

HERCA Multi-Stakeholder Workshop on "Generic Justification", Paris, 24-26 October 2016

Introductory Session:

Setting the Scene & Objectives of the Workshop

Jean-Luc Godet, Jürgen Griebel

Some General Remarks

Justification of Classes or Types of Practices



**three complex terms
to be considered
within the workshop**

Some General Remarks

Justification of Classes or Types of Practices

**occupational
exposures**

**public
exposures**

**medical
exposures**

Some General Remarks

Justification of Classes or Types of Practices

**occupational
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**medical
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Agenda

- I. Setting the Scene → Juergen Griebel
 - What is so Special about Medical Exposure?
 - Principle of Justification in the Medical Field
 - Art. 55.2 (a) EU-BSS Directive
- II. Some Infos about the *Multi-Stakeholder Workshop on „Generic Justification“* → Jean-Luc Godet

Agenda

I. Setting the Scene

- What is so Special about Medical Exposure?
- Principle of Justification in the Medical Field
- Art. 55.2 (a) EU-BSS Directive

II. Some Infos about the *Multi-Stakeholder Workshop on „Generic Justification“*

What is so Special about Medical Exposure?

- It is the combination of **individual benefit** and **individual risk**!
- In **medical exposures**,
the **individual** is directly affected by both:
 - the **potential benefit** from ionizing radiation and
 - the **potential risk** from ionizing radiation!
- This is a **major difference to public or occupational exposures**!

Other Special Issues about Med. Exposure!

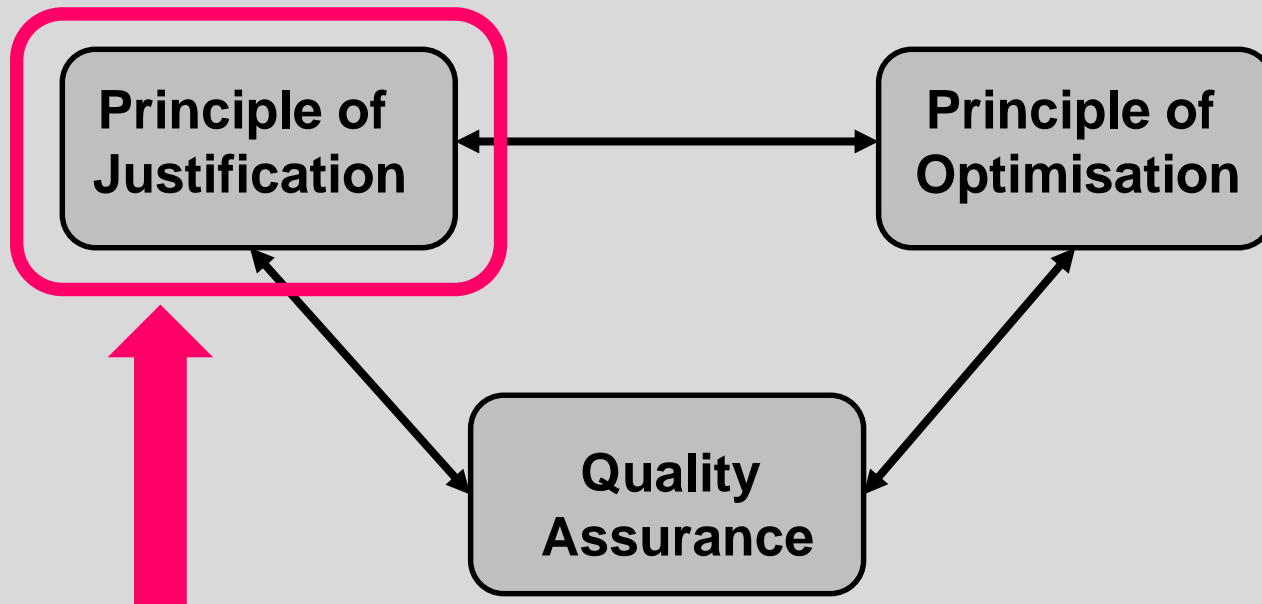
- Tremendous development in medical technology has taken place over the last decade, offering fascinating new clinical options which are of **great benefit to the individual patient being exposed**.
- The growing use of radiation related to this development has also led to a large increase in medical radiation exposure, which raises **radiation protection concerns**.



all this calls for
a specific approach in medical radiation protection!

Other Special Issues about Med. Exposure!

Specific Approach:



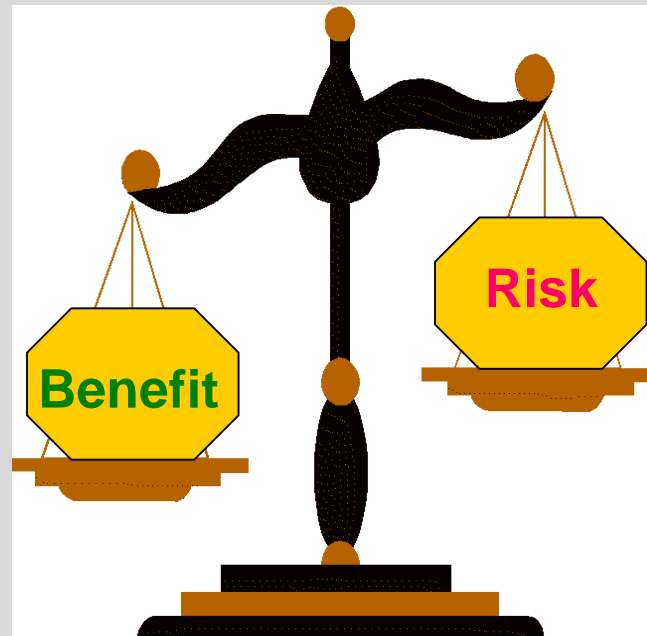
for today's workshop

Principle of Justification: Medical Field

Art 55.1 EURATOM-Basic Safety Standards Directive, 2014:

Medical exposures shall show a **sufficient net benefit**

weighing the total **potential diagnostic or therapeutic benefits** it produces, including the **direct benefits to health of an individual** and the **benefits to society**,



against the **individual detriment** that the exposure might cause,

taking into account the efficacy, benefits and risks of **available alternative techniques** having the same objective but involving no or less exposure to ionising radiation.

Principle of Justification: Considerations

Art 55.1 EU-BSS Directive:

Benefit / Risk Analysis:

direct benefits to health of an individual:

- how to assess this – in particular for diagnostic imaging procedures?

benefits to society:

- even more difficult to assess?



individual detriment:

- exposure level
- age at exposure
- gender
- life expectancy



**appropriate
radiation risk models**

justification process ↔ scientific evidence issues

- **what level of scientific evidence is to be claimed for appropriate justification?**

Principle of Justification: Considerations

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individual detriment:

- exposure level
- age at exposure
- gender
- life expectancy vs. latency period

justification process ↔ governance issues

- how is this process to be carried out?
- what is to be claimed for this process?

Principle of Justification: Scenarios

Art 55.2 EU-BSS Directive:

addresses **six scenarios** concerning the medical application of ionising radiation, where the **principle of justification** has to be applied



for today's workshop
I will need to address
only two of them!!!

Principle of Justification: Scenarios

Scenario #1: Individual Medical Exposure (Healthcare)

an *individual patient*:

- *symptomatic individual*
- *high prevalence of disease*

undergoing X-rays as part of his own *medical treatment*

⇒ *X-ray of chest in chest pain*



Scenario #2: New Type of Practice

a *new type of practice*

being *introduced* in the *medical treatment*,

i.e. in the *diagnosis or therapy*,
of *patients*

⇒ *newly developed CT, dedicated for breast imaging in healthcare,*

⇒ *newly introduced screening based on well-established CT technology*

Medical
Breakthroughs

New
CT screening
reveals health
problems
sooner



Principle of Justification: Scenarios

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both scenarios follow
completely different justification processes:

Art 55.2 (b) EU-BSS Directive

Art 55.2 (a) EU-BSS Directive

Principle of Justification: Scenarios

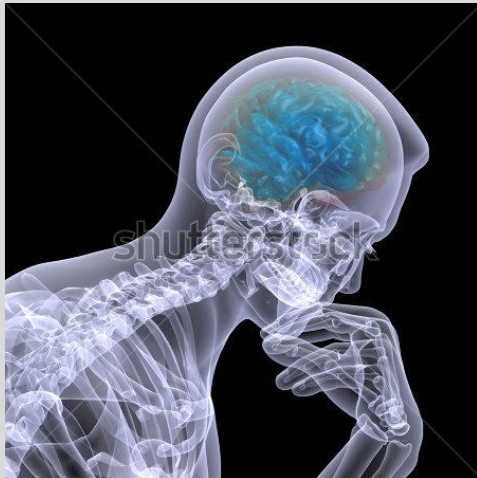
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focus of today's workshop:
Art 55.2 (a) EU-BSS Directive

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Art 55.2 (a) EU-BSS Directive:

new types of practices
involving
medical exposure

are justified
in advance
before

being generally
adopted

principle of justification

benefit versus risk analysis

Art. 55.2 (e) EU-BSS Directive:
bio-medical research

model, which may be helpful for a first common understanding, but
which needs to be refined during the workshop

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MSW Generic Justification: Background



October 2014

- In 2014, the HERCA Board of Heads approved an **Action Plan** in support of the transposition of the **new Council Directive 2013/59/Euratom**.

MSW Generic Justification: Background



October 2014

- In relation to medical exposures, the Action Plan identified
- the **justification of new types or classes of practices** and
 - the **interrelation with bio-medical research** as **key topics** where HERCA could add value to the transposition process.

Council Directive 2013/59/Euratom:

- Article 19 and 55.2 (a),
- Article 55.2 (c),
- Article 55.2 (e)

MSW Generic Justification: Background

- To further explore the transposition process of the EU-BSS Directive on the justification of new types of practices, HERCA organised today's

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MSW Generic Justification: Agenda

- The **Agenda** of the workshop includes **three parts**:
 - **Introductory Session** → **to develop a common understanding concerning the *Justification of New Types of Practices* for the MSW**
 - ✓ Legal Basis
 - ✓ Conceptual Considerations & Regulatory Requirements
 - ✓ Existing Challenges in the Member States
 - ✓ Views of International Organisations
 - **Plenary Session 1 – 6** → **to discuss various transposition approaches within Member States**
 - ✓ Health Technology Assessment
 - ✓ CE Marking
 - ✓ “Standard Medical Practice List”
 - ✓ Authorization Process
 - ✓ Further Approches in MS
 - ✓ New Types of Practices versus Biomedical Research
- } → **Stakeholder's Platform:**
- Feedback from *European Medical Associations & Manufacturers*
 - Round Table Discussion

MSW Generic Justification: Agenda

- **Towards a Framework for Good Governance**

- ✓ Perspectives from Manufacturers
→ *COCIR Position Paper*
- ✓ Perspectives from Medical Associations
→ *ESR, EANM, ESTRO, EFRS*
- ✓ General Discussion
→ *All Participants*



- **here, HERCA expects an active role of the Stakeholders:**
 - to raise concerns
 - to support / to criticise approaches
- **all this will have an important input on the outcome of the *MSW on Generic Justification***

MSW Generic Justification: Objectives

- The **objectives** of the workshop are:
 - to **explore a common understanding** of the **new requirements**;
 - to **exchange information** on **national approaches** relating to the transposition and implementation of these new requirements;
 - to **collect the opinion** of **important European stakeholders**, particularly the European medical societies and manufacturers;
 - to **assist in the development** of a **HERCA Position Paper** intended to facilitate the transposition and implementation of the Council Directive 2013/59/Euratom.

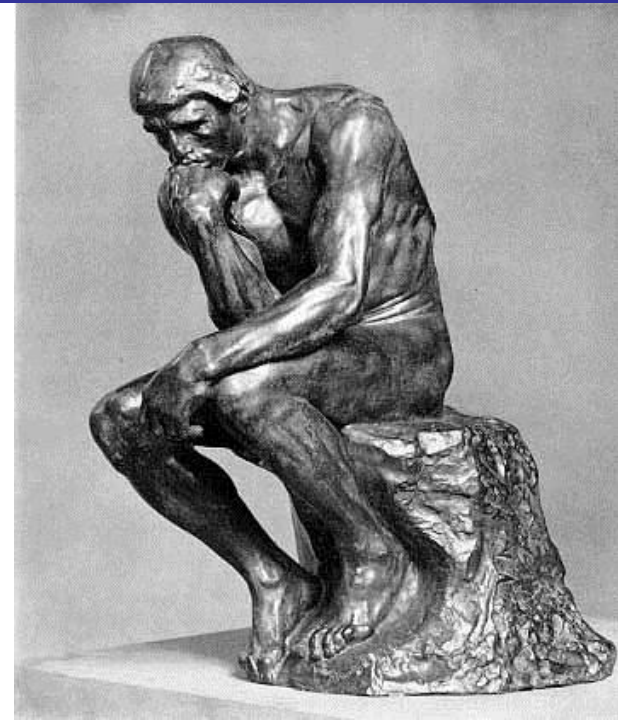
MSW Generic Justification: Objectives

Transposition and Implementation
of
Council Directive 2013/59/Euratom
laying down Basic Safety Standards for Protection
against the Dangers arising from Exposure to Ionising Radiation:

**Justification of Types or Classes of Practices
Resulting in Medical Exposures**

– Discussion Paper –

HERCA-Working Group „Medical Applications“



- In view of **today's workshop** and as a first step towards the **HERCA Position Paper**,
 - the *HERCA-Working Group „Medical Applications“* (WGMA) prepared a **discussion paper**.

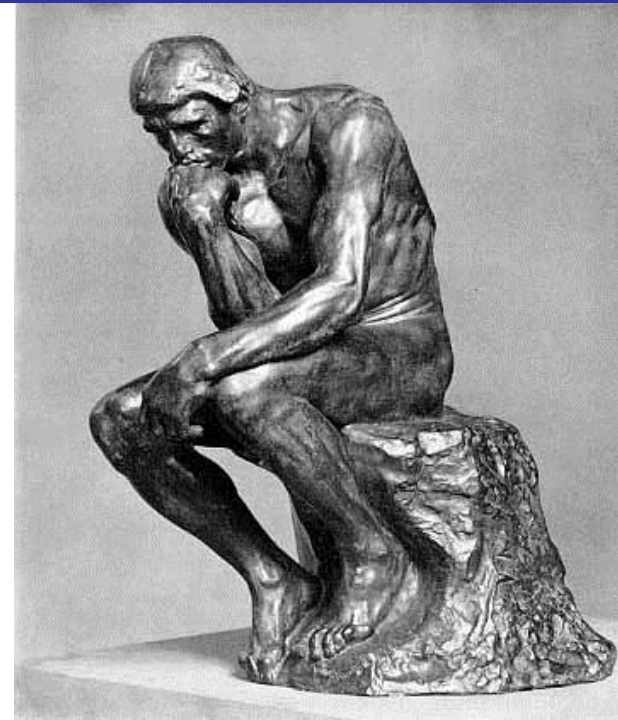
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– Discussion Paper –

HERCA-Working Group „Medical Applications“



- The **aim** of the discussion paper is
 - to **set the scene** - following the discussions within the *WGMA*,
 - to **serve as starting point** for the discussions at the *MSW*
 - **“Questions / Issues to be discussed” with respect to the Plenary and Introductory Sessions**
 - to **initiate** the development of the **HERCA Position Paper** – after today’s workshop.

Thank You for Your Attention!



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protection Competent Authorities

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