SLOVENSKI STANDARD
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Kakovost klinične poti pacienta pri medicinskem slikanju v storitvah radiologije

Quality along the patient pathway in medical imaging in Radiology services

Qualität entlang des Patientenpfads in der medizinischen Bildgebung in der Radiologie

Qualité du parcours patient en imagerie médicale dans les services de radiologie

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03.100.70	Sistemi vodenja	Management systems
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English Version

Quality along the patient pathway in medical imaging in Radiology services

Démarche qualité du parcours patient en imagerie médicale

Qualität entlang des Patientenpfads in der medizinischen Bildgebung

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 470.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 18167:2025) has been prepared by Technical Committee CEN/TC 470 “Quality along the patient pathway in medical imaging”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

Introduction

This document deals with quality in diagnostic and interventional Radiology practiced in Radiology services.

The medical speciality Radiology is also known as Radiology and Medical Imaging and is referred to as Medical Imaging (MI) throughout this document. It is exercised within a multi professional team consisting of radiologists, radiographers and other professionals related to the context and the complexity of the examinations.

This quality management standard refers to all diagnostic and interventional methods in MI especially using X-rays, ultrasonography, and magnetic resonance imaging (MRI).

All healthcare professionals also using such imaging techniques are invited to adopt the standard.

MI activities are exercised for preventive, diagnostic, therapeutic, surveillance and follow-up purposes.

As is the case for all healthcare services, the objectives of MI activities are to provide patient care that is appropriate, compliant with the current standards, with controlled risks that are announced, understood as far as possible and accepted by the patient, for the correctly identified person, accessible to all, taking the patient's expectations into account and administered with care.

Obviously, MI extends beyond the mere production of images or the performance of a procedure, and includes, in particular, all opinions or discussions on the justification and optimization of such procedures, and their use in the subsequent management of patients.

This document enables peer assessment, through external peer audits, of the quality and competences of an MI Organization to perform MI procedures. Conformity with this document aims to ensure the appropriateness and quality of the procedures and patient care, and the safety of practices. It enables professionals to improve their practices, while still having the time and energy for proper management of patients.

Meeting the prevailing statutory and regulatory requirements of the prevailing jurisdiction is an essential prerequisite.

This document was written according to the principle of a process-based approach, by presenting the support processes first, then the patient management processes and finally the quality management system, including assessments.

1 Scope

This document specifies the requirements for implementation of a quality system along the patient pathway in Radiology services. The objective is to ensure high quality delivery of all aspects of the examination safety and patient care.

This document deals with procedures using X-rays, ultrasonography and magnetic resonance imaging on humans, including diagnostic procedures and interventional Radiology as well as remote practices. It also applies, in its principles, to any other technique and modality that would be used in Radiology services.

The document covers:

— the different steps of patient care (from the imaging referral, before, during, and after the examination);

— the corresponding human resources and technical-medical requirements;

— quality and risk management.

This document does not apply to radiotherapy and nuclear medicine, nor to equipment and radiation controls which are covered in other standards. This document excludes requirements related to research and education themes.

This document establishes best practices description which constitutes a reference for audits, including clinical audits. Nevertheless, the clinical audits methodology, already defined at the European level, and implemented under the responsibility of each country is excluded from the document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
diagnostic reference levels
DRLs
dose levels in medical radio diagnostic or interventional Radiology practices, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment

[SOURCE: Council Directive 2013/59/Euratom, modified: reference to radiopharmaceutical aspects removed[1]]

Note 1 to entry: DRLs are used as a tool to aid optimization of protection in the medical exposure of patients.

[SOURCE: ICRP, 2017[2]]

3.2
documented procedure
set of written rules that specify the manner in which an activity is exercised

Note 1 to entry: A procedure is a quality document included in the document system. The procedure, and the medium on which it is contained, are controlled, and kept up to date.

Note 2 to entry: Documented procedures can be on any medium, in any format and from any source.

3.3
entitlement
formal validation by the manager of the MI Organization of the capability of a person working under its responsibility to perform the assigned tasks

Note 1 to entry: The manager is the head of the MI Organization or is the person(s) delegated by this authority for that purpose.

Note 2 to entry: Entitlement guarantees the capability of a professional to proficiently exercise an activity in a given MI organization.

Note 3 to entry: Entitlement takes account of the regulatory requirements of the country concerned for the exercise of an activity (initial qualification and continuous professional development) and the organization of every MI organization, including, in particular, the experience of the professional concerned, in order to validate the command of the activity exercised by every professional in every job (and before occupying this function independently for the first time). Its renewal is conditional on an appropriate level of practice.

Note 4 to entry: Entitlement is personal.

3.4
governance
human-based system by which an organization is directed, overseen and held accountable for achieving its defined purpose

[SOURCE: ISO 37000:2021, 3.1.1[3]]

3.5
healthcare organization
entity, institution, or system that provides medical and healthcare services to individuals and patients

3.6
interventional imaging
all invasive medical procedures intended to diagnose and/or treat a pathology that are guided and monitored by a means of medical imaging

3.7
just and learning culture
balance of fairness, justice and learning and taking responsibility for actions

Note 1 to entry: It is not about blame but it is also not about an absence of responsibility and accountability.

[SOURCE: 'Being Fair' – NHS Resolution, 2019[4]]

3.8
Medical Imaging
MI
medical specialty “Radiology” also known as “Radiology and Medical Imaging”

Note 1 to entry: MI is the term used in this document to clearly state that imaging techniques used by the medical speciality named Radiology are not limited to the use of X-rays.

Note 2 to entry: It covers diagnostic and interventional imaging, performed by MI organizations, and includes the procedures performed in operating suites by MI personnel.

Note 3 to entry This definition is specific for this document.

Note 4 to entry: Images that are conventional optical images (endoscopy, funduscopy…), photographs of patients or lesions, anatomopathology are not in scope.

3.9
MI doctor
radiologist or non-radiologist medical doctor who works in the MI Organization and adopts this document

Note 1 to entry: This also applies to non-physician healthcare professionals within the scope of medical activities that are delegated to them in accordance with the different national regulations (for example, in certain countries, the validation of the justification of certain imaging referrals, the issuing of certain reports…).

Note 2 to entry: The same applies to the trainees.

3.10
MI medical device
products or equipment intended for MI procedures

3.11
MI organization

designates the imaging departments, imaging centers, medical imaging facilities, performing MI procedures

Note 1 to entry: An MI Organization can be independent or part of a healthcare organization.

Note 2 to entry: National regulation may have an equivalent term for MI organization.

3.12
MI procedure
all kind of diagnostic and interventional methods performed within the MI organization

Note 1 to entry: These methods are used for diagnostic purposes or in order to monitor, guide and perform an interventional procedure. They especially use X-rays, MRI, and ultrasonography.

Note 2 to entry: MI procedure also refers to everything associated with the procedure from the imaging referral to the report and clinical discussion.

Note 3 to entry: MI procedures performed within a MI Organization are defined by the MI Organization itself.

Note 4 to entry: Where appropriate, the MI procedure also includes the decision not to proceed with the procedure after analysing the case.

3.13
MI team
multi professional team of the MI Organization consisting of radiologists, radiographers and other professionals related to the context and the complexity of the examinations

3.14
procedure
specified way to carry out an activity or a process

Note 1 to entry: A procedure can be documented or not.

[SOURCE: EN ISO 9000:2015, 3.45[5]]

3.15
process
set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE EN ISO 9000:2015, 3.4.1[5]]

3.16
quality assurance
planned and systematic operations required to guarantee that a facility, a system, an item of equipment or a procedure will function in a satisfactory manner in accordance with the established standards

3.17
quality management system
QMS
part of a management system with regard to quality

Note 1 to entry: The series of interdependent and interactive actions and processes work in harmony, enabling an MI Organization to define and then implement its policy based on the objectives that it has predefined.

[SOURCE: EN ISO 9000:2015, 3.5.4[5]]

3.18
quality policy
policy related to quality corresponding to the strategic priorities, intentions, and general objectives of the MI Organization regarding quality

Note 1 to entry: The policy is expressed via a written document and formally adopted by the highest level of management of the MI organization.

Note 2 to entry: In healthcare establishments where the MI Organization is not independent, the quality policy of the MI Organization is included in accordance with the general policy of the healthcare establishment.

[SOURCE: EN ISO 9000:2015, 3.5.9 – modified and Notes to entry 1 and 2 added[5]]

3.19
radiology
science of ionising radiation and its application to the diagnosis and treatment of disease

Note 1 to entry: Radiology in this document excludes Nuclear Medicine and Radiotherapy but includes non-ionising imaging methods such as MRI and Ultrasound.

Note 2 to entry: The medical speciality "Radiology" is also called "Radiology and Medical Imaging" implying that this speciality involves techniques other than just X-rays.

[SOURCE: EN 60601-1-3 :2008+AMD1 :2013+AMD2 :2021, 3.68, modified: Notes to entry 1 and 2 added[6]]

3.20
radiology services
services in healthcare of patients connected to diagnostic or interventional procedures carried out in a MI Organization under the authority and responsibility of radiologists

Note 1 to entry: By extension, this term also applies in some countries to units which, under the coverage of their national regulations, could be managed by radiographers.

3.21
relevance
requested examination of the correct patient at the right time in the proper place by the right professional using suitable equipment

Note 1 to entry: The relevance of MI care corresponds to the match between the diagnostic and therapeutic procedures and the patient's needs. An analysis of relevance assesses the referral for an examination and/or the appropriate use of MI procedures.

Note 2 to entry: The referred examination may be modified or rejected by the healthcare professional responsible for the MI procedure.

3.22
risk management
coordinated activities to direct and control an Organization with regard to risk

Note 1 to entry: Documented process that aims to identify, assess and mitigate, wherever possible, the risks incurred by patients, visitors and professionals in MI organizations, in order to reduce the number and/or severity of undesirable event.

Note 2 to entry: This also includes environmental risk factors (pollution, radiation, noise and work environment).

3.23
standard operating procedures
SOPs
description of the regularly recurring activities and processes as well as their conditions and requirements relevant to the quality of the procedure

Note 1 to entry: SOPs represent written rules that specify the manner in which an activity is exercised.

Note 2 to entry: SOPs shall be handled as documented procedures.

3.24
systemic analysis
analysis to search for causes and treatment measures

Note 1 to entry: Also known as root cause analysis.

Note 2 to entry: For example, the causes of most adverse events are the result of multiple factors and involve the risks that are inherent in the care procedures, and/or their organization, and/or their environment. Therefore, following an adverse event, an analysis of the immediate causes, followed by a search for the root causes, sometimes referred to as a systemic analysis, is essential.

Note 3 to entry: This approach ensures that the analysis extends beyond the identification of the responsibility of one or more individuals and the immediately apparent cause of the detected issue.

4 Background information

4.1 Which healthcare services are concerned?

MI covers diagnostic imaging and interventional imaging.

MI diagnostic procedures deliver morphological and/or functional and/or metabolic information on the human body. MI interventional procedures have investigational or therapeutic objectives and are guided and monitored by imaging.

The corresponding procedures are performed on humans, from foetuses to the elderly, including postmortem procedures.

MI activities are medical procedures. Their main steps are: the analysis and approval of the imaging referral for the purposes of justification; scheduling; the prescription of the medicine required for the MI procedure, where necessary; the preparation and performance of the MI procedure, including its optimization; image processing if necessary and the production and delivery of the report. The MI procedure is associated with pre- and post-procedure assessments and discussions, which, in particular, may be multidisciplinary.

The healthcare services concerned call on all the skills and organizations required to perform these MI procedures.

The MI Organization itself, or the healthcare organization which it belongs to, is responsible for meeting the requirements of this document.

4.2 Where are these healthcare services provided?

MI procedures are performed in imaging departments and imaging centres, hereafter referred to as MI organizations. Procedures performed by MI professionals, outside these locations, e.g. in operating suites or by the use of mobile units, are also part of the scope.

These MI organizations are independent and autonomous, or part of a healthcare organization.

The MI Organization can have one or more sites belonging to the same public, private or mixed legal entity. It can be associated with other healthcare organizations.

The MI Organization can be in healthcare units in specific environments (detention centres, or others). However, facilities which do not administer any patient care, are outside the scope of this document.

4.3 Who performs the procedures defined in this document?

The healthcare professionals who collaborate in the MI Organization do so within a team. The team includes two key categories of licensed professionals: the radiologist, who is a physician specialized in Radiology, and the radiographer. They work in a complementary manner according to their respective qualification, training and entitlement, the techniques employed, the situations encountered, as well as with national regulations and their developments.

Along the patient pathway some activities require specific competences (such as those related to safety or mastery of certain examinations) which require specific qualifications. For this reason, and without aiming to be exhaustive, in paragraph 5.7.2. reference is made to the roles of the Medical Physics Expert (MPE) and of the Radiation Protection Officer (RPO), in paragraph 5.8.2 to the roles of the MR Medical Director (MRMD), MR Safety Officer (MRSO), MR Safety Expert (MRSE) and in paragraph 7.4. to the role of the quality manager.

NOTE 1 The MI team includes:

—non-radiologist doctors who work in the MI Organization and adopt this document.

—the professionals providing the support functions required to exercise the main activity.

—all those in training.

NOTE 2 The authorized health care professional also called the referrer who asks for the examination is not part of the MI team.

4.4 Who can access the healthcare services concerned?

The healthcare services concerned can be accessed by the entire prenatal, child and adult population likely to suffer from a health disorder (exploratory phase), with a health disorder (additional diagnosis, treatment using MI, regular monitoring or in the case of possible complications), or subject to screening.

The activities of MI organizations are scheduled or performed in emergencies, for both hospitalized patients and outpatients.

Each MI Organization defines the types of MI procedures it performs and for which populations.

4.5 What are the characteristics of these healthcare services?

The objective is that the management of patients be administered with due quality and safety, in accordance with the regulations and the recommendations on best-medical practices, including risk management.

The internal rules of the organization comply with applicable regulations and recommendations. Information, consent and the protection of professional confidentiality comply within the values, obligations and rules of the healthcare professions and of other professionals who participate in the activity of the MI organization, in accordance with the applicable regulations.

MI procedures involve the use of equipment and, in particular, of medical image acquisition devices (CT scanners, magnetic resonance imaging (MRI), fixed or mobile radiography and radioscopy equipment, ultrasonic scanners, hybrid devices, etc.), the use of other medical devices, which may be implantable or not, and of medicines including contrast agents.