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

Quality along the patient pathway for 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

Ta slovenski standard je istoveten z: **EN 18167:2026**

ICS:

03.100.70	Sistemi vodenja	Management systems
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English Version

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European foreword

This document (EN 18167:2026) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2026, and conflicting national standards shall be withdrawn at the latest by December 2026.

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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 performed within a multi professional team consisting of radiologists, radiographers, medical physicists and other professionals related to the context and the complexity of the examinations.

This document 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 performed 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. These services are provided to the correctly identified person, accessible to all, considerate of their expectations and administered with care.

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

This document is not meant or presented as a general quality management standard even if the structure and background of quality management standards mentioned in the document are used for several topics.

Conformity with this document aims to ensure the appropriateness and quality of the procedures and patient care, and the safety of practices. It should enable professionals to improve their practices, while still having the time and energy for proper management of patients.

The document will support audits, especially with peer assessment, as well as the implementation of solutions for quality requirements, typically within an applied quality management system.

Meeting the prevailing statutory and regulatory requirements of legislation and jurisdiction is an essential prerequisite. The MI organization and the healthcare organization which it belongs to are responsible for meeting the requirements of this document.

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, definitions and abbreviations

3.1 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/

3.1.1
competency matrix
management tool used to map, track, evaluate and document the skills, qualifications, and expertise of individuals within an organization

Note 1 to entry: The purpose is to identify who is qualified to perform certain tasks, spot training needs, plan staffing and succession and to demonstrate compliance.

3.1.2
diagnostic reference levels
DRLs
ionizing radiation dose levels in diagnostic or interventional radiology practices, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment

Note 1 to entry: DRLs are used as a tool to optimize medical radiation exposure of patients.

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

[SOURCE: ICRP, 2017[2]]

3.1.3
documented procedure
set of written rules that specify the manner in which an activity is performed

Note 1 to entry: A procedure is a 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.

3.1.4
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]]

3.1.5
healthcare organization
entity, institution, or system that provides medical and healthcare services to individuals and patients

3.1.6
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

Note 1 to entry: For example, for introduction of devices or substances into the body.

3.1.7
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: Images that are conventional optical images (endoscopy, funduscopy…), photographs of patients or lesions, anatomopathology are out of the scope.

3.1.8
MI doctor
MI practitioner
radiologist or non-radiologist medical doctor who works in the MI organization

3.1.9
MI medical device
products or equipment intended for MI examinations

3.1.10
MI organization
imaging departments, imaging centres, medical imaging facilities, performing MI examinations

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

3.1.11
MI examination
diagnostic and/or interventional procedure performed within the MI organization

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

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

Note 3 to entry: MI examinations performed within a MI organization are defined by the MI organization itself.

3.1.12
MI team
multi professional team of the MI organization consisting of radiologists, radiographers, medical physicists and other professionals related to the context and the complexity of the examinations

3.1.13
privileging
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: Privileging guarantees the capability of a professional to proficiently perform an activity in a given MI organization.

Note 3 to entry: Privileging takes account of the regulatory requirements of the country concerned for the performance of an activity (initial qualification and continuous professional development) and the organization of every MI organization. It includes in particular, the experience of every professional concerned, in order to validate their command of the activity in every position and every relevant task. Its renewal is conditional on an appropriate level of practice.

Note 4 to entry: Privileges are personal.

3.1.14
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, 3.4.5[4]]

3.1.15
process
set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: EN ISO 9000:2015, 3.4.1[4]]

3.1.16
quality assurance
planned and systematic preventive and corrective actions 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

[SOURCE: ISO 13628-10:2005, 3.1.38, modified [5]]

3.1.17
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[4]]

3.1.18
quality policy
policy related to quality corresponding to the strategic priorities, intentions, and general objectives of the MI organization regarding quality along the patient pathway

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: The quality policy of a MI organization integrated into a healthcare organization aligns with the general policy of this healthcare organization.

[SOURCE: EN ISO 9000:2015, 3.5.9, modified and Notes to entry 1 and 2 added [4]]

3.1.19
radiology
medical speciality using ionizing and non-ionizing radiation and its application for examination of humans for diagnostics, treatment or screening

Note 1 to entry: Non-ionizing radiation in radiology primarily includes MRI and ultrasound.

Note 2 to entry: Nuclear Medicine and Radiotherapy are excluded.

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

3.1.20
radiology services
patients healthcare services providing diagnostic and/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.

3.1.21
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 examinations.

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

3.1.22
risk management
coordinated activities to direct and control an organization regarding risks

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).

3.1.23
standard operating procedure
SOP
detailed, step-by-step written instruction designed to achieve uniformity in the performance of regularly recurring activities and processes

Note 1 to entry: SOPs should be handled as documented procedures.

3.1.24
systemic analysis
root cause analysis
methodical search for causes and corrective measures

Note 1 to entry: Systematic or root cause analysis goes beyond identification of immediate causes and responsibility and focuses on cause of the event.

3.2 Abbreviations

AI	Artificial Intelligence
ALARA	As Low As Reasonably Achievable
CPD	Continuing Professional Development
CISO	Chief Information Security Officer
DPO	Data Protection Officer
DRLs	Diagnostic Reference Levels
GPDR	General Data Protection Regulation
MI	Medical Imaging
MPE	Medical Physics Expert
MRI	Magnetic Resonance Imaging
PDCA	Plan-Do-Check-Act
QMS	Quality Management System
RF	radiofrequency
RPO	Radiation Protection Officer
SDG	Sustainable Development Goals
SOP	Standard Operating Procedure

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 examination, where necessary; the preparation and performance of the MI examination, including its optimization; image processing if necessary and the production and delivery of the report. The MI examination is associated with pre- and post-procedure assessments and discussions, which can be multidisciplinary.

4.2 Where are these healthcare services provided?

MI examinations 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 privilege, 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 and risk 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 perform 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 investigation, treatment using MI, 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 examinations 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.

MI examinations involve the use of equipment and, in particular, of medical image acquisition devices (CT scanners, 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.

The MI examination implements the principles of justification and optimization, whether it uses ionizing radiation or not. The operational implementation of the principle of justification consists of choosing the right procedure for the right patient, as described in *"6.1 Imaging referrals for MI examinations"* and *"6.2 Justification and approval of the imaging referral*". The adoption of the principle of optimization by the professionals involved aims to limit the doses of exposure to ionizing radiation and electromagnetic waves for the exposed persons, and to choose the adequate type and dose of contrast agents administered, while guaranteeing the adequate diagnostic quality of the examination.

Medical activity is usually conducted face to face, but it can also be performed remotely (e.g. by teleradiology) under conditions defined by regulations and procedures. In this case, the MI organization procedures include those performed on-site and those performed externally/remotely under the organization's control, and in particular their relevance and optimization.

All the activities are performed in accordance with the patient's rights.

4.6 When do the rules outlined in this document apply?

This document applies to the medical activity of the MI organization at all times.

5 Technical medical requirements

5.1 General

The MI organization shall control the processes and risks related to the pathway and care of the patient and the performance of the MI examinations. The performed MI examinations are defined by the MI organization.

5.2 Human resources

5.2.1 General

The MI organization shall determine and ensure that its workforce possesses the competence, especially knowledge, skills and experience, required for safety, effectiveness, proper patient management of patients and the expertise needed for the MI examinations that it performs. To this end, it shall determine and provide the necessary human resources for the implementation of its quality management system (QMS).

The relevant composition and structure of the MI organization shall be defined in a document which describes the roles, tasks and responsibilities of all the categories of professionals. A competency matrix may be another tool for documentation.

The MI organization shall ensure that all relevant roles, responsibilities and training of the workforce from external resources used are defined in the service contract and tracked.

The management conditions of human resources and the quality of life at work shall be concerns and responsibility of the MI organization, which shall take and follow up actions. The organization shall create and promote a positive safety culture.