HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Position paper

HERCA Working group on Medical Application

HERCA's view on patient radiation protection in medicine

2: - Essential requirements of a Quality Management System (QMS) regarding radiation protection and safety

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Purpose and Scope:

The primary purpose of this HERCA position statement is to enhance the radiation protection of patients, staff and the public by defining the essential requirements for radiation protection and safety that should be included in a Quality Management System (QMS) in medical services using ionising radiation within Member States. By giving a general recommendation to the national radiation protection authorities on what a QMS should include and how a QMS should be implemented in radiological facilities, HERCA strives to enhance radiation protection beyond the basic requirements of the current regulations.

In many Member States the use of a QMS in medical services is mandatory while in others it is at least strongly recommended. The QMS of a department using ionising radiation should be an integrated part of the overall QMS of the medical service (e.g. hospital, clinic, institute. etc.). The purpose of this HERCA position statement is to state the importance of a QMS and why radiation protection should be a part of the overall quality management system of the medical service and not a standalone entity. A QMS should integrate all of an organisation's systems and processes into one complete framework, enabling the organisation to work as a single entity with unified objectives.

In this position statement the essential requirements of a QMS on radiation protection and safety are defined and the central elements of a QMS are identified. The extent of the QMS should depend on the size of the medical service using ionising radiation and the potential risk to patients, staff and the environment and therefore a graded approach should be used when establishing or reviewing a QMS. A more comprehensive and extensive QMS should be implemented when diagnostic or treatment procedures are more complex, and/or when the potential risk to the patients, staff or the environment is greater.

A QMS which includes radiation protection and safety helps ensure consistent practices. The QMS should be applied across all aspects of radiological care - from initial indication of a medical exposure, to image acquisition, diagnostic finding and finally to the reporting - or in therapeutic applications - from treatment planning to safe, optimised treatment delivery and patient follow-up. An effective QMS helps to ensure that patients receive safe, high-quality radiologic examinations or treatments. The QMS should also consider radiation protection of staff, the environment and the public.

Although the Council Directive 2013/59/EURATOM does not stipulate that a QMS must be in place, this position statement of HERCA recommends that national radiation protection authorities should encourage medical services to implement a QMS. Including radiation protection comprehensively in the QMS is useful and will enhance radiation protection beyond the requirements of the regulations. Furthermore, when a QMS which integrates radiation protection is implemented into clinical practice, a medical service can demonstrate its comprehensive compliance with the legislative requirements necessary for using ionising radiation in medical applications.

Definitions:

Quality Management System:

A Quality Management System (QMS) is a formalised system that documents processes, procedures, responsibilities, and resources needed to achieve quality objectives and ensure continuous improvement in an organisation's operations and outcomes. The purpose of a QMS is to ensure high quality while planning, leading, and enhancing operations. It encompasses the identification and definition of roles, responsibilities, authority, risks, and opportunities, all contributing to continuous improvement. By utilising documented processes and routines alongside systematic improvement efforts, processes are expected to achieve the desired quality standards and to improve with time. This systematic approach to quality improvement should include risk analysis, self-monitoring, and the management of deviations.

Quality control is part of quality assurance, and both are integral components of a QMS (see Figure 1).

Figure 1: Relationship between quality management system, quality assurance and quality control.

Quality Assurance:

Quality Assurance (QA) is a set of systematic activities and processes designed to ensure that a structure, service, system, component or procedure meets defined agreed standards and performs reliably, safely, and consistently[1].

Quality Control:

Quality Control (QC) means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled[1].

Introduction:

The advantages of using ionising radiation in medical applications for diagnostic and treatment of diseases are well recognised. However, with the rapid increase in the use of these medical applications in recent decades, it is crucial to ensure that the management of patient safety is appropriately maintained. All examinations and treatments must be justified and thoroughly optimised to minimise unnecessary dose. Unfortunately, this is not always the case; several studies[2] indicate that 20% to 40% of all examinations are unjustified or should have been conducted using alternative modalities such as MRI or ultrasound. Additionally, the radiation doses received from similar types of examinations can vary significantly between different hospitals both locally and across Europe[3]. Implementing a Quality Management System (QMS) which includes all aspects of radiation protection in all medical services using ionising radiation, will improve the radiation safety situation in Europe.

Medical radiological applications are utilised across various departments in hospitals and facilities, involving multiple professionals such as medical doctors, radiographers, radiation therapists, medical physicists, nurses and engineers. Therefore, it is crucial to integrate radiation protection into the overall QMS within medical services to ensure the safe delivery of patient care. Experiences of the national radiation protection authorities, along with investigation and analyses of reported radiation incidents, have revealed that noncompliance with radiation protection standards often stems from deficiencies in overall management and a lack of control or oversight of existing procedures. Through the active implementation and consistent integration of a comprehensive QMS into daily practice, the goals of preventing or reducing radiation incidents and mitigating their consequences can be effectively achieved.

[1] 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

[2] e.g. EU-JUST-CT https://www.eurosafeimaging.org/eu-just-ct/about report accessible at https://op.europa.eu/en/publication-detail/-/publication/dc071d95-7179-11ef-a8ba-01aa75ed71a1, Almen et al. SSM (2009) Survey on justification of CT exams in Sweden, Oikarinen et al. Eur Radiol (2009) Unjustified CT exams in young patients

[3] International variation in radiation dose for computed tomography (BMJ, 2019, Jan 2;364:k4931); EuroSafe Imaging: Radiation Protection 180 (European Commission, 2014); Benchmarking adult CT-dose levels to regional and national reference levels (Insights Imaging, 2017, Sep 7;8(5):513–521.); Nuclear cardiology practice and associated radiation doses in Europe (EJNMMI, 2015, Dec 19;43:718–728)

There are many different roles, duties and responsibilities within the community using ionising radiation for medical purposes. While the role of national radiation protection authorities is clearly defined in principle, differences may arise at the national level for example due to different legislative interpretation within Member States. In this regard, this position statement aims to provide a better understanding of the national radiation protection authorities authority's role concerning implementation and control of the QMS in medical services, which may in turn minimise the differences across member states.

All European radiation protection legislation is based on ICRP recommendations[4], which are transposed into the latest European radiation protection directive (BSSD)[5]. While the BSSD does not stipulate that a QMS is mandatory, based on experiences in regulating services, HERCA's view is that a QMS facilitates medical services to reach compliance with the regulations. Additionally, it can drive radiation protection beyond the basic requirements of the regulations to further enhance the quality and safety of the service for patients and optimise radiation protection.

A modern radiation protection authority must be willing to respond to changes, ensure that their roles and tasks are up-to-date, and keep up with the technological developments in health care. Several roles and responsibilities for the radiation protection authority have been identified by stakeholders to facilitate medical services to reach an appropriate level of radiation safety[6]. However, it is not the role of the radiation protection authority to oversee day-to-day operations, such as the justification and optimisation process in detail, as these are the responsibility of the medical service, which is also accountable for radiation safety and radiation protection. One of the main tasks of a radiation protection authority is to verify compliance with the regulations. One mechanism to achieve this is to encourage organisations to establish a QMS that encompasses all processes relevant to radiation protection. The radiation protection authority (or others delegated with responsibility, such as professional bodies or auditing teams) can act as an adviser and should be active in communicating and providing the management team of the medical service with useful information about what a complete and comprehensive QMS should include.

[4] ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
[5] 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
[6] An extensive discussion of the roles is presented in the HERCA report on "Stakeholder Involvement in Medical Practices"

Position Statement of HERCA:

Essential requirements of a quality management system regarding radiation protection and safety

A QMS is relevant in all medical services. This position statement focuses on the QMS aspect related to procedures using ionising radiation for medical procedures. This includes radiological procedures in radiology (medical and dental), nuclear medicine, radiation oncology departments and in all other departments using ionising radiation such as angiology, cardiology, urology, gastroenterology, general surgery, orthopaedics and pain therapy.

A QMS integrating radiation protection and safety is an essential tool for effective radiation protection. The QMS should be an integral system in the sense that all possible influencing factors on quality and safety on the entire patient pathway, along with the safety of the staff and the environment should be taken into account. The QMS must, in particular, include the procedures for justification and optimisation of the applications of ionising radiation on patients, and include radiological safety of the staff and the environment and define the roles and the responsibilities of all relevant stakeholders.

The QMS should be dynamic and agile in the sense that it can advance with the rapid technological developments (i.e. artificial intelligence, detector technology, etc.) in healthcare and should be able to include new applications, radiological procedures or techniques. Therefore, the QMS requires continuous improvement and regular updates.

The QMS should be effective in the sense that it is easily accessible and usable for the medical staff in their daily work and generally creates an added value to the medical service.

When wider systems of quality management in healthcare are in place and working effectively, the radiation protection authority should encourage medical radiological services to incorporate radiation protection of medical exposures into these systems. Similarly, if a national system for clinical auditing is in place medical radiological services should be encouraged to participate and this should be described in the QMS as a dedicated process.

What are the most important radiation protection components in a QMS?

A QMS includes several key components aimed at improving the quality of patient care, enhancing safety and ensuring compliance with standards and regulations. The key building blocks or components of a QMS, as shown in Figure 2, should include:

Figure 2: Key components of a quality management system

Leadership:

Leadership is an essential component to incorporate and maintain an effective QMS. It is the driving force behind all components. The senior management team of a medical service facility has responsibility for the implementation of the following elements:

1. **Quality policy and objectives:** Establish clear quality objectives and a quality policy that demonstrate the medical service's commitment to maintain high standards of patient care and safety.

2. **Organisational structure:** Define roles, responsibilities, and competencies within the medical service, including appointing the adequate number of quality management staff at appropriate managerial levels.

3. **Empowerment:** Encourage, motivate, inspire, and challenge the entire team to deliver their best performance. Empowerment involves transferring authority and responsibility from senior management to frontline quality team leaders.

4. **Process and activity management**: Ensure the development, documentation, and standardisation of clinical procedures and work processes - such as referring for a radiological procedure based on the clinical indication, image acquisition, treatment, reporting, and archiving - are clearly defined and managed. This should incorporate the dynamic nature of technological advancements, especially with the rapid growth in the use of Artificial Intelligence in medical radiological facilities[7].

5. **Compliance with legal requirements and standards**: Ensure compliance with all relevant legal requirements and adhere to recommendations for Good Clinical Practice. The QMS should describe how this will be achieved.

6. **Patient focused:** Ensure all processes are patient-centred, justified and optimised. Patient care should emphasise respect, communication, and individualised attention and focus on meeting patients' needs and expectations while providing them with relevant information.

7. **Stakeholder communication:** Establish effective communication with all stakeholders, including patients, employees, referring physicians, suppliers, equipment manufacturers, and the national radiation protection authority.

Resources:

When evaluating resource needs, the senior management team should take the following factors into account:

8. **Competence management:** Ensure that staff are appropriately qualified and receive continuous training and support in all process workflows, both in radiation protection and in the QMS.

9. **Control and surveillance:** Manage the radiological installation, by defining the purchasing process and how the installation is subsequently managed, as well as processes for the disposal of equipment that is no longer needed. Maintenance, technical verification, calibration, and quality control (as part of quality assurance) of the equipment is also essential to ensure it is functioning properly.

10. **Information management:** In diagnostics: ensure the use of relevant and appropriate information systems such as HIS (Hospital Information System), RIS (Radiology Information System) and PACS (Picture Archiving and Communication

[7] HERCA WGMA Report on Artificial intelligence in healthcare - possible impact on radiation protection

System) to support the QMS. This also includes patient data management and monitoring of patient radiation exposure (e.g. with a Dose Management System DMS). Furthermore, it includes the management of the occupational dose of staff and, if required, doses concerning the environment. In therapy: ensure the use of a dedicated Oncology Information Systems (OIS) to support the QMS, including a Therapy Planning System (TPS) and patient data management.

Risk and Safety:

When evaluating risk and safety needs, the senior management team should ensure that the following factors are considered:

11. **Risk management:** In diagnostics: Identify and minimise risks in connection with imaging examinations, and ensure all radiation protection measures are employed. In therapy: Identify, assess and minimise risks associated with radiotherapeutic procedures including all activities for treatment prescription, treatment planning and treatment delivery.

12. **Security management:** Consider and plan for the prevention and detection of, and response to, theft, sabotage, unauthorised access, illegal transfer or other malicious acts involving radioactive material and radiological equipment.

13. **Emergency preparedness:** Plan for situations where equipment failure may occur and for the consequences for the patient treatment (e.g. shifting the treatment to another treatment facility). Planning for emergencies involving the handling of radiological equipment with radioactive substances and the protection of the staff, the population and the environment. Protocols for normalising the emergency (e.g. decontamination of radioactive material), should be considered.

14. **Data protection and data security:** Ensure the protection of staff and patient-related data in accordance with data protection laws and implementing data security measures.

15. **Management of environmental protection for nuclear medicine applications:** Ensure comprehensive waste management and contamination control. Provide patients with all relevant information and guidelines, living rules and behavioural recommendations for the patient to protect others, such as family members, after procedures are completed.

Review:

Reviewing a QMS is essential to ensure that it remains suitable, adequate and effective, and that it continues to align with strategic goals and regulatory requirements.

16. **Review of the QMS:** regularly review to verify that all processes described in the QMS represent the actual state. The review should ensure that the processes are lived, respected and followed by the involved staff. The frequency of review should be defined by the senior management and documented in the QMS. Further, it is important to identify non-compliances with the national regulations in the processes of the QMS and implement necessary corrective actions and updates.

The following points will provide additional insights for reviewing the QMS:

17. **Clinical Audits**[8]**:** Ensure preparation for and participation in an appropriate and comprehensive Clinical Audit programme.

18. **Incident Reporting and Learning System**[9]**:** Establish a system for reporting anonymised incidents and near misses with the following essential components: an adequate reporting system, systematic analysis of incoming reports, an appropriate response to the reports received, and the ability to learn from experience and share this learning.

19. **Notification of incidents to the authority:** Outline the procedure for notifying the relevant authorities about reportable medical incidents, in compliance with national requirements. Additionally, a mechanism to receive feedback of reported incidents from the national authority should be considered.

20. **Complaints management:** Establish an effective system for recording, processing and analysing patient and staff complaints as part of the feedback mechanism.

The following two items - Document Management and Continuous Improvement - are overarching processes of the Quality Management System that encompass all the previously mentioned elements.

Document management

The QMS (processes, forms, records, and templates) must be adequately described and documented.

[8] HERCA Position Paper Clinical Audit in medical Radiological practices (www.herca.org) and European Commission: Directorate-General for Energy and Transport, European Commission guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy), Publications Office, 2009

[9] EC Marlin Project: SAMIRA Study on Reporting and Learning from Patient-Related Incidents and Near Misses in Radiotherapy, Interventional Cardiology, Nuclear Medicine and Interventional and Diagnostic Radiology

21. **Document management:**. Ensure that all policies, procedural instructions, and protocols related to the QMS are well-documented and easily accessible to all staff members. Ensure a process is in place for updating with accurate version control mechanisms and ratification/approval processes is in place.

Continuous improvement

A continuous improvement process should be established to constantly enhance service quality.

22. **Continuous improvement:** Establish a continuous improvement process, such as CIP – PDCA-Cycle[10]. The continuous improvement process analyses if there are general new processes to look at (i.e. new technology installed), or if there is new scientific evidence to change a patient track, or new tools for patient safety (i.e. electronic patient identification), etc.

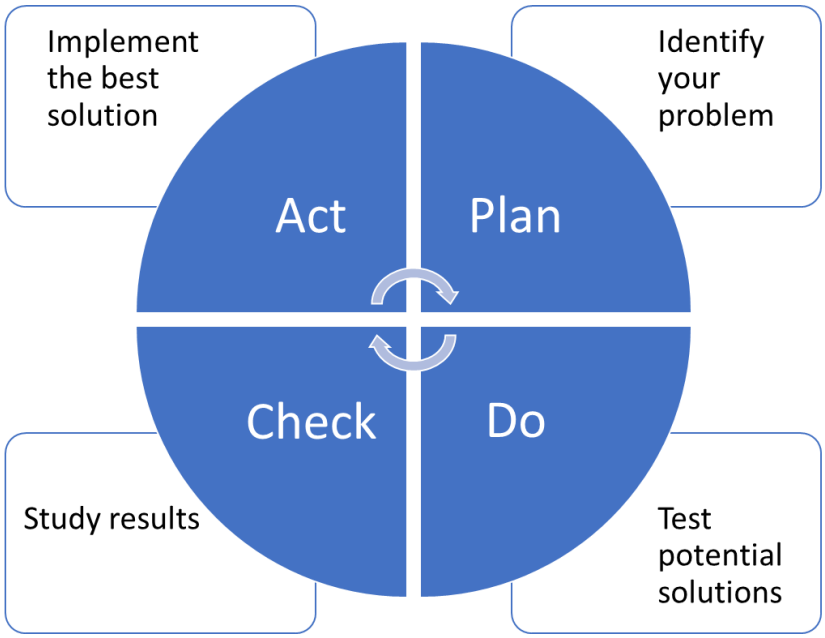

Figure 3 CIP-PDCA Cycle

Implementing these key components in the QMS necessitates a systematic approach and the commitment of senior management, as well as all employees involved in the medical service. Regular, proactive reviews of the QMS are essential to assess its effectiveness and make any necessary adjustments.

[10] CIP: Continuous Improvement Process, PDCA-Cycle: Plan-Do-Check-Act-Cycle; Systematic review of the application of the plan–do–study–act method to improve quality in healthcare (BMJ Qual Saf. 2013 Aug 23;23(4):290–298)

Grading the QMS according to the size, scale and complexity of the service:

The QMS shall be developed and applied using a graded approach as it is described in IAEA GSR Part 2. The QMS can be categorised based on the size, risk, and complexity of the medical service.
The criteria used to grade the development and application of the QMS should be documented in the QMS. The following shall be taken into account:

(a) The complexity of the organisation, operation of the facility or conduct of the activity.
(b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each service, facility or activity.
(c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out.

Promoting and Communicating:

The national radiation protection authorities for radiological procedures, nuclear medicine and radiotherapy should promote the establishment of a QMS and communicate its' importance to ensure the highest standards of patient care, safety of the staff and the public, and environmental protection. National radiation protection authorities may adopt several strategies to effectively promote and communicate a Quality Management System (QMS), such as:

- Convincing: Clearly convey the necessity, goals, objectives, and benefits of the QMS to the senior management and the staff of the medical service, highlighting the role of the QMS in enhancing patient outcomes and safety.

- Commitment: Promote the commitment of the medical service to a QMS for radiological procedures through direct contacts, marketing materials, website content, and other channels. Engage with patient organisations, professional societies (including medical doctors, medical physicists, technicians), and other stakeholders (such as hospital management and medical device companies).

- Integration: Stress the importance of incorporating radiation protection aspects into the overall hospital QMS rather than treating it as a separate entity.

- Communicate successes: Acknowledge and promote achievements related to the QMS, such as the successful implementation of new processes or improvements in patient outcomes.

- Continuous improvement: Highlight the benefits of a QMS in fostering a culture of continuous improvement within organisations. Encourage staff to actively participate in identifying opportunities for enhancing the QMS.

By implementing these strategies, radiation protection authorities can effectively promote and communicate the value of a quality management system in radiological procedures, ultimately leading to improved patient care outcomes, enhanced patient safety, increased staff safety and security, and greater trust from stakeholders.

Inspection:

During inspections and other monitoring activities, the radiation protection authority's role is to verify that the medical service adheres to all applicable legal requirements and standards. During inspections, the national radiation protection authorities should review the QMS, placing particular emphasis on the integration of radiation protection measures, in order to identify areas for improvement and to ensure compliance with legal requirements and relevant standards. A significant part of this role will be to verify the efficacy of the QMS, and to verify that the staff utilise the QMS in their daily practice.

An implemented and effective QMS, integrated into daily practice by staff, supports compliance and can demonstrate adherence to regulatory requirements. Any deviations from legal requirements and standards (noncompliance) should prompt corrective measures aimed at improving practices, such as behavioural adjustments and QMS revisions.

Additionally, national radiation protection authority or authorised institutions should play a key role in investigating, benchmarking, and sharing best practices with radiological medical services. This can be achieved through guidance during the licensing process, inspections, organising specialised seminars for QMS managers in medical services, and publishing dedicated materials and directives.

Conclusion:

A well-established Quality Management System (QMS) including radiation protection, integrated into the medical service and actively practiced by staff will improve quality and safety. It will help maintain compliance and demonstrate adherence to the legal requirements and to radiation protection authorities' guidance.

HERCA firmly believes that a medical service implementing a QMS, which addresses all relevant aspects of radiation protection and considers potential risks and safety concerns for patients, staff, third parties, and the environment, offers substantial value. This position statement, intended for the radiation protection authorities of Member States, outlines the framework, the structure and content for such a QMS and specifies the role of these authorities regarding communication, control and surveillance.

Literature

The list includes national and international guidelines but is not exhaustive.

- ICRP, 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).
- IAEA, Radiation Protection and Safety in Medical Uses of Ionising Radiation. Specific Safety Guide No. SSG-46, 2018
- IAEA, Leadership and Management for Safety, General Safety Requirements, No. GSR Part 2
- EUROPEAN 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
- ISO 9001:2015: Qualitätsmanagementsysteme – Grundlagen und Begriffe (Quality management systems - basics and concepts)
- ISO 13485: Although this international standard is primarily aimed at medical device manufacturers, it can also be applied to healthcare service providers and ensures that consistent design, development, production, installation and delivery services are offered.
- EC Protection Radiation N° 181 General guidelines on risk management in external beam radiotherapy