HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

New technologies: What “intelligence” do we need?

Katrien Van Slambrouck

HERCA BSS Workshop 20-22 May 2024, Madrid

Session 4: Justification - Medical


EU guidelines and regulations
National competences and concrete regulations
Rapidly evolving and put on the market
Lifesaving evolutions!?
Many possible risks
Evidence based medicine?
Big money
...
Healthcare sector

Overview

1. EU regulatory framework
2. Recent developments
3. RP authorities

Overview

1. **EU regulatory framework**
2. Recent developments
3. RP authorities

Justification of new technologies

Euratom/2013/59

CHAPTER VII

MEDICAL EXPOSURES

Article 55

Justification

1. Medical exposure 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.

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

(a) new types of practices involving medical exposure are justified in advance before being generally adopted;

(b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

General justification

→Types of practices

→Before being generally adopted

Justification of new technologies

Medical device regulation - Regulation 2017/745

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

Justification of new technologies

Health technology Assessment regulation - Regulation 2021/2282

entered into force on 11 January 2022 and will apply from 12 January 2025.

Article 1

Subject matter

1. This Regulation establishes:

(a) a support framework and procedures for cooperation of Member States on health technologies at Union level;

(b) a mechanism which lays down that any information, data, analyses and other evidence required for the joint clinical assessment of health technologies is to be submitted by the health technology developer only once at Union level;

(c) common rules and methodologies for the joint clinical assessment of health technologies.

2. This Regulation shall not affect Member States' competence to draw conclusions on the relative effectiveness of health technologies or to take decisions on the use of a health technology in their specific national health context. It shall not interfere with the exclusive national competence of Member States, including those for national pricing and reimbursement decisions, or affect any other competences which concern Member States' management and delivery of health services or medical care or the allocation of resources assigned to them.

Overview

1. EU regulatory framework
2. **Recent developments**
3. RP authorities

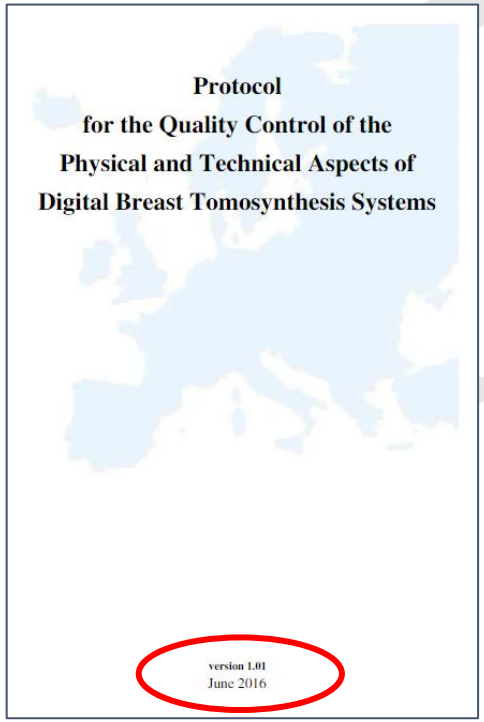
New technologies

Digital Breast Tomosynthesis

- new device, usually subjected to licensing within the RP competent authority
- different technology
- use in diagnosis-patient setting versus screening of healthy individuals

New technologies

Digital Breast Tomosynthesis – QA/QC



New technologies

Digital Breast Tomosynthesis

- Can practices be justified if evaluation/testing of the radiation safety is unclear?

- Can practices be justified if users are not trained to use it?

New technologies

Digital Breast Tomosynthesis

European guidelines on breast cancer screening and diagnosis

Justification

The majority of the GDG agreed that the balance of desirable and undesirable effects probably favours DBT. The overall certainty in the evidence is very low because of the uncertainty in the effect for interval breast cancer, and the absence of data regarding the downstream impact on breast cancer mortality.

The evidence shows that when using DBT there are greater numbers of breast cancers detected. In addition, there may be less overdiagnosis when using DBT since a higher proportion of invasive breast cancers are detected compared with non-invasive ductal carcinoma (DCIS) which are clinically less relevant cancers. Evidence also found that there may be fewer women returning for assessment because of a false positive result. However, adding DBT may have little to no effect on interval breast cancers, but this evidence is very uncertain. Overall, the moderate desirable effects of adding DBT probably outweigh the small harms.

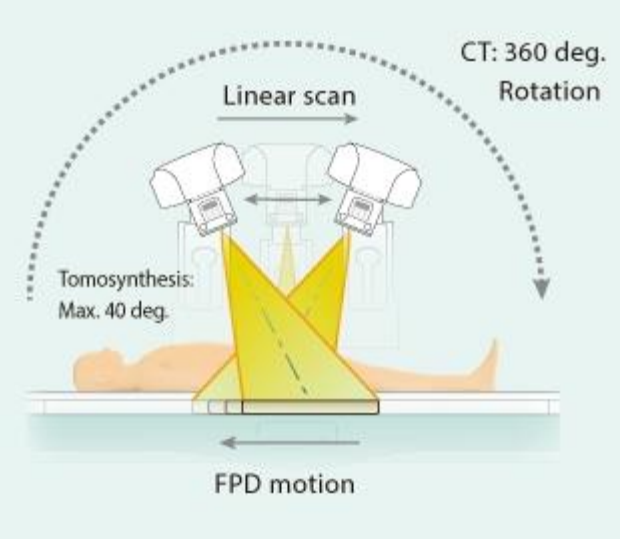
There are moderate costs associated with DBT over DM, which could increase health inequities if implemented. However, implementation of DBT would be facilitated by increased availability of DBT machines, adequate human resources (radiologists and technical personnel), and financial resources.

The majority of the GDG agreed with the recommendation: 8 members voted for a conditional recommendation for the DBT, 1 member voted for a strong recommendation for DBT, 3 members voted for a conditional recommendation for either DBT or DM, and 1 member abstained.

New technologies

Digital Breast Tomosynthesis

→*What about tomosynthesis on radiography tables?*

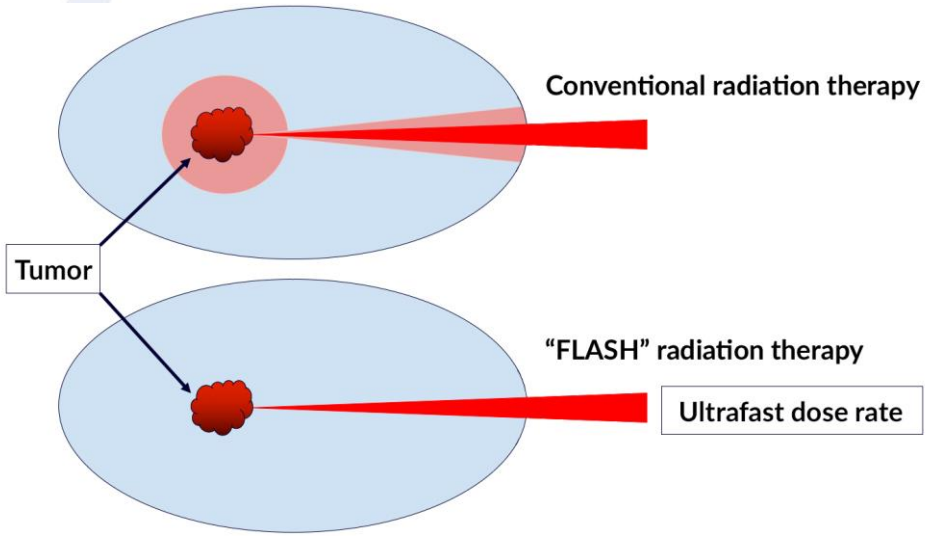


https://www.shimadzu-medical.eu/sonialvision-g4

New technologies

Flash therapy

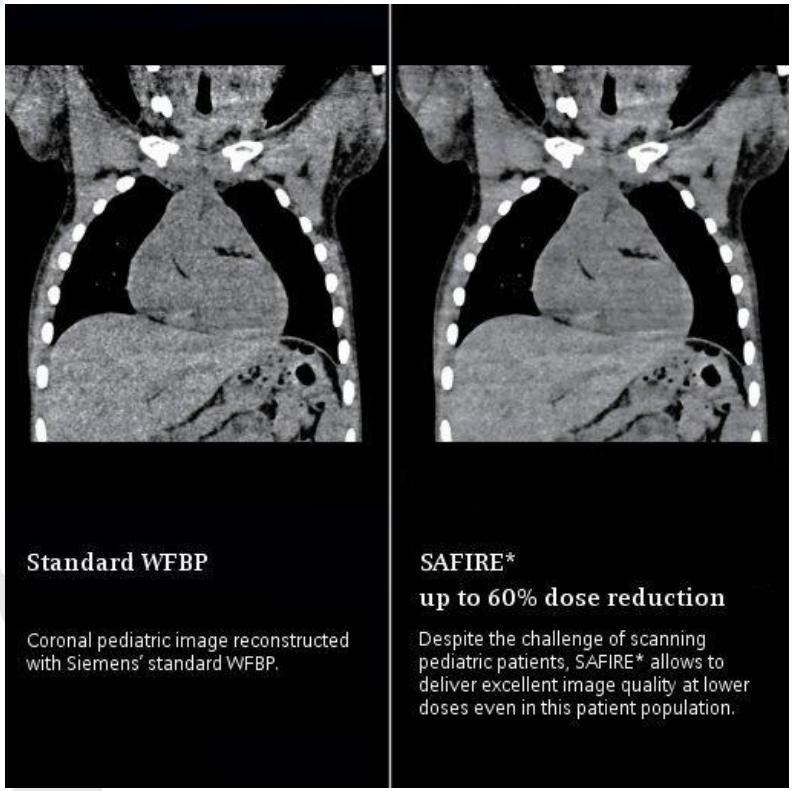
- High doses in short time
- Existing linear accelerators or cyclotrons can be modified
- Consequences of accidents?



New technologies

Iterative reconstruction for computed tomography

- new software on (existing) devices
- different approaches (e.g. reconstruction or postprocessing)
- QA/QC?



New technologies

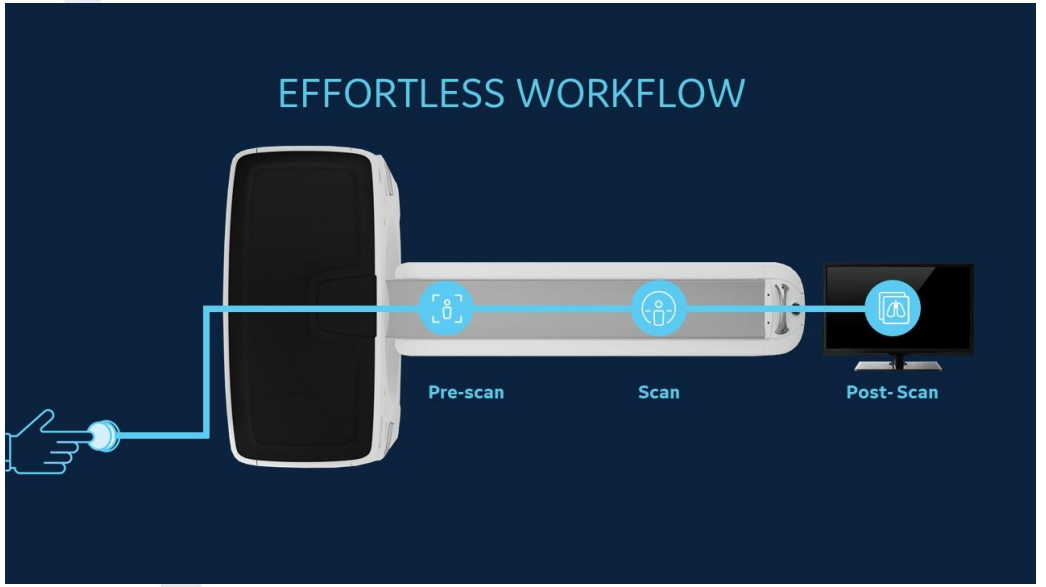
Artificial Intelligence

- new software on (existing) devices
- applications in all domains and all parts of the process
  - Treatment and diagnosis
  - Reconstruction and image analysis/review
  - Quality assurance
- AI can change (learn) after installation of the software

Insights • Article

From order to report: Maximizing AI solutions to streamline the CT workflow

Nov 15, 2022



New technologies

Artificial Intelligence

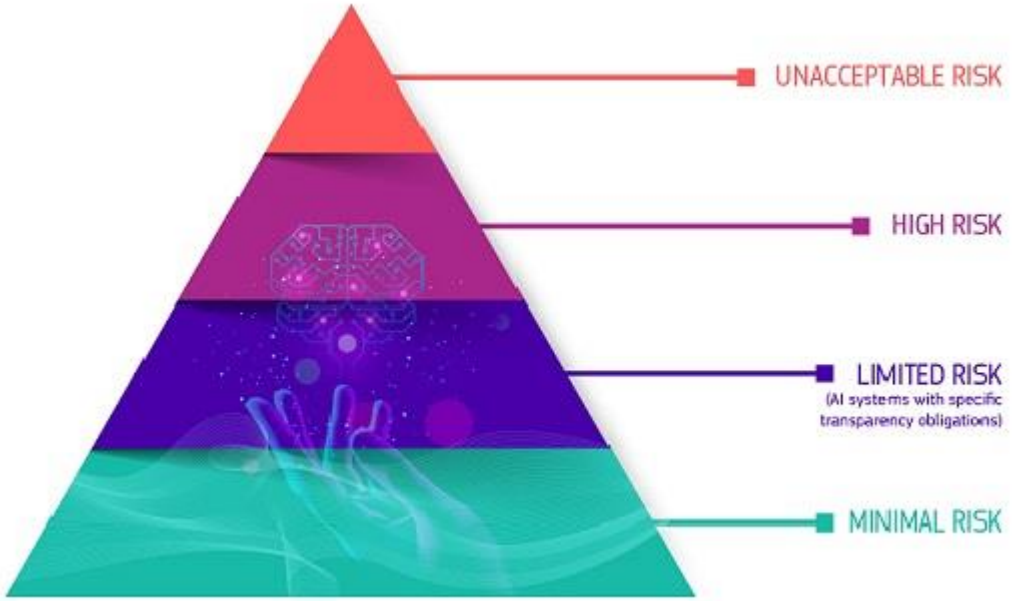
European Commission

English Search

Shaping Europe's digital future

The proposed rules will:

- address risks specifically created by AI applications;
- prohibit AI practices that pose unacceptable risks;
- determine a list of high-risk applications;
- set clear requirements for AI systems for high-risk applications;
- define specific obligations deployers and providers of high-risk AI applications;
- require a conformity assessment before a given AI system is put into service or placed on the market;
- put enforcement in place after a given AI system is placed into the market;
- establish a governance structure at European and national level.



Overview

1. EU regulatory framework
2. Recent developments
3. **RP authorities**

Justification

… 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 …

→ **How to comply with this very extended requirement?**

New technologies

How can radiation protection competent authorities judge the justification of new technologies?

1. **Clinical Need:** Competent authorities assess whether there is a genuine clinical need for the new technology. They consider factors such as the prevalence of the condition being diagnosed or treated, the limitations of existing technologies, and the potential benefits of the new technology in improving patient outcomes.
2. **Diagnostic Efficacy:** Authorities evaluate the diagnostic efficacy of the new technology, including its ability to provide accurate and reliable diagnostic information. This assessment involves reviewing clinical studies, evidence-based guidelines, and expert opinions to determine whether the technology offers advantages over existing diagnostic methods.
3. **Therapeutic Benefit:** If the new technology is used for therapeutic purposes (e.g., radiation therapy), competent authorities assess its potential therapeutic benefit in treating medical conditions. They consider factors such as treatment effectiveness, dose delivery accuracy, and patient outcomes to determine whether the technology is justified for clinical use.

ChatGPT

New technologies

4. **Radiation Exposure:** Competent authorities evaluate the radiation exposure associated with the new technology and ensure that it is justified based on the ALARA (As Low As Reasonably Achievable) principle. This involves assessing factors such as the radiation dose delivered to patients and healthcare workers, as well as the potential risks and benefits of radiation exposure in the context of the clinical indication.
5. **Cost-Effectiveness:** Authorities may consider the cost-effectiveness of the new technology, weighing the potential benefits against the financial costs and resource implications. This assessment involves analyzing factors such as the technology's impact on healthcare outcomes, resource utilization, and long-term sustainability within healthcare systems.
6. **Ethical and Legal Considerations:** Competent authorities also consider ethical and legal aspects of the new technology, including patient consent, privacy concerns, and compliance with regulatory requirements and standards. They ensure that the use of the technology is consistent with ethical principles and legal obligations, such as patient autonomy and professional accountability.
7. **Stakeholder Consultation:** Authorities may consult with stakeholders, including healthcare providers, professional organizations, patient advocacy groups, and industry representatives, to gather diverse perspectives and input on the justification of the new technology. This consultation process helps ensure that regulatory decisions reflect the interests and concerns of those affected by the technology's introduction.

ChatGPT

Justification

What is the role of a RP competent authority?

To what extent can or should we harmonise and collaborate?


EU guidelines and regulations
National competences and concrete regulations
Rapidly evolving and put on the market
Lifesaving evolutions!?
Many possible risks
Evidence based medicine?
Big money
...
Healthcare sector