HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Report

HERCA Working group on Medical Application

Artificial intelligence in healthcare
Possible impact on radiation protection

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Contents

Introduction

Artificial intelligence (AI) is expected to have a profound impact on healthcare. The medical field has long been a focus of research and development in this area. However, the implementation of AI in clinical practice also raises important questions about its potential benefits and the risks it may pose, particularly in relation to radiation protection. The primary aim of this introductory work was to provide an overview of AI applications in hospitals, raise awareness among HERCA members, and highlight relevance for radiation protection. The document focuses specifically on the consequences of AI for radiation protection issues affecting patients.

AI was identified as a topic of interest for WGMA members, and the WP on New Technologies began work on the subject following the September 2023 WGMA meeting in Oslo. The work included a brief investigation into the types of AI tools currently used in hospitals, with several countries sharing relevant national reports. References from the scientific literature were also identified, and experts were invited to online meetings to share their experiences. A workshop with WGMA members was held during the September 2024 WGMA meeting in Bern. One perspective discussed was the legal requirements, with particular focus on the Basic Safety Standards Directive 2013/59/Euratom.

This document places particular emphasis on identifying radiation protection issues related to AI use in healthcare, with the aim of offering guidance to HERCA members. It should be noted, however, that this report is not intended to provide a comprehensive overview of AI applications in healthcare. Sections 1 and 2 present a brief overview of AI applications. Section 3 outlines the legal landscape, with particular emphasis on the Euratom BSSD, and also covers national AI legislation and initiatives. The document concludes, in Section 4, with a summary of implications for radiation protection, including supervision activities.

Finally, this document is also linked to the recent position statement HERCA's view on patient radiation protection in medicine 2: - essential requirements of a Quality Management System (QMS) regarding radiation protection and safety. The use of AI applications will certainly need to be integrated into hospital quality management systems, including procurement, implementation, and quality assurance processes throughout their lifecycle.

The work on AI is expected to continue, with the aim of developing more targeted key issues for communication with stakeholders.

Summary and steps forward

The nature of radiation risks is changing with the ongoing introduction of AI technologies in healthcare. These changes necessitate a proactive adaptation of existing radiation protection frameworks to ensure they remain fit for purpose in the face of emerging technological developments and evolving clinical practices. One key challenge is that many AI systems offer limited user access and customisation capabilities, often requiring vendor involvement to modify or optimise settings. This can hinder the ability of healthcare professionals to understand risks and optimise radiation protection. Moreover, this raises questions about responsibility and accountability, particularly as AI technologies advance toward greater autonomy in clinical decision-making.

In addition to their technical implications for patient exposure, AI applications also bring changes that may not be immediately recognised as radiation protection concerns. Such applications, referred to in this report as clinical AI, must be integrated into the broader risk assessment processes. A challenge is that both direct and indirect radiation protection implications must be considered and evaluated.

AI technologies are already having a great impact on radiation protection practices. Their integration into medical imaging and radiotherapy introduces both opportunities for improvement and challenges related to safety and oversight. The changes span the entire clinical workflow and carry significant implications for quality assurance systems. As outlined in this report, the use of AI connects directly with the requirements in the Basic Safety Standards Directive (BSSD), highlighting the urgent need to embed radiation protection considerations into all phases within AI system design, device approval, implementation, and use. This means that several other legal structures are included foremost the Medical Devices Regulation.

The evolving nature of medical products that involve ionising radiation—and the changing ways in which they are used—further reinforces the need for updated radiation protection strategies. As AI systems increasingly influence clinical decisions and automate parts of the diagnostic and therapeutic process, the associated radiation risks may shift in character and/or magnitude. Consequently, radiation protection measures must be recalibrated to reflect these new realities.

This technological transition will also have a direct impact on operational procedures at national regulatory authorities. It is imperative that competent authorities initiate, or continue, a review of their current work procedures and regulatory frameworks to ensure they are adequately equipped to address the challenges posed by AI integration. Lessons learned from overseeing other complex technologies may offer valuable insights, but specific guidance and capacity-building will be necessary to address the characteristics of AI in radiation-related healthcare applications.

This report highlights several key issues related to AI technologies. Many of these require further discussion with various stakeholders, primarily suppliers and end users, but also regulatory authorities, standardisation bodies, and other institutions involved in bringing these products to market. Certain topics warrant deeper analysis from a regulatory perspective, including responsibility and accountability of AI use, technical transparency, and the necessary competencies for safe implementation. Additionally, one area not extensively covered in this report, but deserving of further exploration, is the potential for AI technologies to enhance radiation protection in healthcare.

1. Artificial intelligence (AI)

1.1 AI an old concept

The concept of artificial intelligence was first introduced in the 1950s [1] and the early goal was to explore the idea that machines could simulate human intelligence. This marked the beginning of AI as a field of study. The main reasons for the advances in recent years are increased computational power, availability of Big Data and improved algorithms[2].

An AI tool is a software application, component or system that utilises artificial intelligence algorithms and techniques to simulate human intelligence and automate tasks that typically require human cognitive functions including decision-making. These tools may be developed using, or may themselves include, elements of machine learning (ML), deep learning, natural language processing (NLP), computer vision, and robotics, with the aim of performing tasks in an efficient, accurate, or scalable manner.

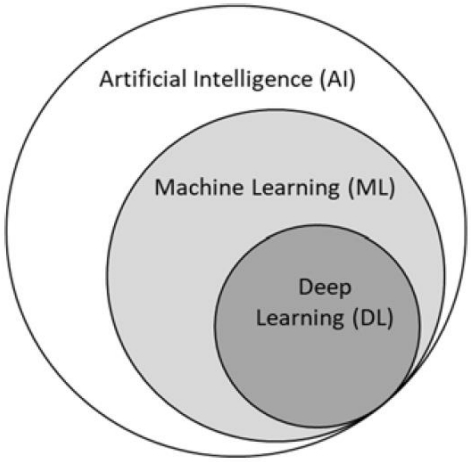

Figure 1. Relationship between artificial intelligence, machine learning and deep learning[3].

Some key features of an AI tool could be identified as:

Data-Driven: AI tools often rely on large datasets to learn from patterns and make predictions, classifications, or recommendations without being explicitly programmed for specific tasks.
Automation: AI tools automate repetitive or complex tasks requiring decision-making, and may automatically learn, or optimise, relevant features from data without explicit definition and programming.
Performance in real time: Many AI tools are capable of processing information and producing results in real time, enabling immediate feedback or dynamic adjustments in tasks.

[1] McCarthy, J., Minsky, M. L., Rochester, N., & Shannon, C. E. (1956)**.** *A Proposal for the Dartmouth Summer Research Project on Artificial Intelligence*. Dartmouth College, Hanover, New Hampshire.
[2] Russell, S., & Norvig, P. (2020)**.** *Artificial Intelligence: A Modern Approach*. (4th ed.). Pearson.
[3] IAEA, Artificial intelligence in medical physics*, Training course series no. 83, 2023*

These and other features could be beneficial for healthcare, including for those medical applications that use ionising radiation which rely on digital images and large sets of data.

The tremendous increase in number of published scientific papers seems to start around 2015 (figure 2) and until 30 June 2025, from a total of 20 320 papers found when performing a search in Pub Med[4]. It is evident that in the last decade, the research and development of AI tools in medicine has accelerated. However, many of the papers include research with AI applications that are not CE marked, meaning that they have not undergone conformity assessment under European legal and technical criteria.

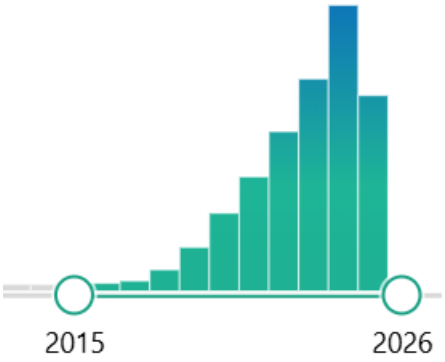

Figure 2. Published scientific papers in the medical field the last 30 years using "artificial intelligence" in the title[4].

1.2. AI used in medical applications – some examples from the literature

Artificial intelligence (AI) is already being utilised in healthcare, with its applications expected to expand further. A study by Potocnik et al.[5] exemplifies some of the areas of application. In medical imaging, these include automated patient positioning in computed tomography (CT), automated identification of regions of interest and scan ranges, as well as image reconstruction techniques for de-noising low-dose CT images. The role of artificial intelligence in radiotherapy has also been explored by researchers such as Landry et al[6], who highlight technical advancements including automatic segmentation, pseudo-CT image generation, radiation dose prediction, automatic treatment planning, and motion tracking as tasks that AI can perform or support. Additionally, AI is mentioned to assist in selecting treatment options and predicting outcomes for individual patients.

Different features, such as deep learning, may be used for quality assurance purposes such as clinical image quality assessment[7]. The use of deep learning for patient- and organ-specific dose estimation in CT-imaging has also been suggested, offering faster and more individualised insights that may prove useful for protocol optimisation and secondary cancer risk assessment[8].

[4] PubMed search title "artificial intelligence".
[5] Potocnik et al. Current and potential applications of artificial intelligence in medical imaging practice. Journal of Medical Imaging and Radiation Sciences 54 (2023) 376–385
[6] Landry G, Kurz C, Traverso A. The role of artificial intelligence in radiotherapy clinical practice. BJR Open (2023) 10.1259/bjro.20230030.
[7] Nousiainen K. et al., Automating chest radiograph imaging quality control, Physica Medica 83 2021 138-145
[8] Myronakis M. Stratakis J. and Damilakis J. Rapid estimation of patient-specific organ doses using: a deep learning network Med Phys. 2023; 50:7236–7244.

1.3. AI related issues raised by healthcare

The effects, including concerns about the introduction of AI into healthcare, have been addressed in the literature. An article discussing the introduction of AI in radiology highlights the increasing need to critically evaluate claims about its usefulness and to distinguish safe and efficient products from those that may be potentially harmful or fundamentally unhelpful[9]. The article states that many aspects must be considered before introducing AI into clinical practice, including methods to monitor stability and safety during clinical use, as well as its suitability for potential autonomous functions. It also emphasises that the integration of AI into radiological practice requires increased monitoring of both its utility and safety. At the same time, the authors note that AI is promising and could enhance patient care if its integration is carefully evaluated.

A paper based on a questionnaire of UK hospitals rated top priorities for successful AI adoption[10]. The top 5 items were: Guidance/standards on AI validation and evaluation; a robust, unified AI governance framework; Training for staff on AI basic principles and key concepts; Leadership to manage AI adoption; Research to create the evidence base for AI governance. Robust AI governance frameworks and tailored AI training to meet each profession's needs, strengths and knowledge gaps are needed to facilitate successful AI adoption.

Today, an increasing number of AI-based applications are receiving CE marking[11]. However, many of these still lack robust evidence from high-quality studies. An article by Antonissen et al.[12] emphasises the need for more independent high-quality research to demonstrate real-world effectiveness and added value—evidence that is essential for broader adoption and inclusion in clinical guidelines.

The medical physics community has also performed a survey among members of the European Federation of Organizations for Medical Physics (EFOMP)[13]. The survey gathered information on an AI-related education, knowledge, needs, and research involvement. The findings highlight a positive perception of AI, i.e., that AI will enhance the daily work of Medical Physicists (MP). The vast majority of the respondents expressed a need for specific training. The average self-reported AI knowledge level was moderate with nearly all having an interest in improving their skills. The survey indicated that a slight majority was not involved in AI projects. While interest in AI skill development is high, there is a clear need for targeted training. This survey primarily concerned MPs, but the need for training generally applies to all medical professional categories. Efficient and safe utilisation of AI tools requires adequate training.

[9] Brady et a. Developing, Purchasing, Implementing and Monitoring AI Tools in Radiology. Radiology: Artificial Intelligence 2024; 6(1): e230513

[10] Stogiannos et al. Black box no more: A cross-sectional multi-disciplinary survey for exploring governance and guiding adoption of AI in medical imaging and radiotherapy in the UK. International Journal of Medical Informatics 186 (2024) 105423

[11] www.healthairegister.com

[12] Antonissen et al. European Radiology https://doi.org/10.1007/s00330-025-11830-8

[13] Diaz et al. Artificial intelligence in the medical physics community, Physica Medica 81 (2021) 141–146

Many features of AI are challenging, these have to be faced by both healthcare and authorities:

- **Standardisation and validation**: The "black-box" nature of many AI algorithms makes them hard to validate. Standards and protocols must be in place to ensure that AI solutions reliably produce results that are safe and accurate to the degree which is expected. Proposals for systems for quality control have been drawn up[14].
- **Hardware and software dependencies:** AI models may be optimised for specific hardware configurations. A change in hardware can impact performance. Both software and associated hardware need to be evaluated to ensure consistent and safe performance.
- **Liability and accountability:** There have to be a clearly defined responsibility in case an AI-driven process results in a mistake or harm. Is it the AI developer, the equipment manufacturer, the clinician, or the medical establishment that is responsible?
- **Integration with existing systems:** AI solutions must be integrated within existing medical systems and equipment. The safety or functionality of this integration needs to be evaluated.

The one feature of some AI systems that could be considered different from other complex technologies used in healthcare is continuous learning and model updates. Unlike most traditional software in medical devices, some types of AI models can continuously evolve, introducing e.g. bias or data drift. There has to be a framework for how often and under what circumstances AI models can be updated, and how those updates will be reviewed and approved.

1.4. AI on the European level

The European Commission highlighted the need for Europe to innovate and adopt artificial intelligence in all areas[15] but also raised the question of the need for safe implementation and use[16]. The Medical Device Coordination Group[17] issued guidance on how to classify AI products under the Medical Devices Regulations.

The EU-supported project (NFRP-2019-2020-13) EURopeAn MEDical application and Radiation prOteCtion Concept: strategic research agenda aNd ROadmap inter Linking to health and digitisation aspects (aka ROCC-N-ROLL project) a research roadmap for medical applications of ionising radiation included some aspects of AI. The report D2.6 “Regulators’ needs and expectations relevant to medical radiation protection research” includes a number of future needs[18]. The need for quality assurance of AI products is expressed as: i) Research is needed for quality assurance of new AI technologies for medical applications of ionising radiation to diagnostics ii) Research is needed for quality assurance of new AI technologies for medical applications of ionising radiation to radiotherapy. iii) Research needed to develop AI-tools for inspection and surveillance of medical applications of ionising radiation. The report

[14] Ketola et al. Testing process for artificial intelligence applications in radiology practice Physica Medica 128 (2024)
[15] European Commission. On Artificial Intelligence - A European approach to excellence and trust. White paper. Brussels, 19.2.2020 COM(2020) 65 final
[16] European Commission. REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. Brussels, 19.2.2020 COM(2020) 64 final
[17] Medical Device Coordination Group. Document Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR. MDCG 2019-11
[18] EURAMED project report included in EURAMED ROCC-N-ROLL

also mentioned the present lack of quality assurance and links the quality assurance requirements of AI products to the requirements in the European Basic Safety Standards.

2. AI tools "characteristics"

2.1 Current AI-Tools

Currently, self-learning and evolutionary AI systems, such as those based on Meta-Learning, AutoML, or Neural Architecture Search (NAS) technologies, are not yet widespread in clinical practice. These advanced algorithms, known as "self-learning or evolutionary", represent a frontier in AI research. However, their use in medicine is limited by challenges related to safety, reliability, and the difficult control of development.

Most of the AI algorithms currently integrated into clinical practice are based on supervised learning techniques. In this approach, models are trained using labelled datasets to perform specific tasks, such as recognising pathologies in medical images or classifying clinical data. Before being implemented in clinical workflows, these algorithms must undergo validation and testing processes to ensure their effectiveness, safety, and reliability.

2.2 Categorisation of AI-Tools in Radiation Protection

2.2.1 Clinical AI

Clinical AI refers to the application of artificial intelligence tools designed to assist healthcare professionals in the management, diagnosis, and treatment of patients. It employs advanced algorithms and machine learning models to analyse medical data such as patient histories, symptoms, clinical observations, and diagnostic images. By doing so, Clinical AI aims to enhance the accuracy, efficiency, and effectiveness of clinical decision-making and patient care, with the help of the available referral guidelines.

The core function of Clinical AI is to process and interpret large datasets, identifying patterns, trends, and correlations that may not be immediately apparent to human clinicians. These systems are capable of making predictions, automating diagnostic tasks, and recommending treatment options based on the analysis of historical and real-time data. They are aimed at supporting medical professionals by providing insights that would enable faster, more precise decision-making and would allow for more personalised care.

Clinical AI can be integrated into a variety of healthcare settings to assist in the diagnosis of diseases, the identification of potential risks, and the development of treatment plans. It is designed for healthcare professionals making data-driven clinical decisions. Examples of Clinical AI Tools use in the different fields include:

In Radiology:

- Automatic selection of diagnostic tests: AI can analyse the patient's medical history, reported symptoms, previous test results and referral guidelines to suggest the most appropriate diagnostic exam (e.g., MRI or CT scan).
- Automatic detection of lesions: AI can assist in analysing medical images to identify pathologies.

- Recognition and classification of pathologies: AI helps differentiate between similar conditions, such as distinguishing between benign and malignant tumours, and identifying different types of tumours.

- Assessment of recurrence risk: After surgical or radiotherapy treatments, AI can monitor the physiological development across multiple medical images to predict the risk of tumour recurrence, analysing changes in the characteristics of tumour masses over time.
- Assistance in early diagnosis: AI can identify malformations or pathologies at an early stage.
- Assistance in writing medical reports: Generative tools can help doctors write reports.

In Radiation Therapy:

- Auto-contouring: AI can recognise and separate the different OARs and CTV to draft a first treatment plan.
- Radiotherapy treatment planning: Optimises the distribution of radiation dose.
- Predictive analysis of treatment: AI analyses patient data to predict the effectiveness of treatments, aiming to help physicians choose between therapy options and reduce the risk of side effects.
- Adaptive radiotherapy: During treatment, AI monitors and automatically adjusts the patient's position and treatment parameters to ensure precision in radiation delivery.

In Nuclear Medicine:

- Automatic interpretation of PET and SPECT images: AI examines images to detect metabolic abnormalities, indicative of conditions like cancer or cardiovascular diseases.
- Quantification of activity: AI can increase quantitative accuracy of activity in PET/SPECT images, improving diagnosis and treatment planning, such as identifying tumour metastases.
- Prediction of treatment response: By analysing PET/SPECT images, AI can predict how a tumour will respond to treatments like radiotherapy or chemotherapy.
- Early detection of cardiovascular or neurological conditions: AI can identify early signs of conditions like myocardial ischemia or neurological disorders, improving the timeliness of diagnosis.

2.2.2 Technical AI

Technical AI refers to a subset of artificial intelligence that focuses on optimising technological and operational functions of medical equipment, specifically within diagnostic imaging and therapeutic devices. Unlike Clinical AI, which is centred on patient management and diagnosis, technical AI aim to enhance the accuracy, efficiency, and safety of equipment and processes used in medical procedures. This category of AI comprises algorithms embedded directly within the hardware or software of imaging machines, treatment devices, and diagnostic tools. These algorithms work autonomously or semi-autonomously to improve the performance of medical technologies, ensuring that they operate with a set of precision.

Technical AI aims to optimise workflow, reduce human error, and ensure that medical equipment operates with minimal intervention. By focusing on aspects such as image quality, radiation dose optimisation, and equipment maintenance, technical AI may play a role in

ensuring that healthcare providers can deliver more reliable and effective treatments. The main objective of technical AI should not be only to improve the operational aspects of medical equipment but should be also to enhance overall patient safety by reducing unnecessary exposure to radiation, optimising treatments, and reducing equipment failures.

As part of its operational role, technical AI aims to provide high standards of quality control in medical imaging and radiotherapy. While clinical AI typically supports healthcare professionals like doctors and radiologists in decision-making, technical AI is more commonly used by medical physicists and radiology technicians to monitor, calibrate, and maintain the equipment used in diagnosis and treatment. Technical AI has the potential to enhance healthcare workflow efficiency and improve safety.

The applications of technical AI can be broadly divided into two key areas: **patient exposure optimisation** and **quality control**. Both areas aim to improve the reliability and effectiveness of medical interventions while ensuring patient safety and operational efficiency.

2.2.2.1 Patient Exposure Optimisation

Technical AI could play a role in minimising unnecessary patient exposure to radiation and optimising treatments. This is particularly important in diagnostic imaging and radiotherapy, where excessive exposure can pose risks to patients. Key applications in this area include:

- Exposure optimisation.
- Patient positioning.
- Automatic adjustment of equipment parameters and dose optimisation.
- Image reconstruction.
- Image post-processing with noise reduction / contrast enhancement.

By focusing on these aspects, technical AI may enhance patient safety and reduce the risks associated with medical radiation procedures.

2.2.2.2 Quality Control

Technical AI may also ensure a sufficient standard of quality control in medical imaging and therapeutic devices. This involves maintaining the accuracy, reliability, and efficiency of equipment, which directly impacts the quality of care delivered to patients. Key applications in this area include:

- Image reconstruction.
- Image quality control.
- Automatic image segmentation.
- Prediction and prevention of equipment failures.

These quality control measures may ensure that medical equipment operates at its highest possible level of precision, contributing to more reliable diagnoses and treatments.

2.3 Quality assurance of AI technology

Systematic quality control of AI applications will be a major challenge. Ketola et al[19] propose a three-phase testing process where multidisciplinary teams (physicians, physicists, IT experts) should be involved:

Phase 1: Initial Evaluation – Market analysis, identification of relevant AI applications, and definition of requirements.

Phase 2: Testing and Analysis – Includes retrospective and prospective testing to evaluate AI performance using local data. Ethical aspects such as transparency should also be covered.

Phase 3: Evaluation and Deployment – use of Key Performance Indicators (KPIs) (e.g., sensitivity, specificity, user feedback) to evaluate performance, summarising test results, decision-making, and integrating the AI into clinical workflows.

They emphasise the importance of testing with local patient data to identify potential biases and other weaknesses in the algorithms. Also, continuous monitoring is required, ensuring long-term quality. A similar stepwise approach has also been recommended[20]. Here, the following six phases are considered: analyse the needs (including an initial risk assessment), market analysis, evaluation of own ability to implement (human and technical factors), procurement process, introduction and quality assurance, and finally, how to operate and manage the AI-system (including monitoring).

3. The legal landscape

Three regulations need to be considered by radiation protection authorities: the Euratom Basic Safety Standards Directive (BSSD), the European AI Act and the European Medical Device Regulation (MDR). Each of these regulations have a distinct area of focus— ethical oversight for AI within medical devices via the AI Act, releasing and maintaining safe medical devices on the EU market under the MDR and radiation protection of the public, patients and staff when using medical devices through the BSSD. In addition, the Regulation on health technology assessment (HTAR) may also need to be considered.

3.1 Euratom BSSD

The Euratom BSSD (Council Directive 2013/59/Euratom) specifically addresses radiation protection for the public, patients and workers across all EU Member States. It applies to any practice using medical devices that emit ionising radiation or radioactive sources used in medicine. It complements the MDR by ensuring that radiation protection measures are embedded in their usage, maintenance, and disposal. The responsibility to comply with the national rules resulting from the directive lies with the license holders and practitioners.

[19] Ketola et al. Testing process for artificial intelligence applications in radiology practice Physica Medica 128 (2024)
[20] Norwegian Directorate of Health (2025 May 23). Report on quality assurance: Use of artificial intelligence in health and care services [Internet]. Helsedirektoratet. https://www.helsedirektoratet.no/rapporter/report-on-quality-assurance-use-of-artificial-intelligence-in-health-and-care-services

For medical exposures, it focuses on:

- Justification of medical exposures.
- Optimisation of radiation protection.
- Licensing, quality assurance program and testing of equipment and procedures.

And more generally on:

- Quality assurance of medical procedures.
- Licensing of the use of the medical device.
- Education and training of staff using the medical devices.
- Learning from accidental and unintended exposure.

The stakeholders consist of practitioners (i.e., licence holders), RPEs, MPEs and national competent authorities.

The following articles of the BSSD could have a link to AI usage and must be observed closely, and the following challenges have been identified:

3.1.1 Article 5 General principles of radiation protection: Justification Optimisation and Dose Limitation; Article 55 Medical Exposure Justification; Article 56 Optimisation

AI embedded in clinical decision support systems can assist in recommending or prioritising diagnostic procedures based on patient data. However, the “black-box” nature of many AI algorithms may make it difficult for practitioners to understand and validate the reasons behind AI-suggested medical exposures. This lack of transparency could make it challenging to determine whether each medical exposure is justified. Over reliance on AI-based tools could lead to unjustified medical exposures.

AI-based tools are increasingly used to control and enhance the exposure and image reconstruction, which affects the radiation dose and can also have an impact on the clinical output. Ensuring that AI algorithms are properly calibrated and tested across different populations and modalities is a significant technical and regulatory challenge.

Authorities may need to emphasise the importance of guidelines for how AI should handle patient-specific justification (clinical AI tools) and optimisation tools (technical AI tools). This may include requiring transparency in AI output or developing criteria to assess the validation of AI-generated recommendations for radiation use and as well as for optimisation.

3.1.2 Article 14, 15, 18, 59 Training

The integration of AI requires additional training for healthcare professionals to understand how to use, interpret and monitor AI-powered systems. Healthcare authorities must ensure that training curricula are updated to cover the functionality, risks and limitations of AI so that healthcare professionals are equipped to challenge or question AI results when appropriate. In addition, new roles and expertise may be required for the use of AI.

3.1.3 Article 19 Justification of Practices

Authorities must ensure that the evaluation of when, what, how and which AI components can be used safely is included in the justification process.

3.1.4 Article 27, 28 Licensing

Licensing procedures should ensure that processes are in place in the hospital for evaluating AI systems, covering areas such as accuracy, consistency, reproducibility and compliance with radiation safety principles.

3.1.5 Article 57 Responsibilities

The introduction of AI may blur the lines of responsibility, as both professionals and AI systems influence treatment outcomes. Authorities will face the challenge of defining accountability for AI-influenced decisions regarding patient safety, including exposure levels.

3.1.6 Article 58 Procedures

AI-driven procedures must be carefully documented, standardised, and incorporated into existing procedural frameworks. Any variations introduced by AI – such as different exposure levels based on algorithmic judgment or data changes – must be applied consistently, understood by operators, and regularly reviewed to ensure they meet procedural standards. This will be done during treatment or examination, which will impact the ability to control changes and consequences. The higher the consequences if errors occur, the higher the priority, for example, adaptive radiotherapy.

3.1.7 Article 60 Equipment

AI-enhanced equipment requires unique protocols for quality assurance, maintenance, and calibration, which adds complexity to the regulatory body that oversees the safety of the equipment. AI systems must be calibrated and tested as part of routine equipment quality assurance. However, the unique nature of AI calibration – often involving large amounts of data and complex setup parameters – can make these tasks more challenging than for traditional equipment. Ensuring that AI algorithms are kept up to date and operate correctly across different machines is critical to avoiding incorrect exposure or image errors.

3.1.8 Article 63 Accidental and unintended exposure

If an AI system is involved in an unintended exposure, identifying the root cause can be complicated due to the complex and sometimes opaque nature of AI decision-making. Incident investigation protocols may need to assess both human and AI factors and contributions, including the AI's algorithmic processes.

3.2. EU Artificial intelligence Act

The European Union has introduced its first legislation on artificial intelligence: The EU AI Act[21] (EU, 2024). It assigns AI applications to **four risk categories**. Firstly, applications and systems that pose an unacceptable risk, such as social scoring systems or manipulative AI, are prohibited. Secondly, high-risk applications, such as a tool for scanning CVs that ranks applicants, are subject to special legal requirements. All medical devices fall into this category. Finally, the applications with limited or minimal risks (regarded as two separate levels) , such as chatbots and deep fake where end-users must be made aware that they are interacting with AI, remain largely unregulated.

[21] EU. (2024, July 12). Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence. Official Journal (2024).

According to the EU AI Act, **the provider** is the entity that develops, manufactures or releases an AI system on the EU market, which bears the main responsibility for compliance with statutory standards, risk assessment and necessary certifications. The **deployer** uses the AI system for its intended purpose, follows usage guidelines, monitors performance and reports incidents without modifying the system for professional activities. The **distributor** acts as an intermediary and makes the AI system available on the EU market while ensuring it has the necessary conformity marking and documentation, and notifies the authorities if safety or compliance issues arise.

The key requirements for risk categorisation of medical devices are summarised in Figure 3.

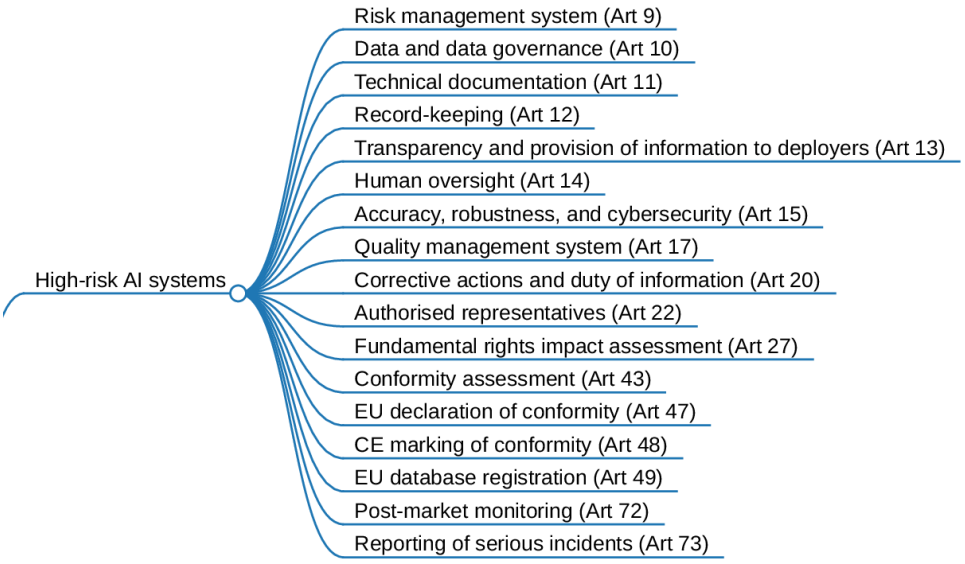

Figure 3: Hierarchical tree structure of the EU AI Act requirements for high-risk AI systems adapted from[22] (Busch, 2024), non-exhaustive list of the key requirements in the AI Act. Articles not included refer to the cooperation and interaction with authorities or specific obligations for other stakeholders involved. AI artificiel intelligence, Art article, CE Conformité Européenne, EU Européen Union.

For high-risk AI systems, the majority of obligations fall on providers (developers).

High-risk AI **providers** must:

- Establish a **risk management system** throughout the high-risk AI system's lifecycle;
- Conduct **data governance**, ensuring that training, validation and testing datasets are relevant, sufficiently representative and, to the best extent possible, free of errors and complete according to the intended purpose.
- Draw up **technical documentation** to demonstrate compliance and provide authorities with the information to assess that compliance.
- Design their high-risk AI system for **record-keeping** to enable it to automatically record events relevant for identifying risks and substantial modifications throughout the system's lifecycle.
- Provide **instructions for use** to downstream deployers to enable the latter's compliance.

[22] Busch, F. (12. August 2024). Navigating the European Union Artificial Intelligence Act for Healthcare. npj Digital Medicine, S. 210.

- Design their high-risk AI system to allow deployers to implement **human oversight**.
- Design their high-risk AI system to achieve appropriate levels of **accuracy, robustness, and cybersecurity**.
- Establish a **quality and risk management system** to ensure compliance.

The providers must also establish post-market monitoring systems under Article 72, enabling continuous evaluation of AI performance and patient safety. This is challenging since some health effects, including those of ionising radiation, become apparent only after a long time. Effective monitoring requires robust infrastructure; The European Society of Radiology (ESR) believes the European Health Data Space (EHDS) could facilitate this[23]. Authorities might have to ensure adequate surveillance.

Deployers, i.e., natural or legal persons that deploy an AI system in a professional capacity, not the end users of high-risk AI systems, also have some obligations with respect to the AI Act. The deployer is responsible for using the system in accordance with the provider's instructions, ensuring appropriate human oversight by competent personnel, monitoring the system's operation, keeping relevant logs, informing affected persons when applicable, and cooperating with authorities in compliance and reporting obligations.

3.2 Medical Devices Regulations (MDR)

The European MDR (EU 2017/745) sets a framework for ensuring the safety and performance of medical devices, including those that use or emit ionising radiation. Its primary scope is patient safety and clinical effectiveness, ensuring that medical devices marketed and sold within the European Union meet standards of quality, safety, and reliability.

Under the MDR, **manufacturers** must meet requirements regarding the production and post-marketing performance, focusing on:

- Quality management system used in the production process.
- Use of technical standards and common technical specifications.
- Surveillance and vigilance during the life cycle of the product.

The MDR also imposes requirements for the devices, such as:

- General safety & performance requirements. Medical devices must conform to specific European technical standards (EN standards).
- Clinical evaluation of safety product performance, mandatory for high-risk devices.
- Classification, conformity assessment and certification, necessary for the making available of devices on the market.

The stakeholders consist of manufacturers, notified bodies (entities responsible for conformity assessment and certification), national competent authorities and the EC (MDCG and experts).

[23] Kotter, E. et al. (2025) Guiding AI in radiology: ESR's recommendations for effective implementation of the European AI Act. Insights Imaging 16, 33. doi: 10.1186/s13244-025-01905-x

3.3 National AI legislation and initiatives

3.3.1 Switzerland

Switzerland has signed Council of Europe Convention on Artificial Intelligence (AI). Only key areas relevant to fundamental rights, such as transparency, data protection, non-discrimination and oversight will be subject to general, cross-sectoral regulation. In addition to legislation, non-legally binding measures such as self-disclosure agreements or industry solutions will be developed.

3.3.2 USA

On 28 March 2024, the US government (Office of Management and Budget OMB) issued a memorandum entitled 'Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence' [24] (OMB, 2024). This formulates guidelines for the use of artificial intelligence (AI) by federal authorities. Among other things, it emphasises the need to exploit the possibilities of AI (e.g., to promote innovation) while managing its risks.

3.3.3 Norway

To address the upcoming challenge of an increasing aging population and the lack of access to healthcare personnel, the Norwegian government has high expectations for an increased use of AI. The National Digitisation Strategy[25] focuses on establishing a national infrastructure for AI, while the governmental White Paper on Health[26] highlights how AI can play a role in ensuring a sustainable health service. As a consequence, several national measures for the safe and effective implementation of AI in healthcare have been initiated by the Ministry of Health. In Norway, a joint AI-plan was launched in 2024[27], focusing on sector collaboration (including AI advisory board), cross-agency regulatory guidance, framework for use (including quality assurance), use of large language models and boosting AI skills. The main focus areas are to enhance sector cooperation, provide cross-agency regulatory guidance, establish a robust framework for the use of AI and identify competence needs for digital transformation with AI in the healthcare sector. In addition, a national framework agreement for the use of AI in diagnostic imaging was signed in 2024. In 2025, a report on quality assurance of AI in healthcare was published[28], and a report on large language models is now under preparation. The government also supports AI research and has allocated a significant amount of money to the National Research Council to strengthen the research program on AI called the "AI-billion". The Norwegian Radiation and Nuclear Safety Authority (DSA) participates in the Joint AI plan and is a member of the National AI Advisory Board. The role and mandate are to increase awareness of radiation protection regulations and address radiation protection issues related to the implementation of AI in healthcare.

[24] OMB, O. o. (28. March 2024). www.whitehouse.gov. Von https://www.whitehouse.gov/wp-content/uploads/2024/03/M-24-10-Advancing-Governance-Innovation-and-Risk-Management-for-Agency-Use-of-Artificial-Intelligence.pdf

[25] https://www.regjeringen.no/en/dokumenter/the-digital-norway-of-the-future/id3054645/

[26] https://www.regjeringen.no/no/dokumenter/meld.-st.-9-20232024/id3027594/

[27] https://www.helsedirektoratet.no/rapporter/joint-ai-plan-for-the-safe-and-effective-use-of-ai-in-the-norwegian-health-and-care-services-2024-2025

[28] Norwegian Directorate of Health (2025 May 23). Report on quality assurance: Use of artificial intelligence in health and care services [Internet]. Helsedirektoratet. https://www.helsedirektoratet.no/rapporter/report-on-quality-assurance-use-of-artificial-intelligence-in-health-and-care-services
The Digital Norway of the Future https://www.regjeringen.no/en/dokumenter/the-digital-norway-of-the-future/id3054645/

3.3.4 Italy

The Council of Ministers approved a bill regulating the use of artificial intelligence in sectors that the Regulation entrusts to the normative autonomy of Member States. The bill (S.1146) was approved by the Senate on 20 March 2025 and transmitted to the other parliamentary chamber. The bill became Law No. 132 of September 23, 2025, which entered into force on October 10, 2025. The bill aims to promote the correct, transparent and responsible use of artificial intelligence in an anthropocentric way to improve citizens' living conditions and social cohesion. In particular, in the healthcare sector, the bill stipulates that the use of AI:

- must contribute to improving diagnostic and treatment processes in a supportive role without prejudicing the professional's decision-making power;
- cannot establish discriminatory criteria for access to healthcare services;
- must contribute to improving the social inclusion for people with disabilities.

Additionally, Section V of the Italian Higher Health Council, a technical advisory body to the Minister of Health, published “Artificial intelligence systems as a diagnostic support tool” in November 2021 to safely introduce AI systems into clinical practice and compete internationally in their implementation and development.

4. Possible impact on radiation protection authorities

In healthcare, several AI tools are already in use, as evidenced by the initial overview that informed the work in our work package (WP). This growing use underlines the need for adaptation of national regulations and the work of the authorities.

The impact of AI on radiation protection can be significant. For example, clinical AI systems may influence justification processes and clinical workflows. Clinical decision support tools must account for the specific considerations associated with examinations and treatments involving ionising radiation. These systems should be based on referral criteria that incorporate radiation risks and justification principles aligned with radiation protection standards.

AI tools used for image interpretation and reporting are typically trained on datasets of a particular image quality. However, image quality can vary as a result of the optimisation processes, potentially affecting both diagnostic accuracy and the reliability of AI support. That is, the clinics may have limited opportunities to perform their own optimisation work. Similarly, technical AI can alter individually planned radiation treatments, impacting not only patient exposure but also the conditions required for validation and quality assurance.

There is an urgent need to include AI technology into existing authorisation and surveillance frameworks. Surveillance bodies should proactively adapt their processes to ensure the safe and effective implementation of AI in healthcare. As many member states have already implemented AI systems—both clinical and technical—it is essential to establish a sustainable framework for high level national governance of these tools. Efforts are already underway in several countries to implement the AI Act at the national level. This framework must strike a balance: it should not hinder innovation that could benefit patients, but it must ensure the safe and effective implementation. Health authorities and decision-makers are often unaware of the radiation protection aspects of the use and that national radiation protection regulations and thus the EU Basic Safety Standards (EU-BSS) complement both the AI Act and the Medical Device Regulation (MDR). As a result, radiation protection authorities are frequently overlooked as stakeholders in the development of national AI governance frameworks.

Consequently, national strategies and measures may fail to adequately address radiation protection concerns or the role of the relevant authorities. Radiation protection authorities should therefore actively engage in national initiatives related to the safe implementation of AI in healthcare. Radiation protection authorities in member states should seek to actively participate in ongoing national initiatives, rather than developing separate frameworks focused solely on radiation protection in the context of AI implementation. Cross-agency collaboration promotes shared knowledge, coordinated action, and more comprehensive oversight of the benefits and challenges associated with the safe and effective integration of AI in healthcare.

4.1 The need for knowledge acquisition

National authorities must strengthen their understanding of AI tools—particularly in relation to the risks they may pose in the use of radiation in healthcare, as well as the opportunities they offer to advance radiation protection. As AI technologies become increasingly integrated into diagnostic imaging and radiotherapy, they have the potential to influence patient safety and impact treatment outcomes, both positively and negatively. A thorough understanding of these tools is essential to ensure their use aligns with existing radiation protection regulations and best practices.

To effectively prepare for the integration of AI into regulatory frameworks, authorities should consider the following actions:

- Stay informed through education, training and collaboration
- Participate in specialised training programs, workshops, and conferences focused on AI applications in healthcare. Build partnerships with medical professionals, AI developers, and research institutions to stay updated on technological developments and their regulatory implications.

- Develop guidelines and policies
  Develop, review and adapt existing guidelines and regulations to ensure they appropriately address the unique characteristics and challenges of AI systems.

- Identify potential radiation risks
  Identify potential risks associated with the use of AI in radiation-based procedures. Integrate risk management strategies into supervision and authorisation.

Building knowledge is essential to identifying and understanding the significance of various AI applications. National radiation protection authorities should begin, or continue, exploring how to incorporate AI tools into their own management and supervision processes. The use of AI has the potential to enhance the quality of review and evaluation in safety assessments, which form the foundation for authorising practices involving ionising radiation in healthcare. Implementing AI within regulatory and oversight processes should follow the phases outlined in Chapter 2.3. Strong leadership, targeted knowledge development, and a commitment to digital transformation are critical to achieving this goal.

4.2 Supervision

This section outlines an approach to supervision of AI systems. Since the use of AI in healthcare is still new to both authorities and healthcare, the methods will need to be developed, adapted, and refined over time. Changes in methods and strategy may also prove necessary as experience grows. Expectations and requirements from both regulators and healthcare providers must be carefully balanced and continuously adapted. Patient safety must remain a top priority. At the same time, inspection parameters should be chosen carefully so that oversight does not unnecessarily hinder innovation and the development of new AI applications.

The very basics to address during an inspection is to verify that the undertaking has developed a sustainable system for implementing and use of AI, containing all phases from planning, risk-assessments, procurement, implementation, verification, QC and QA, drifting and monitoring. Written procedures for QC and QA should be available and implemented in the quality management system and the QMS should adequately address how to ensure human and technical resources together with adequate skills and knowledge. The role of the medical physics expert (MPE) and all relevant personnel should be clearly stated. Strong leadership involvement and safety culture should include radiation protection aspects in relation to AI-systems.

Routines for reporting of accidents and unintended events and how this is used as input in risk-assessments as part of the post implementing monitoring of the AI-system should be inspected. Statistics of reported events related to AI and how these events are followed-up is a manageable task to inspect. Further, different strategies and topics to inspect may differ for clinical-AI and technical-AI. For clinical-AI, local validation on local data is crucial, level of human oversight and possible impact on roles and responsibilities in relation to EU-BSS should be addressed. For technical-AI, proper acceptance testing and QC-regimes is of high importance. This can be a challenging task, both for the undertaking and the inspector, since adequate QC protocols may not be available. The protocols are essential for adequately monitor and check for proper functionality of the system.

The development of an inspection method to AI systems could be developed regarding different levels, starting at Level 1 and then evolving to be more and more sophisticated as illustrated in Figure 4.

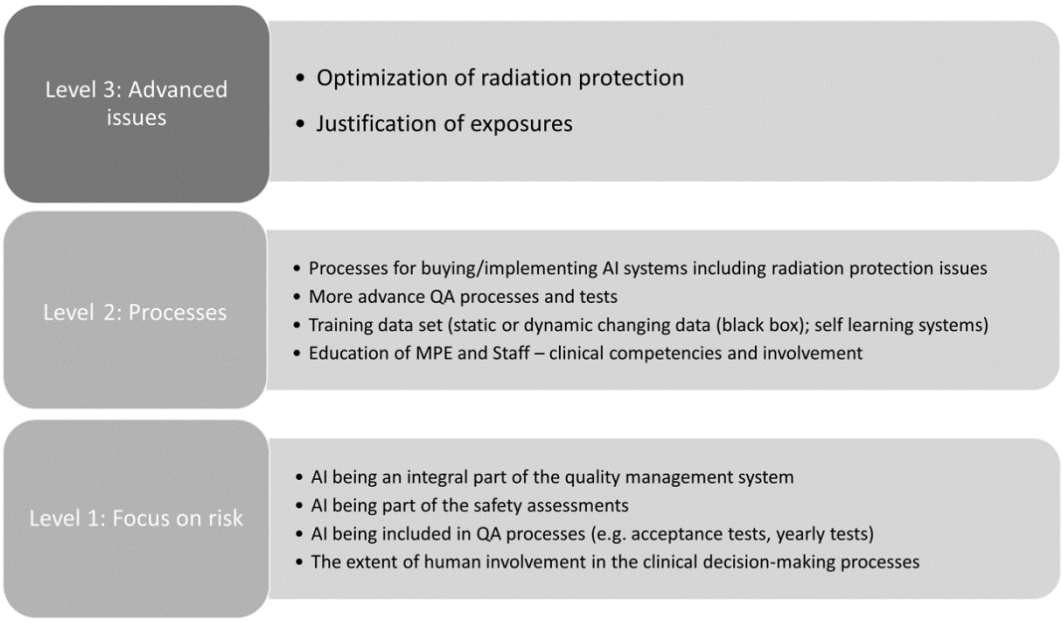

Figure 4. Supervision activities may be developed across these three levels.