X-ray examinations and pregnancy: Legal framework

Katrien Van Slambrouck, *PhD*

katrien.vanslambrouck@fanc.fgov.be

Health and Environment – Health Protection

Theme coordinator medical X-ray applications

FANC AFCN

federaal agentschap voor nucleaire controle

agence fédérale de contrôle nucléaire

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Overview

- Legislative grounds
- In general
- Medical exposures
- Accidental or unintended exposures

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ARBIS/RGPRI

Current legislation:

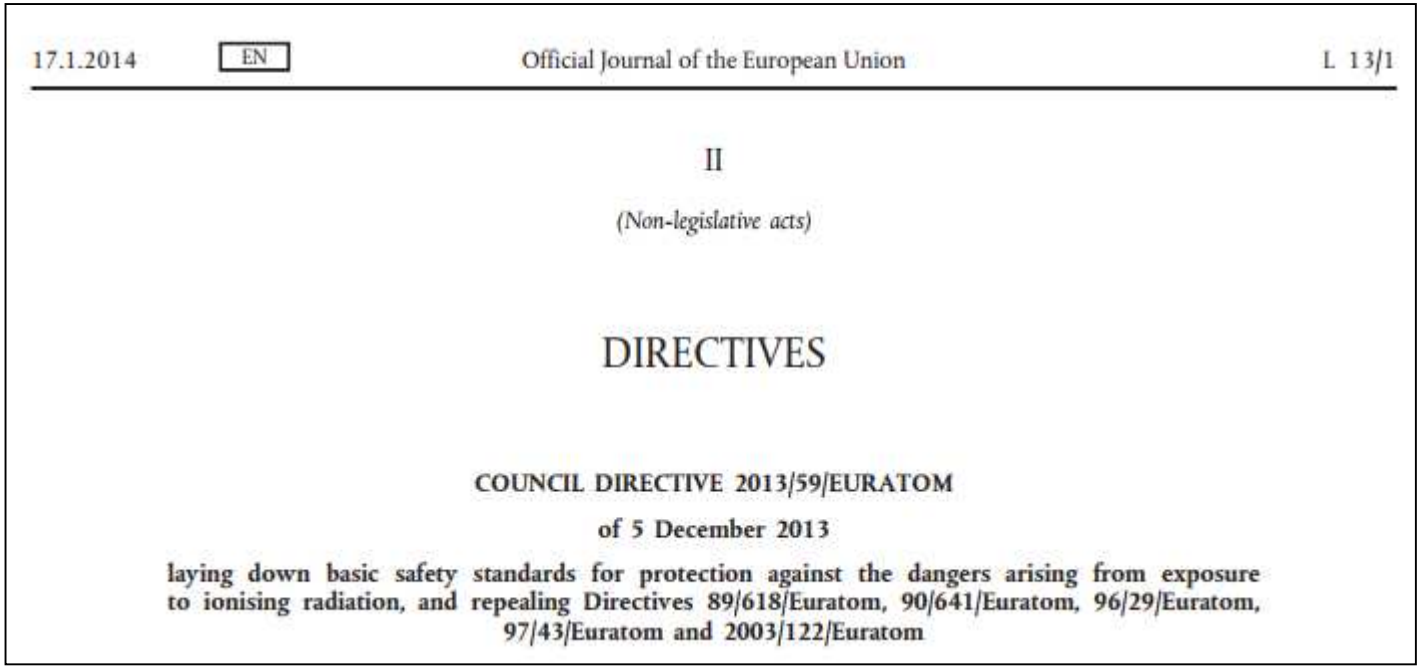
20/07/01 ARBIS

Koninklijk besluit van 20 juli 2001 houdende algemeen reglement op de bescherming van de bevolking, van de werknemers en het leefmilieu tegen het gevaar van de ioniserende stralingen

20/07/01 RGPRI

Arrêté royal du 20 juillet 2001 portant règlement général de la protection de la population, des travailleurs et de l'environnement contre le danger des rayonnements ionisants

Future



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

Future

- Transposition EURATOM/2013/59 directive
- Clarify ambiguities
- Catching up frequently occurring issues

→ Sector independent requirements will stay in the ARBIS/RGPRI

→ Current sector specific chapters of ARBIS/RGPRI will be separate decrees

Future

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

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AFCN

Overview

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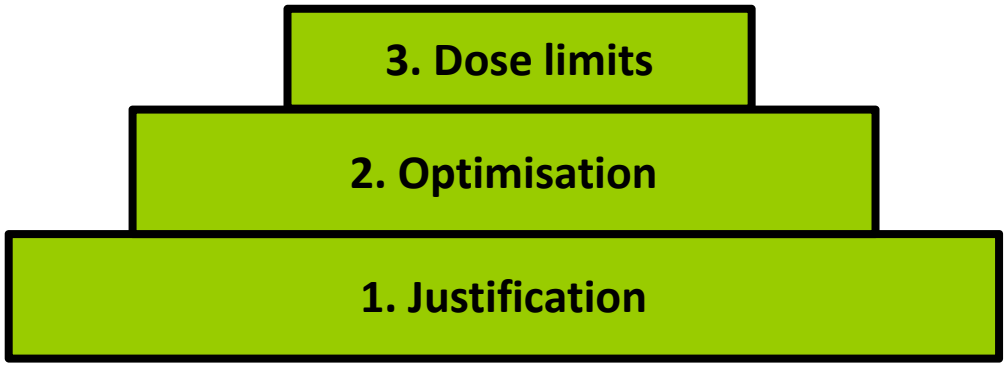
In general

1. Every exposure to ionising radiation should be **justified**, thus also exposures to the unborn child (pregnant women)
2. Every justified exposure should be **optimised** following the ALARA principle
3. The **dose limits** should be respected

Basic principles of radiation protection



In general

	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

Unborn child is considered as a member of the public !

! DOSE LIMIT ≠ DOSE CREDIT !

In general

- Unborn child is considered as a member of the public
  → 1 mSv during the pregnancy
- This is not a choice of the mother
- Occupationally exposed person
  → she should inform employer asap
  → employer should contact health physics and occupational physician
  → when needed: adapted tasks

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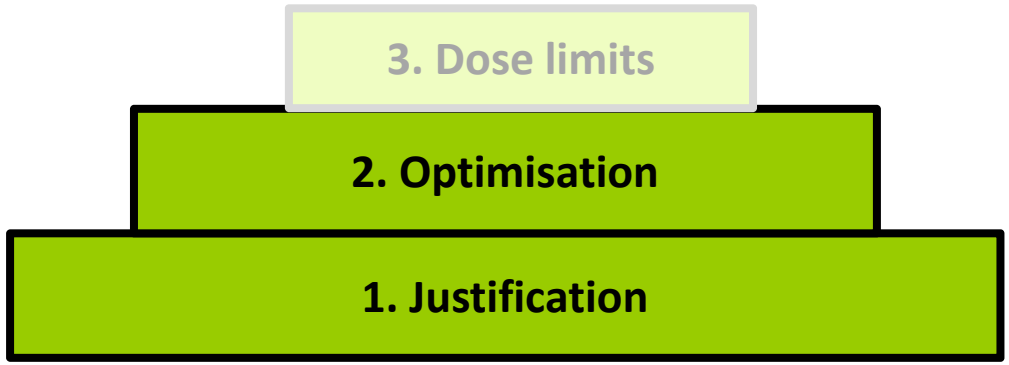
Medical exposure

Well-considered exposure of a pregnant woman, and thus unborn child, for the medical care of the mother

or

Exposure to the unborn for its medical care

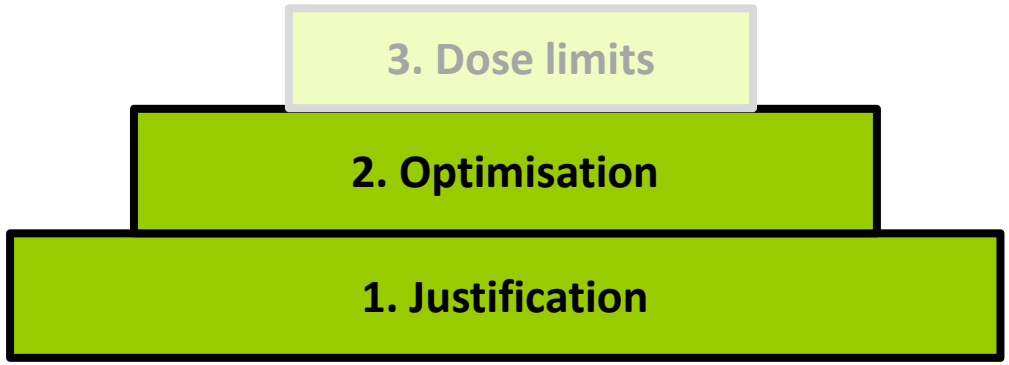
Basic principles of radiation protection



Medical exposure

1. Every medical exposure should be individually justified
2. Every medical exposure should be optimised = kept ALARA but keep the necessary medical information
3. No dose limits for medical exposures

Basic principles of radiation protection



Medical exposure

Step 0: **Awareness**

- Be aware of the risks related to the exposure of an unborn child

  → education and training

Presentation of dr. Smeesters

- Install **procedures** in your department
  - In the justification process
    - How to inquire about possible pregnancies
    - How to use the answer in the justification of the exposure
    - How to inform the parents
  - How to optimise in case of a known pregnancy
  - What to do in case of an accidental/unintended exposure

Medical exposure

Step 1: **Inquire** about possible pregnancy

- Formulation of the questions:
  - You are not pregnant? *versus* Could you be pregnant?
- Not limited to written declaration
- Use graded approach: ask further questions for potentially high dose applications in the abdomen/pelvis regions (e.g. CT)
  - When were your last menstruations?
  - Do you use anti-conception?
  - Are you trying to become pregnant?
- Think ahead about “difficult situations”
  - Language barrier
  - Intellectual barrier
  - Cultural barrier
  - “Authority” barrier (e.g. teenager with mother)

Medical exposure

Step 2: **Justification** of the examination

Answer on pregnancy question(s) should be noted in the patient file

New

If your patient is pregnant

- Use this information during the **justification** process
  - Is this procedure urgent or could it be postponed?
  - What are the risks for mother and child?
  - What is the estimated dose for the unborn child? (questions? → medical physics expert)
- Inform your patient

Presentation of dr. Aerts

Medical exposure

Step 3: **Optimisation** of the justified examination

for a justified examination of a pregnant woman

- **Optimise** the exposure
  - Parameters
  - Collimation, scan area, field of view
  - Protective devices

  Advice → recognised medical physics expert

Presentation of Prof. ir. Bosmans

Medical exposure

Carers and comforters

New

For women

- Inquire about possible pregnancies
- Inform the carer/comforter (ideally before they arrive, additional role for referrer → inform them!)
- Justify exposure
- Optimise exposure
- Pregnant carer/comforter: dose limit of 1 mSv holds and may not be exceeded !

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Accidental or unintended exposure

Accidental or unintended exposure of an unborn child (most common: pregnancy unknown)

If the estimated dose to the unborn < 1mSv

- Inform patient and referrer
- Register in incident management system
- Analyse the incident
- Learn from the incidents that (nearly) happened (e.g. adapt procedures, extra training for staff, …)

(Partially) new

Accidental or unintended exposure

Accidental or unintended exposure of an unborn child (most common: pregnancy unknown)

(Partially) new

If the estimated dose to the unborn > 1 mSv

- Obligatory dose calculation by recognised medical physics expert
- Inform patient
- Inform referrer, other relevant caregivers: e.g. gynaecologist
- Register in incident management system
- Analyse incident
- Learn from the incident

Accidental or unintended exposure

Accidental or unintended exposure of an unborn child (most common: pregnancy unknown)

(Partially) new

If the estimated dose to the unborn > 1 mSv

- Dose limit exceeded thus inform Agency
  - event@fanc.fgov.be
  - Soon dedicated notification form available at

    www.fanc.fgov.be > Professionelen > Radiologische toepassingen

    www.afcn.fgoc.be > Professionnels > Applications radiologiques
  - Analysis, measures/actions taken or to be taken
  - No blame no shame

Thank you !

Questions?

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