Regulatory aspects concerning Radiation Protection: European Directive 2013/59/Euratom

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1. Introduction

2. Basic principles of radiation protection

3. Radiation protection of exposed workers and public
   3.1. Justification of exposure
   3.2. Optimization of exposure
   3.3. Dose limits + monitoring exposed workers
   3.4. Classification of work places

4. Radiation protection of patient, volunteer, carer/comforter
   4.1. Justification of medical exposure
   4.2. Optimization of medical exposure

Road map

1. JUSTIFICATION
2. OPTIMIZATION
3. DOSE LIMITATION
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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

⇒ Mandatory transposition into national legislation
before the 6th of February 2018

1. Introduction

1. Production

2. *In vitro* testing
   Animal testing

3. Upscaling production

4. Clinical trial

5. (Clinic)
1. Introduction

• Exposure

“Means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure)”

➢ Occupational exposure

➢ Public exposure

➢ Medical exposure

“Means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.”
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   4.2. Optimization of medical exposure
2. Basic principles of radiation protection

1. JUSTIFICATION
   • Have to be applied in the right order!
   • Justification: outweighing advantages – disadvantages

2. OPTIMIZATION
   • Optimization: As Low As Reasonably Achievable (ALARA)

3. DOSE LIMITATION

   Medical exposures:
   ➢ no dose limits (but dose constraints)
   ➢ justification and optimization even more important
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3.1. Justification of exposure

The production of radiopharmaceuticals and their use in biomedical research and medicine is generally accepted as doing more good than harm. Its overall justification is generally accepted.
3.2. Optimization of exposure:
Distance - Time - Shielding - Hygiene
3.2. Optimization of exposure:
Distance - Time - Shielding - Hygiene

The undertaking has to foresee appropriate shielding/protective equipment:

• Individual: glasses, collars, aprons

• Collective: screens, boxes, syringe shields
3.2. Optimization of exposure: Distance - Time - Shielding - Hygiene

When working with open sources (radiopharmacy, nuclear medicine) => Avoid internal and external contaminations of surfaces and people:

- Wear impenetrable gloves
- Wear lab coat
- Wear protective glasses
- Wash hands
- Do not eat, drink or smoke
- Work in rooms with:
  - impenetrable floor
  - impenetrable surfaces
  - limited access
  - far from passing people
3.2. Optimization of exposure
Education of all (potentially) exposed workers

- Radiation protection education linked to the risk on work place
- Before first exposure and repeated
- Specifically oriented towards work place

=> Radiation protection of the exposed worker, public and environment

Mandatory for all (potentially) workers exposed
### 3.3. Dose limits exposed workers

<table>
<thead>
<tr>
<th></th>
<th>Public</th>
<th>Exposed workers</th>
<th>Apprentices (16-18 y)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effective dose</strong></td>
<td>1 mSv/y</td>
<td>20 mSv/y</td>
<td>6 mSv/y</td>
</tr>
<tr>
<td><strong>Equivalent dose</strong></td>
<td></td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>15 mSv/y</td>
<td>150 mSv/y</td>
<td>50 mSv/y</td>
</tr>
<tr>
<td>Skin (dose averaged over any cm²)</td>
<td>50 mSv/an</td>
<td>500 mSv/y</td>
<td>150 mSv/y</td>
</tr>
<tr>
<td>Extremeties</td>
<td>Not applicable</td>
<td>500 mSv/y</td>
<td>150 mSv/y</td>
</tr>
</tbody>
</table>

*DOSE LIMITS ≠ DOSES CREDITS!*
3.3. Dose limits exposed workers
Pregnant and breastfeeding workers

(Unborn) child: higher sensitivity to ionizing radiation
⇒ Extra protective measures for (potentially) pregnant and lactating women that are professionally exposed:

➢ If they work with open sources:
   = risk of irradiation and contamination (internal and external)
⇒ equivalent dose unborn child: ALARA + < 1mSv during pregnancy
⇒ no work involving significant risk of intake of radionuclides or of bodily contamination
3.3. Dose limits exposed workers

Individual dosimetric monitoring

- Dosimeter on the chest
- Read out by a recognized dosimetric service

To measure is to know.
If you can not measure it, you can not improve it.
- Lord Kelvin

Mandatory individual dosimetric monitoring of all exposed workers who could pass one of the dose limits of public exposure.
3.3. Dose limits for exposed workers

Individual dosimetric monitoring

In certain cases, an extra personal dosimeter is mandatory.
Higher local exposure => Finger/hand/eye dosimeter
Higher total exposure => Electronic dosimeter
3.3. Dose limits for exposed workers

Individual dosimetric monitoring

- One central dose register for all exposed workers
- Each individual exposed worker: dosimetric passport

Identification
- Employer (current and earlier)
- Which isotopes

Basic and continuous education
Medical data
Dosimetric data
3.4. Classification of work places

- Classification on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures
- Restricted access, radiation signs, instructions, written procedures,...

=> Radiation protection of exposed workers and public
3.4. Classification of work places

- **Undertaking responsibility of compliance with all legal obligations**
  1. Responsible for installations and radioactive waste
  2. Radiation protection personnel
  3. Medical exposure: advice from medical physics expert

- **Radiation protection expert (RPE) advice on radiation protection of exposed workers and public**
  1. Design of the installation
  2. Warning signs for radioactivity
  3. Sufficient shielding?
  4. Procedures for radioactive waste, decontamination of installation,…

- **Radiation protection officer (RPO) implementation of advice of RPE**
  1. Delegate within the department of the RPE
  2. Warns RPE in case of problems
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4.1. Justification of medical exposure

Medical exposure

Advantages
- Therapeutic effect?
- Impact of the diagnosis?

Costs?
- Accessibility?
- Alternatives?

Disadvantages
- Effects of the exposure?
- RA waste?

Health, social and economical aspects
w.r.t. patient, staff and environment
4.1. Justification of medical exposure

Three levels of justification:

**Level 1**  Justification of use of radiation in medicine
Level 2  Justification of defined medical radiological procedures
Level 3  Justification of a procedure for an individual patient

At the first and most general level, the use of radiation in medicine is generally accepted as doing more good than harm. Its overall justification is generally accepted.
4.1. Justification of medical exposure

Three levels of justification:
- **Level 1**: Justification of use of radiation in medicine
- **Level 2**: Justification of defined medical radiological procedures
- **Level 3**: Justification of a procedure for an individual patient

General justification of specific procedure, for specific objective

- Framework by (inter)national healthcare and radiological protection bodies and authorities → imaging/treatment guidelines based on symptoms, suggested diagnosis, ...

- Are there better alternatives available?
- Alternative that does not use ionizing radiation?
- Not only patients, also staff and public
4.1. Justification of medical exposure

Three levels of justification:
Level 1 Justification of use of radiation in medicine
Level 2 Justification of defined medical radiological procedures
Level 3 Justification of a procedure for an individual patient

Specific characteristics of the individual patient

- Patient history/age/...
- Previous and future treatment
- Is the required information not yet available?
- Expected dose to the patient
- Benefit/risk analysis
4.1. Justification of medical exposure
Women childbearing age

(Unborn) child: higher sensitivity to ionizing radiation
⇒ Extra protective measures for (potentially) pregnant and lactating women

Patient/volunteer childbearing age:
always inform if (potentially) pregnant or breastfeeding
4.1. Justification of medical exposure

A justified medical radiological procedure

- Procedure is generally justified
- According to (inter)nationale guidelines
- Checked for the specific situation of an individual patient

Only in exceptional cases!!!
Not standard practice!!!

- Not generally justified or not according to (inter)nationale guidelines
- Documentation individual justification

level 2
level 2
level 3
level 3
4.2. Optimization of medical exposure

Article 56

Optimisation

1. Member States shall ensure that all doses due to medical exposure for radiodiagnostic interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

Article 83

Medical physics expert

2. Member States shall ensure that depending on the medical radiological practice, the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:
4.2. Optimization of medical exposure

3. Member States shall ensure that for each medical or biomedical research project involving medical exposure:

(a) the individuals concerned participate voluntarily;

(b) these individuals are informed about the risks of exposure;

(c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

(d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.
4.2. Optimization of medical exposure

Child is more sensitive to ionising radiation

⇒ Adapted scanning protocol and administered activity
4.2. Optimization of medical exposure
Quality of radiopharmaceuticals

- Pharmaceutical quality (because of administration to the patient)
- Radionuclidic purity:
  - Is all radioactivity present under the form of the desired radionuclide?
  - No other radionuclides present than the desired one?
  - To avoid unnecessary and useless irradiation of the patient due to the presence of undesired radionuclides
- Radiochemical purity:
  - Is the desired radionuclide present under the form of the desired radiopharmaceutical?
  - No impurities holding the same radionuclide?
  - Diagnosis: To guarantee good images who correlate correctly with the target you want to visualise (and quantify)
  - Therapy: to guarantee that the target tissue is more attacked and non target tissue is less attacked
4.2. Optimization of medical exposure
Quality of equipment

- Acceptance testing (before first clinical use)
- QA and QC of equipment (in use)

=> cameras: guarantee good images
=> dose calibrator: guarantee that right activity is administered
4.2. Optimization of medical exposure

Education of practitioners

• Physician responsible for the medical exposure (radiotherapist, nuclear physician, radiologist, surgeons using Rx, dentists, veterinarians)
• Radiation protection of the patient (and the unborn child), carers/comforters and volunteers in clinical trials:
  ➢ Justification of medical exposure: which exam/treatment most suited?
  ➢ Optimisation of medical exposure: under which circumstances?
• Education: in perspective to the risk of the medical exposure
  ➞ Personal authorisation + continuous education
4.2. Optimization of medical exposure

Education of nurses/technologists

- Practical aspects of medical-radiological procedures
- Radiation protection of the patient (and the unborn child), carers/comforters and volunteers in clinical trials:
  - Optimisation of medical exposure: under which circumstances?
- Education: in perspective to the risk of medical exposure
4.2. Optimization of medical exposure

Education medical physics expert

- (Advice on) radiation protection of patient (and unborn child), carers/comforters and volunteers in clinical trials
- Responsible for dosimetry of the patient: performing prospective and retrospective dose calculation/estimation based on the necessary measurements
- QA and QC of equipment: cameras and dose calibrator to guarantee good images and that the right activity is administered

=> Personal recognition + continuous education
Thank You! Questions?

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