with possible interest for colleagues
- where extra guidance is desired

Examples:

- Exceedance of threshold doses for the skin with risk of serious skin injuries
- Defects
- Wrong patient
- Wrong body part
- Wrong parameters
- Unexpected high dose

Accidental and unintended exposures

What is the aim?

Already in force

- Prevention and exchange of experiences
- No sanctioning
- Suggestions for further treatment
- Identifying 'lessons learned'

Information from notified incident will only be used completely anonymised.

Accidental and unintended exposures

How notify? event@fanc.fgov.be

Already in force



JURION

Pers

Vacatures

Publicaties

Contact

nl | fr

Samen beschermen



HOME

OVER ONS

INFORMATIEDOSSIER

NOODSITUATIES

PROFESSIOELEN ▶



[Home](#) > [Professionelen](#) > [Medische professionelen](#) > [Radiologische toepassingen](#) >

Melding van een (significante) gebeurtenis onder de verantwoordelijkheid van de practicus

Medische professionelen >

Radiologische
toepassingen >

Gebruikers van
radiologische
toepassingen >

Beroepshalve
blootgestelde
personen >

Melding van een
(significante)
gebeurtenis >

Melding van een (significante) gebeurtenis onder de verantwoordelijkheid van de practicus

Sedert de publicatie van het [Technisch reglement van het FANC betreffende de aangifte aan het FANC van significante gebeurtenissen](#) bestaat er een aangifteplicht voor significante gebeurtenissen wanneer zij beantwoorden aan een aantal criteria.

Een significante gebeurtenis wordt gedefinieerd als: "elke gebeurtenis (met inbegrip van een menselijke fout, een bijna-ongeval, een ongeval, een niet toegestane handeling,...) die gevolgen, zelfs potentiële gevolgen heeft op de veiligheid, stralingsbescherming, gezondheid en/of levenskwaliteit van een patiënt en het milieu."

Verplichte melding

Medische blootstellingen vallen onder verantwoordelijkheid van de practicus, zo ook het melden van een accidentele of onbedoelde blootstelling die in dat kader plaatsvindt. Voor medische blootstellingen via

Accidental and unintended exposures

How to notify? event@fanc.fgov.be

Already in force



agence fédérale de contrôle nucléaire



JURION

Presse

Emplois

Publications

Contact

nl | fr

Ensemble pour vous protéger



ACCUEIL

L'AFCN

DOSSIERS
D'INFORMATION

SITUATIONS
D'URGENCE

PROFESSIONNELS ▶



[Home](#) > [Professionnels](#) > [Professions médicales](#) > [Applications radiologiques](#) >

Déclaration d'événements (significatifs) sous la responsabilité du praticien

Professions médicales >

Applications
radiologiques >

Utilisateurs des
applications
radiologiques >

Personnes
professionnellement
exposées >

Déclaration
d'événements
(significatifs) >

Déclaration d'événements (significatifs) sous la responsabilité du praticien

Depuis la publication du [Règlement technique de l'AFCN relatif à la déclaration d'événements significatifs à l'AFCN](#), les événements significatifs doivent être déclarés dès qu'ils répondent à une série de critères.

Ce règlement définit un événement significatif comme « *tout événement (y compris une erreur humaine, un presque-accident, un accident, une manipulation non autorisée,...) qui a des conséquences ou qui s'il n'avait pas été maîtrisé, aurait pu avoir des conséquences au niveau de la radioprotection, la santé, la qualité de vie et/ou la sûreté des travailleurs, le public, les patients et l'environnement* ».

Déclaration obligatoire

Les expositions médicales relèvent de la responsabilité du praticien, tout comme la déclaration de toute



Accidental and unintended exposures

Information on pregnancy and ionising radiation

www.fanc.fgov.be/zwangerschap

www.afcn.be/grossesse

Brochures, posters, movie

Publications

- Brochure "Évitez les rayons pendant la grossesse"
- Affiche "Évitez les rayons pendant la grossesse"

En savoir plus :

- Exposition aux rayonnements ionisants pendant la grossesse : quels risques ? que pouvez-vous faire ?
- Pour les médecins et le personnel médical : consultez le dossier "Exposition médicale de patientes enceintes"



Overview

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - Accidental and unintended exposures
 - **Clinical audits**
- What about the staff?
- Conclusion

Clinical audits

*“A **systematic analysis** of medical-radiological procedures with the aim of **improving quality** and the results of patient care through a structured evaluation in which medical-radiological practices procedures and results are tested against **agreed standards** for good medical-radiological procedures, after which the procedures are **adapted** and whereupon new standard can be applies.*



***Are we doing the right things?**
Are we doing the things right?
Do we follow good practices?*

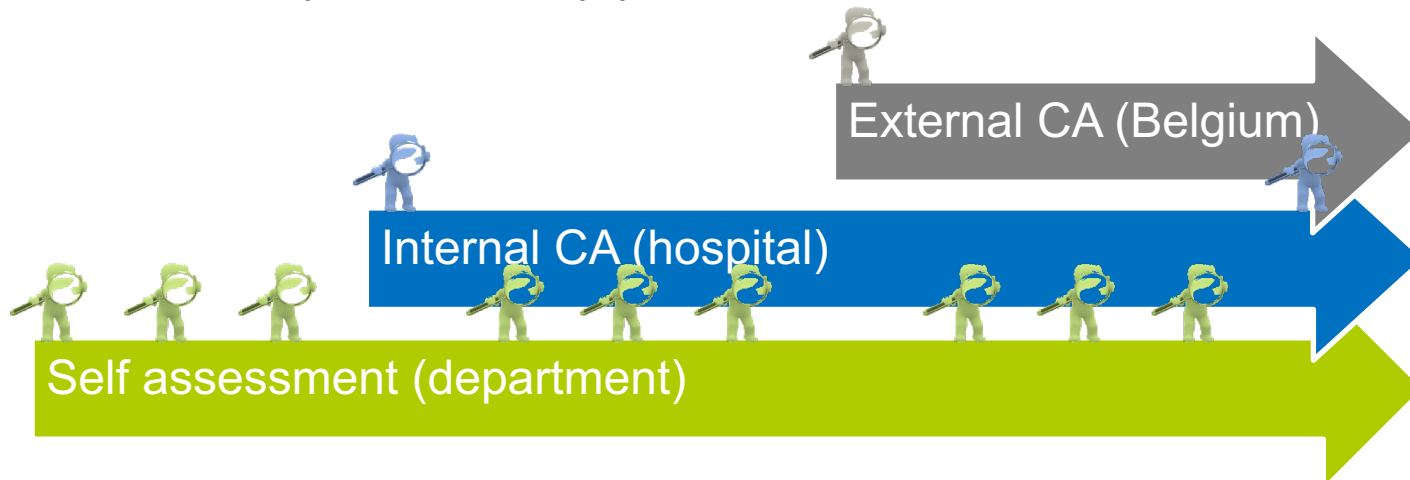


Clinical audits

	Inspection	Audit
Base	Legislation	Standards Good practices
Results	Requirements Enforcement	Recommendations Suggestive
Organisation	Competent authorities with legal mandate	Peer review system
Teams	Inspectors	Professionals from the sector

Clinical audits

- **What?** 3 complementary phases



!!!VERBETERPUNTEN => VERBETERACTIES!!!

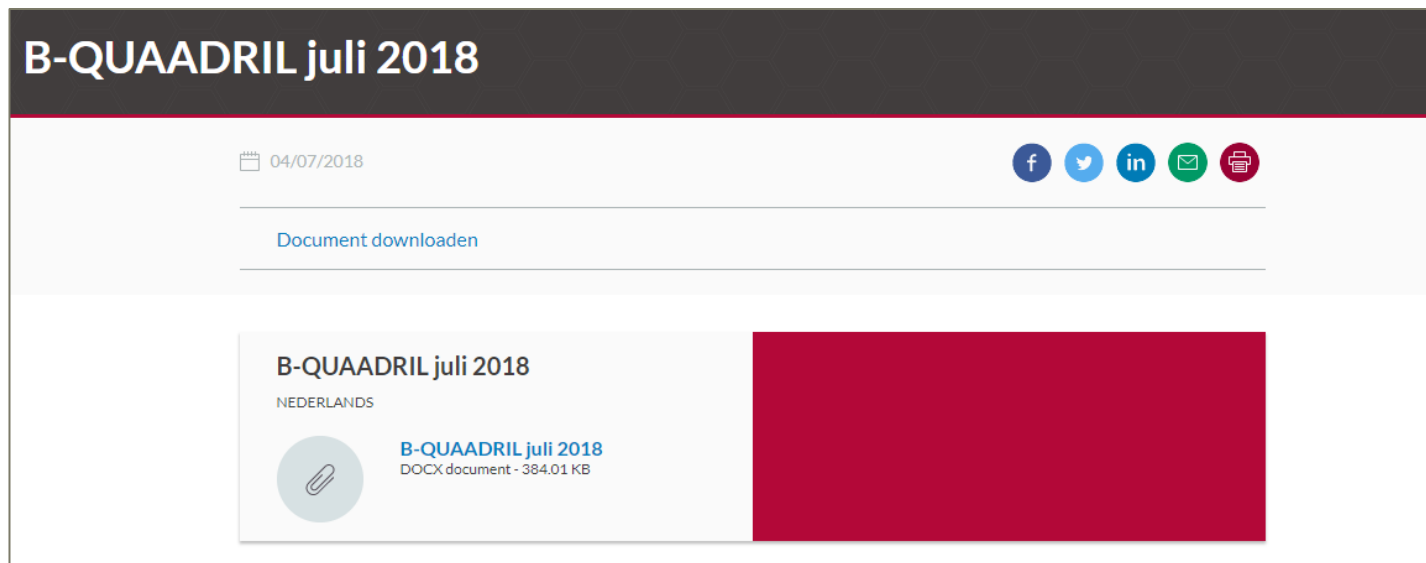
- **Where?** Installations indicated by FANC
- **How?** Modalities set or approved by FANC
- **When?** modalities and frequencies can differ for different installations (technical “FANC” regulations)

Clinical audits

All specialties !

Radiological applications (except dentistry):

- Reference document “B-Quaadriil” (< BELMIP)
- Version for audit coming soon
- Publication technical regulations: 2019
- Start self assessment in 2019-2020: notification



<https://www.health.belgium.be/nl/b-quaadril-juli-2018>

Overzicht

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- **What about the staff?**
- Conclusion

What about the staff?

Physicians should

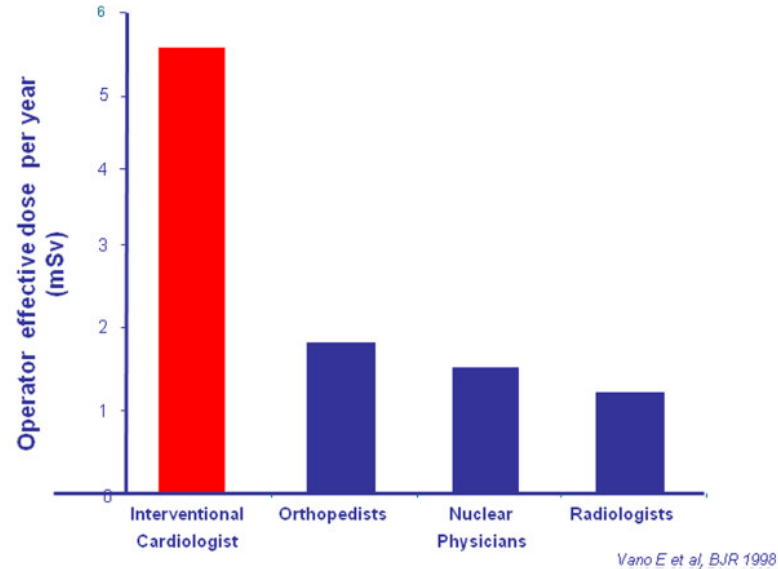
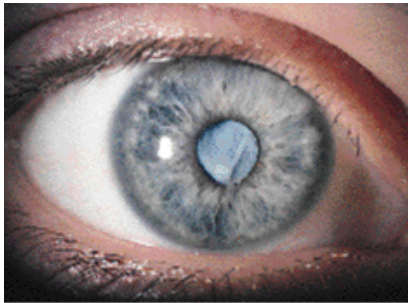
- follow basic radiation protection training (75h)
- be licensed for the use of X-ray applications
- follow continuous training (2h/year)
- be present in the room when applying interventional techniques

Auxiliaries should

- follow basic radiation protection training (50h)
- follow continuous training (1h/year)
- work under the responsibility of a licensed practitioner

What about the staff?

Physicians are not untouchable!

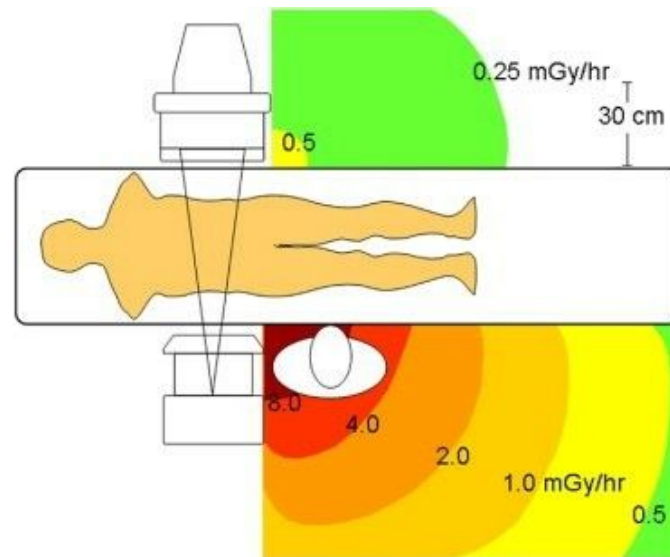
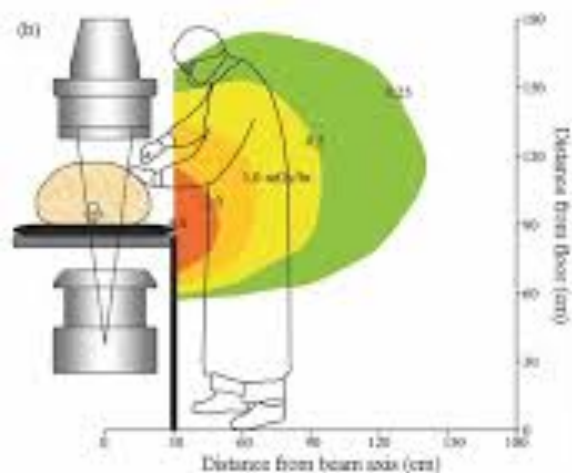
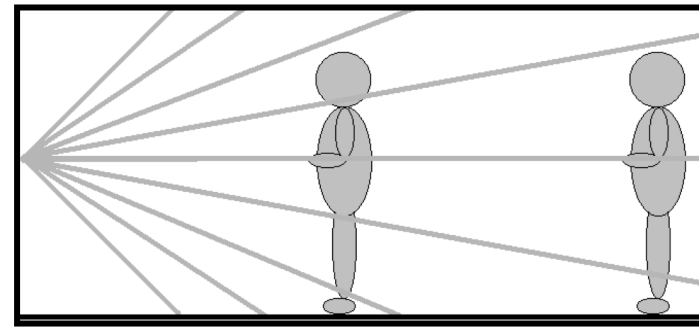
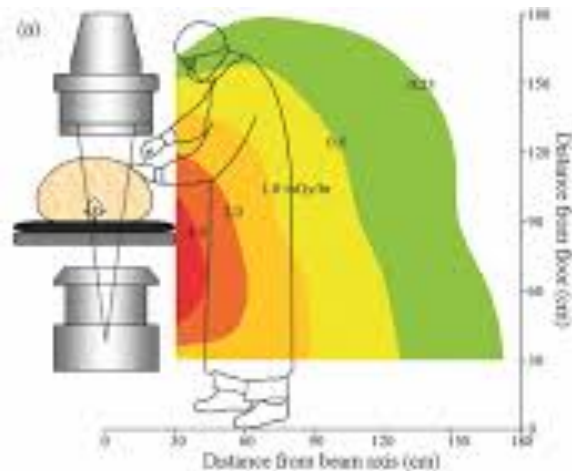


Brain and Neck Tumors Among Physicians Performing Interventional Procedures

Ariel Roguin, MD, PhD^{a,*}, Jacob Goldstein, MD^b, Olivier Bar, MD^c, and James A. Goldstein, MD^d

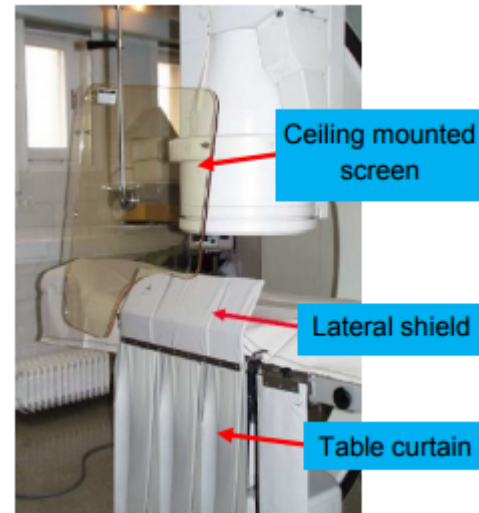
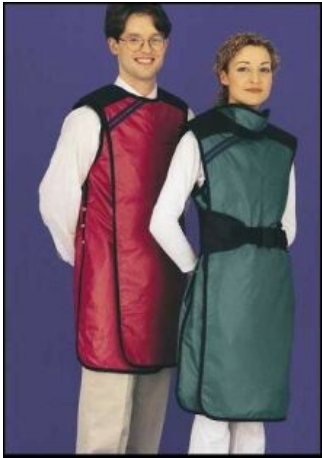
What about the staff?

Positioning of staff and equipment is important!



What about the staff?

Use protective material



What about the staff?

New
ARBIS/RGPRI

Dose limits

	Public	Exposed workers
Effective dose	1 mSv per year	20 mSv per 12 consecutive months
Equivalent dose		
Eye lens	15 mSv per year	20 mSv per 12 consecutive months
Skin (average dose for each 1 cm ²)	50 mSv per year	500 mSv per 12 consecutive months
Hands, arms, fore-arms, feet, legs and ankles	NA	500 mSv per 12 consecutive months

Overzicht

- Euratom/2013/59 directive & Belgian transposition
- Why all those rules?
- New and expected requirement, focus on:
 - Information towards the patient
 - Procedures in interventional settings
 - Medical radiation physics
 - Accidental and unintended exposures
 - Clinical audits
- What about the staff?
- **Conclusion**

Conclusions

- Does your patient know what your procedure entails? What are the advantages and the risks?
- Do you know your medical physics expert? Do you know where he/she can or should assist you?
- How can you optimise your procedures: for your patient, for the staff, for yourself
- What are the barriers installed to avoid incidents in your department?