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

Introductory Session:

Conceptual Considerations & Regulatory Requirements with respect to the Transposition of Council Directive 2013/59/Euratom

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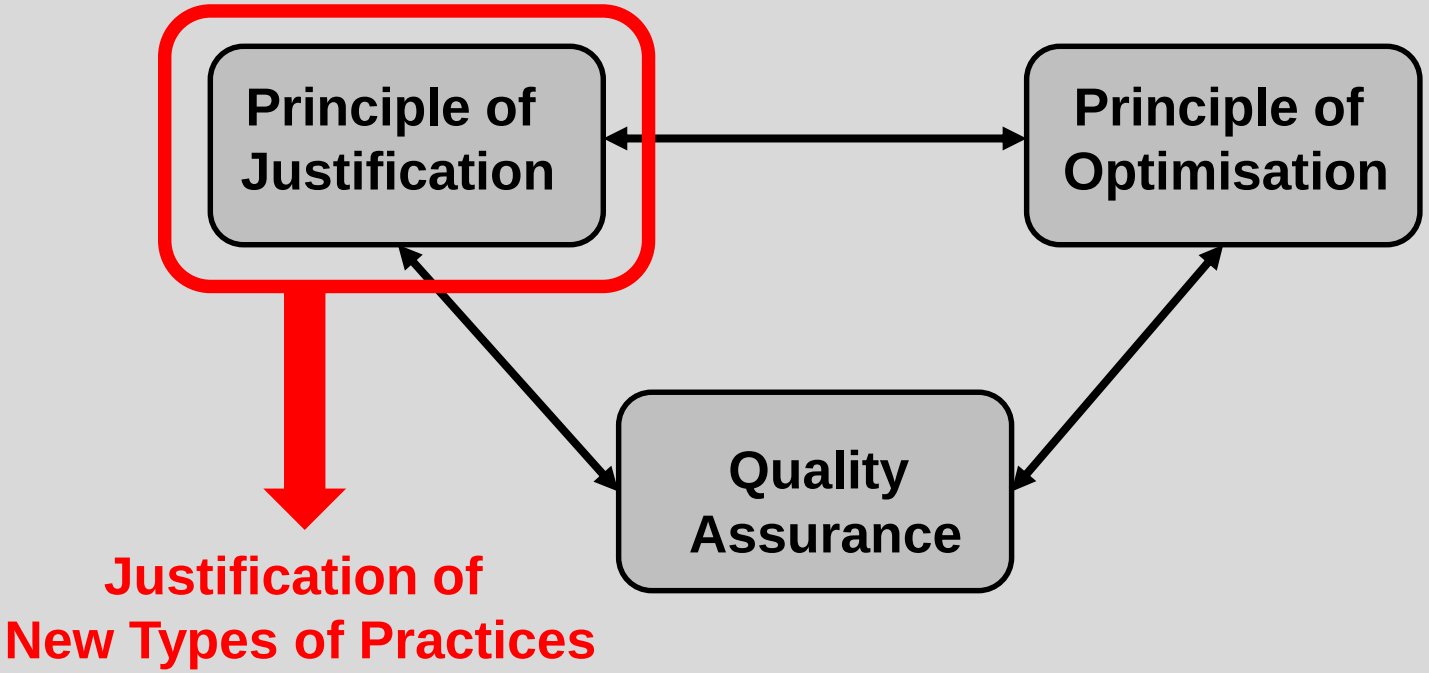
HERCA-Working Group on Medical Applications

HERCA
Heads of the European Radiological protection Competent Authorities

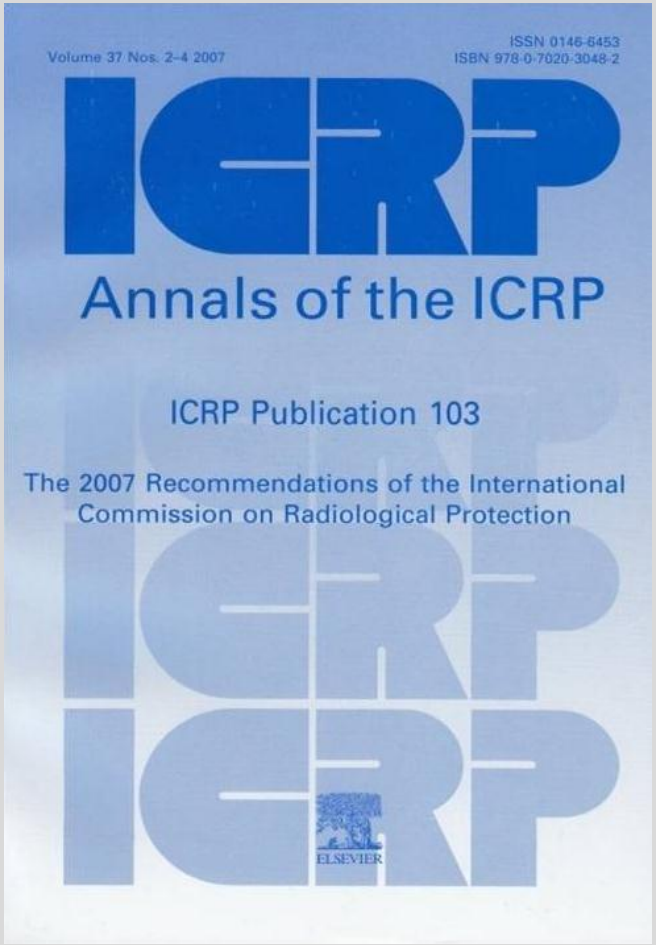
System of Radiation Protection: Medicine

Specific Approach:



System of Radiation Protection: ICRP

ICRP Publication 103, 2007:



ICRP Recommendations

↓

International Basic Safety Standards

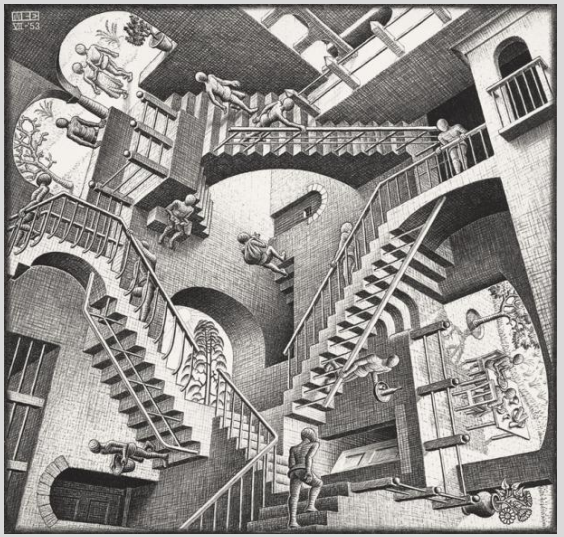
↓

EURATOM Basic Safety Standards Directives:

Council Directive 2013/59/Euratom

System of Radiation Protection: ICRP

The principle of justification applies at three levels in medicine (Section 7.1.1.):



- **First Level:**
  the **use of radiation in medicine** is accepted as doing more good than harm to the patient

  → this can be taken for granted.

- **Second Level:**
  a **specified procedure** with a **specified objective** is defined and justified:
  - chest radiographs for a group of patients showing relevant symptoms,

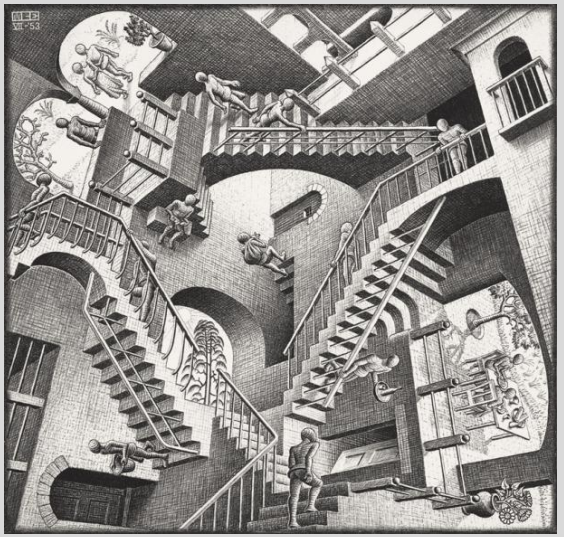
  → the aim is to judge whether the radiological procedure will usually improve the diagnosis or treatment ...

- **Third Level:**
  the **application of the procedure** to an **individual patient** should be justified.

  → the particular application should be judged to do more good than harm to the individual patient.

System of Radiation Protection: ICRP

The principle of justification applies at three levels in medicine (Section 7.1.1.):



ICRP - Level	Responsibility
1	justification can be taken for granted
2	national and international professional bodies in conjunction with • national health and radiological protection authorities, and • the corresponding international organisations
3	practitioners involved

justification of new types of practices due to Article 55.2 (a) Council Directive 2013/59/Euratom

System of Radiation Protection: ICRP

Some Considerations of the *WG Medical Applications* I:

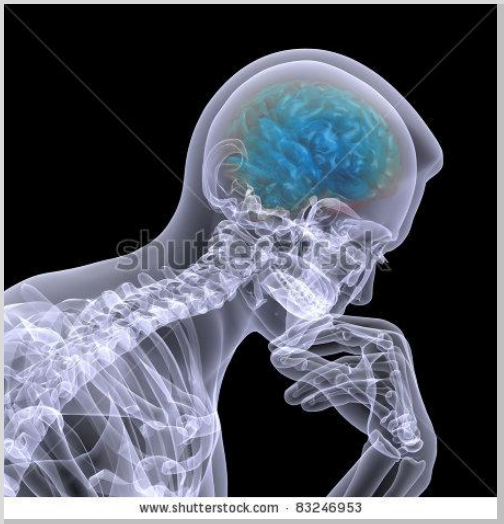
- It is important to note that the fact that a procedure in medicine can be regarded as **justified on level 2** does not necessarily mean that its application to a particular patient is **justified on level 3**.
- From a regulatory point of view this demonstrates that – although level 2 and level 3 justification are closely linked – they need **separate consideration**.
- A national regulatory framework has to ensure a **well defined balance between the two levels**
  - to guarantee a **high level of radiation protection** for the patient in the medical use of ionising radiation, but also
  - to avoid **over-regulation** in the field of medicine.

Justification of New Types of Practices

Art 55.2 (a) EU-BSS Directive:

Member States shall ensure that
the principle defined in paragraph 1 is applied and in particular that:

- **new types of practices** involving medical exposure are **justified in advance** before being **generally adopted**.



What is a
"type of practice"?

the medical device / radio-pharmaceutical to be used !

the objectives to be achieved by the device / radio-pharmaceutical!

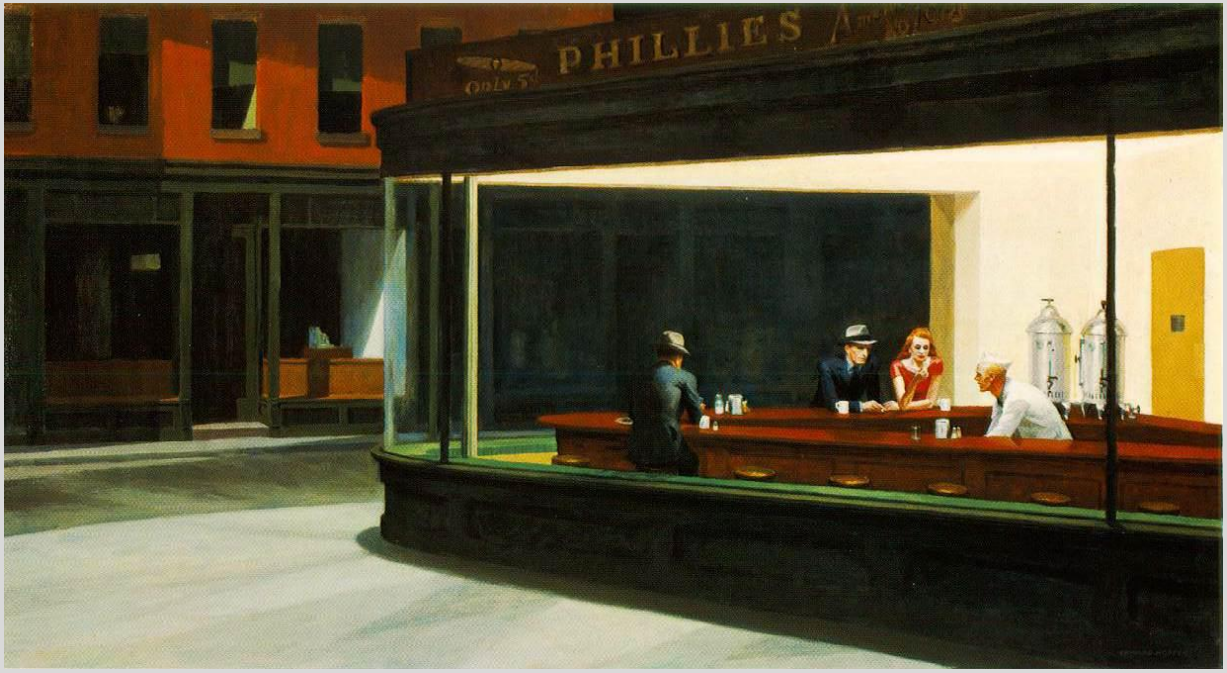
medical device

clinical indication

Justification of New Types of Practices

New Type of Practice:

	Medical Device	Clinical Indication
Case I	newly developed	established / new
Case II	established	new



Justification of New Types of Practices

New Type of Practice – Example for Case I:

Medical Device	Clinical Indication
newly developed	**established**

Koning Breast CT (KBCT):

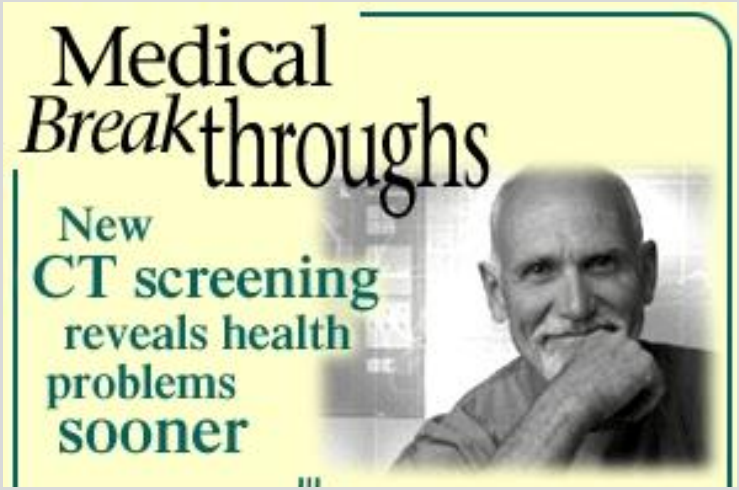
- The KBCT system is a **newly developed dedicated breast imaging system** that acquires computed tomography (CT) images without compressing the breast.
- The KBCT is intended for **breast cancer diagnosis in women**.
- The KBCT is **not** intended for **breast cancer screening**.

FDA Device Approval, 14.01.2015

Justification of New Types of Practices

New Type of Practice – Example for Case II:

Medical Device	Clinical Indication
established	new



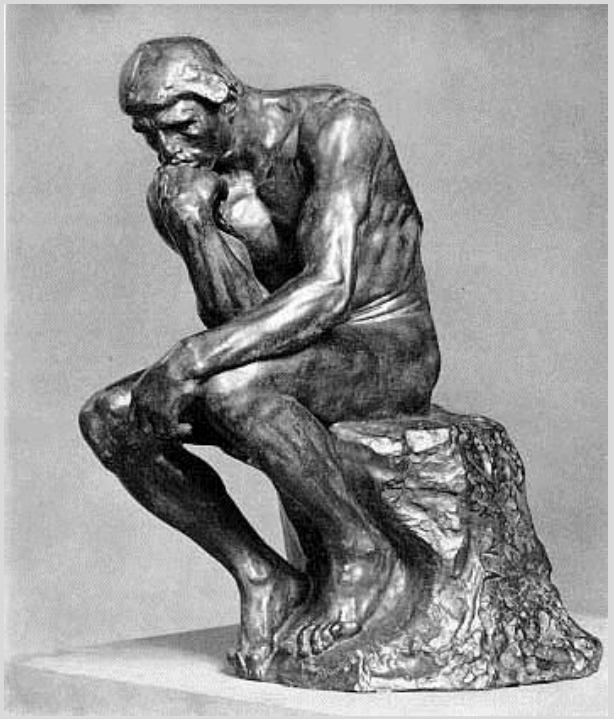
CT based individual health assessment:

- CT is a **well-established medical device** for the clinical diagnosis of patients.
- Individual health assessment is a **new clinical indication**.

Justification of New Types of Practices

Some Considerations of the *WG Medical Applications* II:

- The term "*type of practice*" may have to be considered in a broader sense as compared to the term "*practice*" and thus necessitates some kind of **categorisation** – with respect to both the device or radiopharmaceutical and the clinical indication.



New Types of Practice: Categorisation

A rough model for categorisation – just for illustration:

- **Develop a grid by defining categories for both medical devices and clinical indications**

medical device / *clinical indication*	*conventional X-ray*	*computed tomography*	*fluoroscopy*
healthcare			
screening programme			
individual health assessment			

three times three boxes

New Types of Practice: Categorisation

A rough model for categorisation – just for illustration:

- **Evaluate for each box whether the type of practice – defined by the box - is to be justified in general or not**

medical device / *clinical indication*	*conventional X-ray*	*computed tomography*	*fluoroscopy*
healthcare	justified in general	justified in general	justified in general
screening programme	justified in general	not justified in general	not justified in general
individual health assessment	?	?	?

New Types of Practice: Categorisation

A rough model for categorisation – just for illustration:

- **Investigate a new type of practice with respect to the grid**

medical device / *clinical indication*	*conventional X-ray*	*computed tomography*	*fluoroscopy*
healthcare	justified in general	justified in general	justified in general
screening programme	justified in general	not justified in general	not justified in general
individual health assessment	?	?	?

New Types of Practice: Categorisation

Example – just for illustration:

- **Koning Breast CT in Breast Cancer Diagnosis in Women**

clinical indication \ *medical device*	*conventional X-ray*	*computed tomography*	*fluoroscopy*
healthcare	justified in general	justified in general	justified in general
screening programme	justified in general	not justified in general	not justified in general
individual health assessment	?	?	?

Justification of New Types of Practices

Some Considerations of the *WG Medical Applications* III:

- The **categorisation** has to be **flexible**, in order to cover different transposition approaches in the Member States (MS).
- Here, the **granularity aspect** will be key.
  - The **finer** the granulation is, the **better** the grid may **reflect the complexity of medical exposures.**
  - The **rougher** the granulation is, the **less** the grid may **require resources** from a regulatory and scientific point of view.
- In the MS, there already exist **transposition approaches** with both quite a rough (e.g. UK) and quite a fine granularity (e.g. Luxembourg).
  - The granularity aspect is important to understand the **consequences of these approaches** - in particular with respect to the **resources**, which have to be allocated for the different approaches.
- There are **important lessons** to be learned from existing approaches, which may help other MS in their transposition efforts.

Justification of New Types of Practices

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Further details will be provided in case studies within the Plenary Sessions 1 – 5 tomorrow

Regulatory Requirements for Transposition

The adequate transposition of Art. 55.2 (a) requires a regulatory process to be established in each Member State:

- The requirements of Art. 77 Council Directive 2013/59/Euratom concerning traceability and transparency have to be met.

Article 77

Transparency

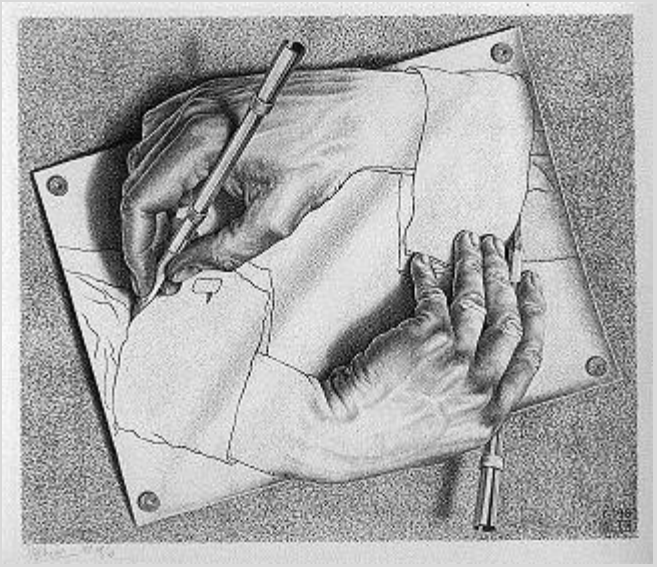
Member States shall ensure that

information in relation to the **justification of classes or types of practices** … is made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure.

Regulatory Requirements for Transposition

The adequate transposition of Art. 55.2 (a) requires a regulatory process to be established in each Member State:

- The minimal set of requirements around this regulatory process needs to be addressed.
- Hereby, the requirement "*that new types of practices … are justified **in advance before** being generally adopted*" needs to be considered.



Questions to be discussed: Regul. Process

- **By what action shall the regulatory process be initiated for new types of practices:**
  - pro-actively by the competent authority?
  - re-actively by e.g. undertakings within a notification / authorization process?
- **By what measures can / must the regulatory process be supported:**
  - establishment of an expert panel (e.g. medical associations, manufacturers, etc) on a permanent base?
  - involvement of relevant stakeholders (e.g. medical associations, manufacturers, etc) on a case by case base?
  - involvement of existing structures / processes in the field, such as
    - *Health Technology Assessment (HTA)* organisations?
    - *CE marking* due to Medical Device Directive / Regulation?
- **What shall the outcome of the regulatory process be:**
  - official statement of competent authority following publication of authoritative report (e.g. COMARE reports in UK)? → pro-active appr.
  - approval with respect to notification / authorization processes (e.g. Luxembourg)? → re-active appr.

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The respective roles of Health Authorities, Radiation Protection Authorities, Medical Societies and Manufacturers in the transposition process will be discussed within Plenary Sessions 1 – 5 tomorrow

Thank You for Your Attention!

HERCA

Heads of the European Radiological protection Competent Authorities

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System of Radiological Protection: ICRP

Principle of Justification:

ICRP Publication 103, 2007 (Chapter 7.1)	Council Directive 2013/59/Euratom (Article 55.1)
The principal aim of medical exposures is to do more good than harm to the patient, subsidiary account being taken of the radiation detriment from the exposure of the radiological staff and of other individuals.	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 …

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